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## The Politics of Medicine: Power, Actors, and Ideas in the Making of Health

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**THE POLITICS OF MEDICINE: POWER, ACTORS, AND IDEAS IN THE  
MAKING OF HEALTH**

by

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# **ABSTRACT**

## **THE POLITICS OF MEDICINE: POWER, ACTORS, AND IDEAS IN THE MAKING OF HEALTH**

Claire Wulf Winiarek  
Old Dominion University, 2021  
Director: Dr. Regina Karp

The practice of medicine has become the prescribing of medicine. Reflecting a construct of health defined by Rationalism, individualism, and biomedical science, medicines (pharmaceuticals) are politically constructed to be the first – and sometimes only prescribed – line of defense against illness and disease. Pharmaceuticals also represent a highly desirable, ‘recession-proof’ component of many Nation-states’ (states’) export strategies, helping advanced economies, in particular, to maintain favorable trade balances and economic growth amidst the headwinds of deindustrialization.

Higher use and the overreliance on pharmaceuticals promote an outsized role for certain actors and ideas in the making of global health, referring to the systems of medical practice, the norms defining health subconsciously and consciously, the politico-economic relations and decisions that prioritize certain qualities and determinants of health, and interventions relating to health. Concentrations of power deepened under globalization, reinforcing and internationalizing specific, hegemonic ideas about health that reflect the ideas and interests of dominant actors. These dynamics further privilege certain actors and ideas in political and economic processes, which have the practical effect of predetermining outcomes. In this way, power sustains the global normative and politico-economic conditions that comprise modern health—power makes health.

This dissertation employs pharmaceuticals as a proxy to examine power asymmetries and market-oriented norms relating to health. The research examines the formative ideas and structuring role of power on the political salience, interests, values, and choices of the leading actors in global

health. Rather than an exclusive focus on health's visible outcomes, the research distinguishes the influence of power asymmetries expressed through norm formation and spread. It finds that health is a core issue of the 21st century global political economy and equitable scholarly focus and practical solutioning must be applied to the ideas, contexts, content, and processes that make health.

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This dissertation is dedicated to my family, especially my children, Jack and Katie. Thank you for sharing your infancy and early childhood with this massive collection of words and doodle sheets.

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## NOMENCLATURE

Abbreviation	Meaning
ACSS	Australia-Canada-Singapore-Switzerland Consortium on pharmaceutical marketing pre-market review, registration, evaluation, and post-market surveillance
ADE	adverse drug event
ADL	activity of daily living
AEC	ASEAN Economic Community
AHA	American Hospital Association (U.S.)
AIDS	acquired immunodeficiency syndrome
AMP	average manufacturer price
ART	antiretroviral therapy
APEC	Asia-Pacific Economic Cooperation
ARV	antiretroviral
ASEAN	Association of Southeast Asian Nations
ASP	average sales price
BIO	Biotechnology Industry Organization (U.S.)
BWIs	Bretton Woods Institutions
CAGR	compound annual growth rate
CBO	Congressional Budget Office (U.S.)
CD	communicable disease
CDC	Centers for Disease Control and Prevention (U.S.)
CDER	Center for Drug Evaluation and Research (U.S.)
CGRP	calcitonin gene-related peptide
CIPHI	Commission on Intellectual Property Rights, Innovation, and Public Health (UN)

Abbreviation	Meaning
CMH	Commission on Macroeconomics and Health
CMPN	communicable, maternal, perinatal, and nutritional diseases
CMS	Centers for Medicare & Medicaid Services (U.S.)
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios (Mexico)
COPD	chronic obstructive pulmonary disease, a category of lung disease inclusive of bronchitis, emphysema, and chronic wheezing or coughing
COVAX	Covid-19 Vaccines Global Access Facility
Covid-19	coronavirus disease 2019, which is caused by the new coronavirus variant known as SARS-CoV-2
CPI	consumer price index
CSDH	Commission on Social Determinants of Health (UN)
CRO	contract (or clinical) research organization
CSO	civil society organization
DAA	direct-acting antiviral
DALYs	disability adjusted life years
DDD	defined daily dose (WHO)
DUR	drug utilization review
EAC	East African Community
EC	European Commission
ECG	excess cost growth
ECOSOC	United Nations Economic and Social Council
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency (EU)
EML	essential medicines list
ERP	external reference pricing

Abbreviation	Meaning
EU	European Union
EUR	Euro
FDA	Food & Drug Administration (U.S.)
FDI	foreign direct investment
FMSH	Foundation Maison des Sciences de L’Homme (FMSH)
FNIH	Foundation for the National Institutes of Health
GAO	Government Accountability Office (U.S.)
GAVI	Formerly known as the Global Alliance for Vaccines and Immunization; now known as GAVI, the Vaccine Alliance
GCS	global civil society
GDP	gross domestic product
GDP/c	gross domestic product per capita
GDP-PPP	gross domestic product-purchasing power parity
GHC	Gulf Health Council
GHI	global health initiative
GKN	Globalization Knowledge Network (UN)
GNI	gross national income
GNP	gross national product
GPG	global public good
GPG-H	global public good for health
GPPPs	global public-private partnerships
HALE	healthy life expectancy
HDHP	high-deductible health plan
HepC	hepatitis C virus
HHS	Department of Health and Human Services (U.S.)

Abbreviation	Meaning
HIV/AIDS	human immunodeficiency virus/ acquired immune deficiency syndrome
HPV	human papillomavirus
IADL	instrumental activity of daily living
IBRD	International Bank for Reconstruction and Development
ICD-10	International Statistical Classification of Diseases and Related Health Problems (10th revision)
ICER	Institute for Comparative Effectiveness Research (U.S.)
ICH	International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSID	International Center for Settlement of Investment Disputes
IDA	International Development Association
IFC	International Finance Corporation
IFI	international financial institution
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGBA	International Generic and Biosimilar Medicines Association
IGDRP	International Generic Drug Regulators Program
IGO	intergovernmental organization
IHR	International Health Regulations, 2005, Revised 2007 (WHO)
IMF	International Monetary Fund
IMR	infant mortality rate
IO	international organization
IP	intellectual property
IPE	International Political Economy
IPRF	International Pharmaceutical Regulators Forum
IPRP	International Pharmaceutical Regulators Program

Abbreviation	Meaning
ISGlobal	Institute for Global Health
JPMA	Japan Pharmaceuticals Manufacturers Association
LDS	Medicare Limited Data Set (U.S.)
LEB	life expectancy at birth
LIMICs	low- and middle-income countries
MERS	Middle Eastern respiratory syndrome
MDGs	Millennium Development Goals (UN)
MDRP	Medicaid Drug Rebate Program (U.S.)
MIGA	Multilateral Investment Guarantee Agency
MMR	maternal mortality ratio
MNC	multinational corporation
MNPC	multinational pharmaceutical corporation
mRNA	messenger ribonucleic acid
NAS	new or novel active substance
NASEM	National Academies of Sciences, Engineering, and Medicine (U.S.)
NCD	noncommunicable disease
NGO	nongovernmental organization
NHS	National Health Service (U.K.)
NIA	National Institute on Aging
NICE	National Institute for Health and Care Excellence (U.K.)
NIH	National Institutes for Health (U.S.)
NPE	New Political Economy (journal)
NTD	neglected tropical disease
OECD	Organization for Economic Co-operation and Development

Abbreviation	Meaning
OOP	out-of-pocket costs for health care goods and services
OPEC	Organization of the Petroleum Exporting Countries
P&A	pricing and access
PAHO	Pan American Health Organization
Part D	Medicare Prescription Drug Program (U.S.)
PhRMA	Pharmaceutical Research and Manufacturers of America (U.S.)
PPP	public-private partnership
PPP	purchasing power parity
R&D	research and development
RA	regulatory authority
RIPE	Review of International Political Economy (journal)
RNA	ribonucleic acid
SADC	Southern African Development Community
SAP	structural adjustment program
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2, which causes the disease called Covid-19
SDGs	Sustainable Development Goals (UN)
SDH	social determinants of health
SSA	sub-Saharan Africa
TB	tuberculosis
TFCs	transnational food companies
TNC	transnational corporation
U5MR	under-five mortality rate
UDHR	Universal Declaration of Human Rights

Abbreviation	Meaning
UHC	universal health coverage
UN	United Nations
UNAIDS	Joint United Nations Program on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Program
U.K.	United Kingdom
U.S.	United States of America, or the United States
USD	U.S. dollar
VC	venture capital
VP	venture philanthropy
TB	tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994
TWB	World Bank Group, formerly “The World Bank”
WAC	wholesale acquisition cost
WDIs	World Development Indicators
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



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# CHAPTER 1

## INTRODUCTION AND RESEARCH DESIGN

“We are tempted to believe drugs are the remedy for all human sorrows and difficulties.”

—Dr. Roy Abraham Kallivayalil (2008)<sup>1</sup>

The practice of medicine has become the prescribing of medicine. From vaccines to treatments to cures, we have made medicines (pharmaceuticals) essential to health. Expanding access to ‘essential medicines,’<sup>2</sup> improving timely therapy initiation as a public health priority,<sup>3</sup> pressing for new drugs for ‘neglected’ diseases, and the “moral urgency” of accessing unapproved, experimental treatments<sup>4</sup> are examples of the myriad ways pharmaceuticals have become primary to the practice of medicine and “one of the most visible aspects of 21st century global health practices.”<sup>5</sup> For example, pharmaceuticals often are the first line of defense against illness in many parts of the world, whether for communicable diseases (CDs)<sup>6</sup> (e.g., influenza, tuberculosis, hepatitis C, Zika, malaria, Ebolavirus, coronavirus),<sup>7</sup> or the noncommunicable diseases (NCDs), like heart disease and

<sup>1</sup> Kallivayalil, “Are We Over-Dependent on Pharmacotherapy?” Page 7.

<sup>2</sup> United Nations, 2030 Agenda for Sustainable Development; Sustainable Development Goals (Resolution).

<sup>3</sup> Andrew J. Karter et al. (2009) find that inadequate adherence to new prescription regimens 24 months after prescribing was more prevalent than previously estimated. As a result, public health efforts that traditionally have focused “on improving adherence in ongoing user” should focus on timely initiation of new therapies, suggesting that “more attention is needed to address nonpersistence in the very first stages after a new medication is prescribed.” See Karter et al., “New Prescription Medication Gaps: A Comprehensive Measure of Adherence to New Prescriptions,” and Ulett et al., “The Therapeutic Implications of Timely Linkage and Early Retention in HIV Care.”

<sup>4</sup> Greene, “Making Medicines Essential: The Emergent Centrality of Pharmaceuticals in Global Health,” 10–11. The U.S. enacted a 2017 law granting individuals with terminal illness ability to access experimental drugs. See Bateman-House and Robertson, “Viewpoint: The Federal Right to Try Act of 2017—A Wrong Turn for Access to Investigational Drugs and the Path Forward.”

<sup>5</sup> Op. cit., Greene, 10-11.

<sup>6</sup> Shaw-Taylor, “An Introduction to the History of Infectious Diseases, Epidemics and the Early Phases of the Long-run Decline in Mortality.”

<sup>7</sup> The name “coronavirus” actually describes a class of viruses that belongs to the Betacoronavirus ( $\beta$ -coronavirus) of the Coronaviridae family. Coronaviruses produce a class of viral respiratory diseases that include Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), SARS caused by the coronavirus (or SARS-CoV-1), and Covid-19 (the disease variant is known as SARS-CoV-2). Per Maldonado, Bertelli, and Kamenetzky, “Molecular Features Similarities between SARS-CoV-2, SARS, MERS and Key Human Genes Could Favor the Viral Infections and Trigger Collateral Effects.”

type 2 diabetes, that globally represent the leading cause of death (71%) and disability.<sup>8</sup>

### 1.1 When the Practice of Medicine Becomes the Prescribing of Medicines

There are those who rely on pharmaceuticals for life-preserving treatment or even simply to maintain health. The evolving role of pharmaceuticals in global health practice, however, is ill-suited to address the major risk factors associated with the seven leading causes of global mortality: heart disease, stroke, chronic obstructive pulmonary disorder (COPD), lung cancers, Alzheimer's disease (AD), Type 2 diabetes, and kidney disease (Figure 1.1). Were the major risk factors for these leading causes of deaths to be eliminated, Catherine Le Gales-Camus, Robert Beaglehole, and Joanne Epping-Jordan (2005) suggest that 80% of non-cancer NCDs and 40% of cancers would be prevented if such risk factors were eliminated.<sup>9</sup> Recent clinical findings have evaluated the potential to reverse NCDs; Type 2 diabetes, for example, is reversible in 60% of diagnoses when social risk factors of health were addressed.<sup>10</sup> For those NCDs with underlying genetic or neurological causalities, including medical health conditions like depression, preventing or reversing co-occurring NCDs, like obesity and diabetes, can alleviate acute and potentially lethal symptom exacerbation.<sup>11</sup> Instead, each NCD reflects an array of pharmaceutical treatments that alleviate pain and symptoms, and prolong life, often without slowing the progression of, or curing, the actual disease.

Our collective relationship with and reliance on pharmaceuticals reflects an unfailing hope in medical science, as Dr. Roy Abraham Kallivayalil (2008) puts it,<sup>12</sup> but this can be for good or for ill (health). For many, this change is for the better, with access to complete ('curative'), preventative, and palliative treatments never before available. For others, it may be for ill, particularly, considering

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<sup>8</sup> Cardiovascular diseases account for most global NCD deaths (17.9 million annually), followed by cancers (9.3 million), respiratory diseases (4.1 million), and diabetes (1.5 million). Per World Health Organization, "Key Facts: Noncommunicable Diseases."

<sup>9</sup> Le Gales-Camus, Beaglehole, and Epping-Jordan, *Preventing Chronic Disease: A Vital Investment*.

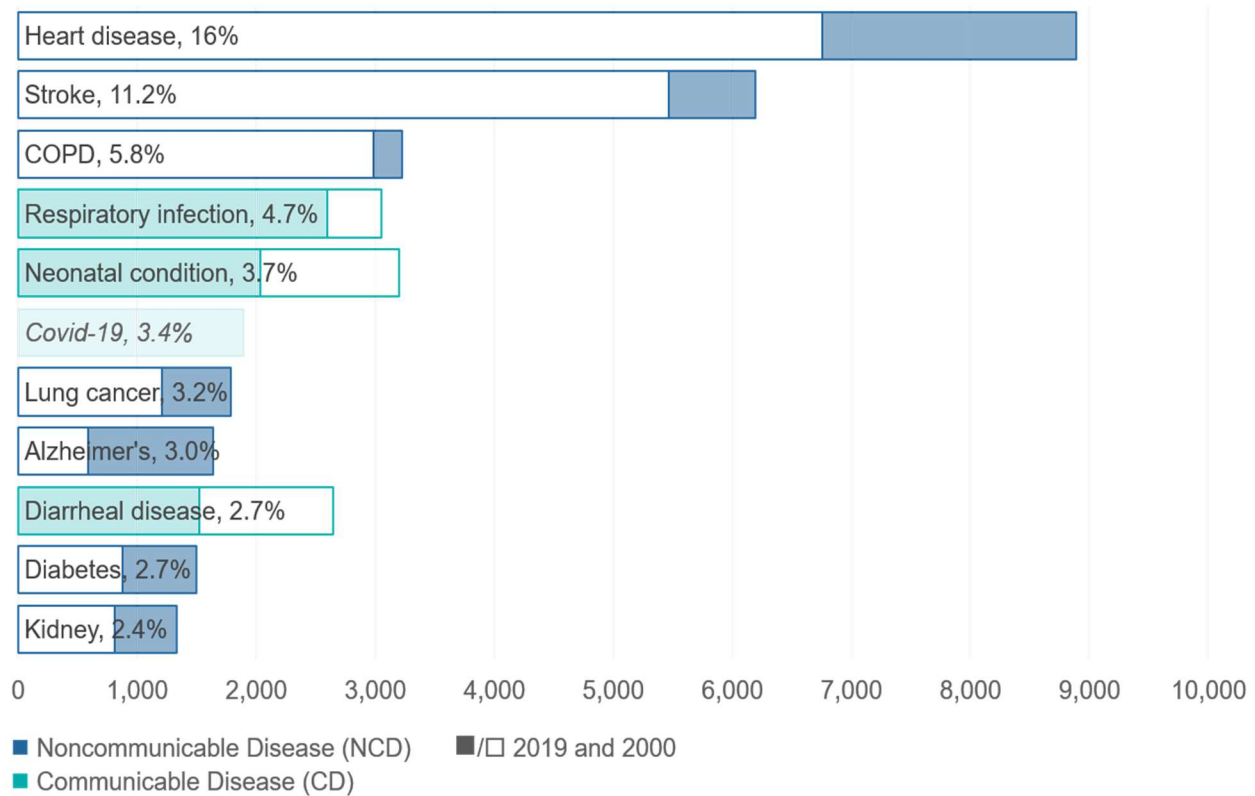
<sup>10</sup> Hallberg et al., "Reversing Type 2 Diabetes: A Narrative Review of the Evidence."

<sup>11</sup> Chapman, Perry, and Strine, "The Vital Link Between Chronic Disease and Depressive Disorders."

<sup>12</sup> Mearsheimer, *The Tragedy of Great Power Politics*, 41.



**Figure 1.1. Leading causes of death globally, Deaths in millions (2000 and 2019)**



The 10 leading causes of death in 2000 included heart disease; stroke; neonatal conditions; lower respiratory infections; COPD; diarrheal diseases; tuberculosis; HIV/AIDS; trachea, bronchus, and lung cancers; and road injury. The leading causes of death in 2019 did not include tuberculosis, HIV/AIDS, and road injury, which were replaced with Alzheimer's, diabetes, and kidney disease. Though Covid-19 deaths are from 2020, not 2019, it is helpful to understand the particular relevance of this infectious disease as compared to others when considering which global health conditions deserve prioritization over others. Covid-19 data reflect global deaths as of January 1, 2021, from the Global Change Data Lab at Oxford University. Author-generated graphic using World Health Organization data. World Health Organization, "Global Health Estimates 2019: Estimated deaths by cause and region, 2000 and 2019," World Bank income groups (2020). Global Change Data Lab, *Our World in Data* (2021).

rising rates of medication overload (i.e., overprescribing<sup>13</sup> and polypharmacy<sup>14</sup>); the already high prevalence of misuse,<sup>15</sup> which is correlated to accessibility;<sup>16</sup> and the myriad avoidable side effects, saying nothing of the prevention of disease that may be possible when the practice of medicine is constituted to be about more than prescribing. Instead of the norms and values generated by the pharmaceuticalization of economies and “medicine as culture,”<sup>17</sup> how different could health be if society and its systems were oriented toward the prevention of poor health and care for the unavoidable, preservation of health and wellness, and acceptance of aging and illness?

Besides their role in medical practice, pharmaceuticals represent a desirable, “recession-proof”<sup>18</sup> share of Nation-states’ (hereafter, states) export strategies, helping select advanced economies, in particular, maintain favorable trade balances and economic growth. Increasingly, pharmaceuticals are a leading component of global economic activity and output, totaling about 400 billion USD in global exports in 2019, up from 337 billion USD in 2015, representing a 17% five-

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<sup>13</sup> Brownlee and Garber, “Overprescribed: High Cost Isn’t America’s Only Drug Problem” and Brownlee and Garber, “Medication Overload: America’s Other Drug Problem.”

<sup>14</sup> A sample of the extant literature on polypharmacy used in this research follows; however, this is a broad and growing area of analysis in Public Health. See Maher, Hanlon, and Hajjar, “Clinical Consequences of Polypharmacy in Elderly,” Nobili et al., “Polypharmacy, Length of Hospital Stay, and in-Hospital Mortality among Elderly Patients in Internal Medicine Wards. The REPOSI Study,” Dwyer et al., “Polypharmacy in Nursing Home Residents in the United States: Results of the 2004 National Nursing Home Survey,” Khezrian et al., “An Overview of Prevalence, Determinants and Health Outcomes of Polypharmacy,” Aljeaidi and Tan, “The Association between Polypharmacy and Cognitive Ability in Older Adults: A National Cohort Study,” Lu et al., “Effect of Polypharmacy, Potentially Inappropriate Medications and Anticholinergic Burden on Clinical Outcomes: A Retrospective Cohort Study,” Millenaar et al., “Cardiovascular Outcomes According to Polypharmacy and Drug Adherence in Patients with Atrial Fibrillation on Long-Term Anticoagulation (from the RE-LY Trial),” Santibáñez-Beltrán et al., “Economic Cost of Polypharmacy in the Elderly in Primary Health Care,” Nguyen et al., “A Qualitative Exploration of Factors Contributing to Non-Guideline Adherent Antipsychotic Polypharmacy,” and Payne, “Polypharmacy and Deprescribing.”

<sup>15</sup> Cotto et al., “Gender Effects on Drug Use, Abuse, and Dependence: A Special Analysis of Results from the National Survey on Drug Use and Health,” Blanco et al., “Changes in the Prevalence of Non-Medical Prescription Drug Use and Drug Use Disorders in the United States: 1991-1992 and 2001-2002,” and Substance Abuse and Mental Health Services Administration (U.S.), “Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health.”

<sup>16</sup> Manchikanti et al., “Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective.”

<sup>17</sup> Lupton, *Medicine as Culture: Illness, Disease And The Body*.

<sup>18</sup> The extant Microeconomics literature exploring price, income, and demand elasticity relating to health care, including pharmaceuticals, has found that “most patient demand for health care is relatively inelastic, which means that it is not especially price sensitive and often cannot be delayed,” per Joshua Cohen (October 2, 2019), “How Recession Proof Is The Pharmaceutical Industry?” See Ringel et al., “The Elasticity of Demand for Health Care: A Review of the Literature and Its Application to the Military Health System,” and also Zhou et al., “New Estimates of Elasticity of Demand for Healthcare in Rural China,” among others.

year increase.<sup>19</sup> Often called the bioeconomy, the research and development (R&D), manufacturing, export, and import of pharmaceuticals represent a major source of net inflows of foreign direct investment (FDI), which historically has been an essential component of states' economic development, industrialization, and balance of trade growth strategies, regardless of their phase of development or national income. For example, FDI in the form of pharmaceuticals represents a significant and growing component of favorable international trade balance for European Union (EU) member states (Chapter 2.2).

Over the prior two decades, the pharmaceuticals share of some advanced economies' exports and trade balances have grown significantly, often making up for trade and employment losses in other sectors to maintain favorable trade balances, grow otherwise declining export markets, and sustain economic growth and development priorities.<sup>20</sup> Many of these states, including the United States of America (U.S.) and leading member states of the EU like Germany and the pre-Brexit United Kingdom, are among the 'great powers' of the contemporary international system, holding roles, relationships, and prestige in regulatory coordination and oversight processes that govern today's global pharmaceuticals market. As Marketplace® Contributor Sabri Ben-Achour describes, "In this millennium, countries don't get much by conquering territory. The war for your country's prosperity is fought in the lab and the marketplace."<sup>21</sup>

Amidst increasing globalization and technology diffusion, 'competition' states' geopolitical relevance in the 21st century relies on the capacity of its respective industries to innovate to meet the challenge of the new 'bio-century.'<sup>22</sup> State investment in and support for innovation also can be

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<sup>19</sup> Department of Commerce (U.S.), "Pharmaceuticals, A Market Assessment Tool for U.S. Exporters;" Workman, "Drugs and Medicine Exports by Country;" Harvard Growth Lab, The Atlas of Economic Complexity.

<sup>20</sup> European Commission, "International Trade in Medicinal and Pharmaceutical Products."

<sup>21</sup> Ryssdal, "Major Scientific and Technological Investments Sought to Better Compete against China."

<sup>22</sup> For Competition state literature, see Porter, "The Competitive Advantage of Nations." For an example of a great power leveraging

reputationally enhancing as it helps maintain their reputational influence as agents of global health change—an increasing priority of global society. A component of the United Nations’ (UN’s) 2015 Sustainable Development Goals (SDGs), which also are known as the Global Goals for a poverty-, hunger-, and disease-free world,<sup>23</sup> pharmaceuticals are politically viewed as essential to the palatability of sustainable development efforts. Contemporary global development strategies are about more than enhancing global capital and trade; it is about lowering the burden of disease by improving access to care for the world’s poor.

Gains are dynamic and often come with costs. For some patients, the orientation of scientific advancement is for the good, with access to curative, preventative, and palliative treatments never available. For others, it may be for ill, resulting in overprescribing, overuse, and the multitudes of comorbidities and avoidable side effects associated with both, saying nothing of the prevention of disease that may be possible when medicine is more than prescribing. From a systems level, tensions include the political complexity of rising disease prevalence and mortality, unaffordable and often inaccessible health care, unsustainable levels of pharmaceutical spending, and a general overreliance on pharmaceuticals to fix every ill—whether from sickness or economies slowing from recession or productivity losses. Alzheimer’s researcher and treating physician Dr. Jason Karlawish implicitly reflects on this dilemma in his explanation of the scientific urgency behind AD pharmacological research:

We really need to think about how we’re going to live with [Alzheimer’s] disease. We are not going to drug our way out of the problem. Banking on a cure for all causes of

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domestic institutions to advance international power, see 117th Congress (2021–2022) - 1st Session, “U.S. Innovation and Competition Act (USICA)”;

White House (U.S.), “statement of President Joe Biden on Senate Passage of the U.S. Innovation and Competition Act,” “Major Scientific and Technological Investments Sought to Better Compete against China,” Elbeshbishi and Behrmann, “Senate Passes Bill to Boost U.S. Science and Tech Innovation to Compete with China,” Lobosco, “What’s in the China Competitiveness Bill?”

<sup>23</sup> World Health Organization, “Sustainable Development Goals.”

late life disabling cognitive impairments is like planning your retirement with lottery tickets: you may win and win big, but odds are you're not going to.<sup>24</sup>

In these ways and others, pharmaceuticals are socially constructed to be more than medicine and sustained these beliefs through political and economic practice. The widening gap, however, between hope and reality is also a risk, one of several that have accompanied recent health gains.

As these tensions demonstrate, there are significant political consequences and particularly acute risks from an overreliance on pharmaceuticals.<sup>25</sup> What is less visible, however, are the political relationships and their origins: the role of power in determining, through direct action or indirect influence, the underlying systems implicit in the gains and the risks. For example, the systems of biomedical (biopharmaceutical) research and development (R&D); pricing, marketing, and access to the resultant biopharmaceutical innovation; common medical practices that facilitate the prescribing of innovation; and even our own idea of health and respective interest in treatment. This narrative construct is itself a symptom of certain deeply embedded norms that give context to and sustain the “powerful logic of neoliberalism.”<sup>26</sup>

State and nonstate actors who benefit from these dynamics may be motivated to sustain the systems, rules, norms, policies, processes, expectations, and other modalities of governance<sup>27</sup> that enhance their power, rather than temper it, which only furthers power asymmetries and the contemporary state of global ill health, including slowed improvements in indicators of population

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<sup>24</sup> As interviewed by Judy George (2021) in “A Revolution Is Underway in Alzheimer’s, and It’s Not All Good.” Karlawish has explored this theme in a recent work on the intersection of Alzheimer’s; see *The Problem of Alzheimer’s: How Science, Culture, and Politics Turned a Rare Disease into a Crisis and What We Can Do About It* (2021).

<sup>25</sup> Risks include the rise in anti-democratic forces and instruments. See Piketty, *Capital in the Twenty-First Century*, among others.

<sup>26</sup> Rushton and Williams, “Frames, Paradigms and Power: Global Health Policy-Making under Neoliberalism.”

<sup>27</sup> “Global health governance” refers to the use of formal and informal institutions, rules, social norms and expectations, policies, and processes by states, intergovernmental institutions, and non-state actors, including transnational companies and international organizations, to deal with challenges to health that require collective action.

health and the dramatic increase in the prevalence of preventable and reversible NCDs.<sup>28</sup> In this way, power and expressions of power, including political relationships and rules, are intuitively applied to practically shift norms and systems to the exclusive role of protecting and advancing certain actors and ideas in the ‘making’ of global health.

Constructing powerful norms, and concentrations of related power, which have deepened under globalization, privilege certain actors and ideas, including the marketization, individualization, and commercialization (commodification) of health. If these power asymmetries are mirrored across the lifecycle of pharmaceutical development – from prioritizing the disease classes that will benefit from biopharmaceutical innovation, the venture capital (VC) and taxpayer funding of research and discovery, distributing pharmaceuticals based on market-generated value, and pricing practices that preserve market failures and restrict access – the global distribution of health inequities is easy to see, nor are the deep discontents they generate.<sup>29</sup>

Health dominates the public dialogue globally and locally, and inevitably involves politics, which is the exercise of power and the mechanism for constructing and distributing ‘good health’ both locally and globally. For example, the global coronavirus disease (Covid-19) pandemic, caused by the second coming of SARS-CoV; unsustainable levels of health care spending, including on pharmaceuticals; and pervasive inequities, rooted in power asymmetries and socio-political determinants of health, have only deepened health’s primacy. Despite this persistent relevance, and global progress on access to health care, improvements in indicators of health and wellness, and stunning technological and biomedical innovation over the past several decades, the distribution of

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<sup>28</sup> Cornia, Rosignoli, and Tiberti find that the rate of improvement of the main health indicators slowed down in most regions of the world between 1980 and 2000. They also note that the postwar gains in global population health were derived from “progress in health technology,” the impact of which “depends on their accessibility,” not only their discovery. See Labonté et al., *Globalization and Health: Pathways, Evidence and Policy*, chaps. 2, “An Empirical Investigation of the Relation between Globalization and Health,” 34-62.

<sup>29</sup> Milner, “Globalization and Its Political Consequences: The Effects on Party Politics in the West.”

health gains versus risks within and between countries “remains extremely and unacceptably uneven.”<sup>30</sup> The same can be said of scholarly examination of the global politics of health. Though political and ethical factors are acknowledged as influences on health, the exercise of power on system, community, and individual preferences, and on outcomes, remain marginalized in International Political Economy (IPE) scholarship and are only nascent in their application and incorporation within Public Health, Medical Sociology, and Health Policy.

The research interprets our collective reliance on pharmaceuticals – whether to meet states’ politico-economic goals for economic growth and legitimacy or individual patients’ wellness priorities – as an ‘imagining’ of the role of medicine in global society across levels of analysis: for the system, state, and individual. Imagining refers to the International Relations (IR) theories, rooted in Sociology and Psychology and reflected in Benedict Anderson’s *Imagined Communities* (1983), of discourse and imagination, which assert that knowledge and ideas are not only intersubjective but reflect constructed assumptions about place and time.<sup>31</sup> In *Imagined Communities*, state nationalism reflects a shared “imagined reality” resulting in the state’s citizens socially constructing a collective consciousness and self-perception of themselves as part of an “imagined community of the nation.”<sup>32</sup> Anderson and others articulate the origins and expression of imagined communities through the lens of the media; it also can refer to a non-state community of interest. The research adopts this latter typology but extends beyond its implicit bounds to discuss how the collective ‘imagining’ of health is politically constructed – through discursive and other forms of power – to align with hegemonic ideas and global market-based or capital-driven norms.

Applying the broader concepts of ‘imagined communities,’ consciousness, and social

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<sup>30</sup> Ottersen et al., “The Political Origins of Health Inequity: Prospects for Change.”

<sup>31</sup> Anderson, *Imagined Communities: Reflections on the Origin and Spread of Nationalism*.

<sup>32</sup> Op. cit., Anderson, 23-25.

construction, the research sets out to explore whether and how the ideas of ‘health’ and ‘medicine’ are made to align with the tenets of global capitalism, specifically, democratic capitalism. As with most things that one imagines, however, the reality is distinct from our collective hope. This ‘idea of pharmaceuticals’ is strikingly compelling because of its alignment with the broader neoliberal discourse and its ability to sustain an outsized and highly influential role for certain actors and ideas in the production, governance, and provision (making) of global health, to the exclusion of other actors and ideas. These leading economic actors (i.e., states and multinational pharmaceutical manufacturers) and global overreliance on pharmaceuticals are dynamics informed by the narrative constructs surrounding health and its dominant ideational factor, the accumulation of capital.

This research hypothesizes that power and expressions of power, including political relationships (actors) and rules (governance), are intuitively applied to practically shift norms and systems to the exclusive role of protecting and advancing hegemonic economic actors and capital-oriented ideas in the making of global health. For example, actors who benefit from these dynamics may be motivated to sustain the systems, rules, norms, policies, processes, expectations, and other modalities of governance<sup>33</sup> that enhance their power, rather than temper it, which only furthers power asymmetries and the contemporary state of global ill health, including slowed improvements in indicators of population health and the dramatic increase in the prevalence of preventable and reversible NCDs.<sup>34</sup>

Before diving into the qualitative and practical analyses of the later chapters, this chapter first outlines how the research design and methods for examining these important questions; the

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<sup>33</sup> “Global health governance” refers to the use of formal and informal institutions, rules, social norms and expectations, policies, and processes by states, intergovernmental institutions, and non-state actors, including transnational companies and international organizations, to deal with challenges to health that require collective action.

<sup>34</sup> Cornia, Rosignoli, and Tiberti find that the rate of improvement of the main health indicators slowed down in most regions of the world between 1980 and 2000. See Labonté et al., *Globalization and Health: Pathways, Evidence and Policy*, chaps. 2, “An Empirical Investigation of the Relation between Globalization and Health,” 34-62.



hypotheticals it intends to examine; and the analytical, theoretical, and conceptual frameworks it relies on to make these arguments. The balance of this chapter aims to do just that: to present the research design, specifically, outlining the research question(s), hypothesis, and methods; articulate the mixed-methods approach of literature-based and practical analyses; and make visible the inherent limitations of the research's methods. How the methods and analyses evolved during the narrative synthesis also are described—from a pair of case accounts focused narrowly on the politics of pharmaceutical pricing. For ease, the chapter closes with a reminder of defining terms, concepts, and theories essential to the research and, sometimes, unique to it (e.g., governance, public goods, Critical Theory and Constructivism, actors, ideas and ideational factors, values).

## **1.2 A Critical Constructivist Analysis of Power**

This dissertation employs pharmaceuticals as a proxy to examine the observed power asymmetries and market-oriented norms relating to health. Specifically, the research asks: what is the role of power, actors, and ideas in the making of global health? This research hypothesizes that power asymmetries sustain and embed market-oriented ideas as global norms, which shape not only the role and interests of actors, but all facets of health, including global health and the practical degree of health equity. In this way, power can practically shift norms and systems to the exclusive role of protecting and advancing hegemonic actors and ideas in the making of global health. Rather than an exclusive focus on health's visible outcomes, in terms of a particular policy and whether it achieved its stated goal, to examine the influence of power fulsomely, the research asserts that equitable scholarly focus and practical solutioning must be applied to the ideas, processes, contents, and contexts that make global health. The research examines the constructing ideas about health and how power sustains their political salience and frames their norm-driven choices.

Now, why pharmaceuticals—let alone health? Neither topic is centered within IPE, but, as the research argues, their exclusion reflects broader ideas and norms about health, rather than IPE

as a discipline being ill-suited to such analyses. But the discipline's interdisciplinary underpinnings and appreciation for systems of economic and political relations makes it well suited to examine systemic issues with their origins and expression across levels of analysis, including the international system level. Pharmaceuticals exist within the same ever-shifting politico-economic context as health and all other areas of global social life: the global political economy, which IPE scholars have rightly examined since the heightened global economic interdependence that so marked the 1970s onward.

In the decades since, globalization has been intentionally shaped by capitalism through the neoliberal discourse. Its myriad of dynamic, interactive forces — centralization and localization ('global versus the local'), positive and negative externalities, integration and fragmentation, valuation and assetization — generate complex political economies from which health and other issues of 'low' politics are not immune and often subordinated. This research suggests that pharmaceuticals are no exception, no deviant. They are a signal of more fundamental trends relating to political representation, inequality, and the legitimacy of democratic processes and values warranting further exploration.<sup>35</sup>

There is a multitude of evidence linking globalization and health, specifically, "the political origins of health inequity"<sup>36</sup> resultant of globalization's penchant for liberalizing and marketizing everything—health included (i.e., turning health into a commodity and service subject to economic rationalism and free trade rules)—which represents a de facto or quasi form of global governance for health. (That is, the governance being of the market.) The research accepts and applies the evidence-based causal relationship (between globalization and health), explicitly rooting health

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<sup>35</sup> We recognize these are bold assertions with which to begin a chapter on research design, but these also reflect the high stakes of imbalances within contemporary global society. For scholars of Development Theory, such stakes and the arguments we will make relating to health likely are familiar. What is old is new; what was a problem of the global South is a problem—not that it was not before, but clearly the problems of the privileged dictate how, even in scholarship, we frame and prioritize the issues worth examining.

<sup>36</sup> Ottersen et al., "The Political Origins of Health Inequity: Prospects for Change."

independently within the global political economy and the IPE discipline—a placement whose acceptance has been too long awaited. This de facto global regulation of pharmaceuticals, a form of global governance, is imparted and sustained through a global politics of health – an array of political economies of medicine (Chapter 2) that reflect certain ideas about health (‘norms’).<sup>37</sup>

These normative ideas have constitutive and constructive affects; for example, they impart competitive interests by actors, which practically result in power imbalances (i.e., zero-sum dynamics) between successful competition states and market-motivated economic actors on the one hand, and other actors and ideas on the other. These power imbalances, driven by particular ideas, pits the purely economic gains of health as a market against the individual and social gains in wellness and equity of *health as a state of being*. Such conflicting tensions, as this research will demonstrate, are often won out by the former, leaving individual patients and sometimes national politicians left to sort out the in-between.

### 1.2.1 Applied Theoretical and Analytical Frameworks

Despite centuries of scholarship on the politico-economic determinants of health, at minimum, a half century of contemporary thinking recognizing the role of power in shaping health policy outcomes, and multiple conceptual and theoretical frameworks exploring this relationship unique to health, the field of IPE continues to self-restrict. The discipline continues to close the aperture to capture health as a development barrier, security risk, or economic threat à la Covid-19. Why not health for *health's* sake?

This intentionally interdisciplinary research draws on the extant Macroeconomics, Microeconomics, IPE, Public Health, Medical Sociology, and Political Science (including Health Policy) literature and richness of existing analytical frameworks (i.e., from the fields of Public Policy

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<sup>37</sup> Specifically, this narrative construct is itself a symptom of certain deeply-embedded norms that give context to and sustain the powerful logic of neoliberalism.

(Health Policy), Public Health, Medical Sociology, and the interdisciplinary community reflected in the London School of Economics' *Globalization and Health* journal) to examine how power and politics influence and shape global health through normative *ideas* about health, the policymaking *processes*, policy as *content* and practical outcomes—all considered within the *context* of the global political economy and geopolitical relations. As Michael Reich (1994a, 1994b, 1995)<sup>38</sup> explained more than a quarter-century ago, health policymaking,<sup>39</sup> the “health policy change process” (i.e., health reform, health system change),<sup>40</sup> and the outcomes of such processes – whether globally through international regulatory coordination, policy convergence or harmonization, or global regulation in hard-law treaties or multilateral agreements – are profoundly political. The analysis of health policy, however, often is devoid of recognition of power, as Michel Foucault (1982) explains:

Why study power? [To understand] the different modes [of objectification] by which, in our culture, human beings are made subjects... and the objectivizing of the subject in which I shall call ‘dividing practices.’ The subject is either divided inside himself or divided from others. This process objectivizes him. Examples are the mad and the sane, the sick and the healthy, the criminals and the ‘good boys.’<sup>41</sup>

Such analysis also often focuses exclusively on the content of the policy and its outcomes, versus the preexisting and preceding factors that compel, shape, or curb policymaking, and Gill Walt and Lucy Gilson (1994) explain:

Much health policy wrongly focuses attention on the content of reform, and neglects the actors involved in policy reform (at the international, national, and sub-national levels), the processes contingent on developing and implementing change, and the context within which policy is developed. Focus on policy content diverts attention

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<sup>38</sup> Reich, “Bangladesh Pharmaceutical Policy and Politics” (1994a); op. cit., “The Political Economy of Health Transitions in the Third World,” in Chen et al., eds., *Health and Social Change in International Perspective* (1994b); and op. cit., “The Politics of Health Sector Reform in Developing Countries: Three Cases of Pharmaceutical Policy” (1995).

<sup>39</sup> In this sentence and elsewhere in this chapter, for simplicity, we refer to policy, which we treat as a general term referring not only to legislative policy in the traditional sense but also rules (that is, regulations), standards, and formal or codified norms (e.g., requirements codified via international legal instruments, treaties, trade agreements).

<sup>40</sup> Op. cit., Reich (1995).

<sup>41</sup> Foucault, “The Subject and Power,” 777.

from understanding the processes which explain why desired outcomes fail to emerge.<sup>42</sup>

This research employs an original analytical model, the Four Factors of Power Expression in Governance and Policymaking, reflecting the Critical Theory variant of Constructivism, or Critical Constructivism (Chapter 1.2.3). Critical Constructivism assumes a structuring role of power and hegemonic actors<sup>43</sup> that is not dissimilar to the expectations of Realism and Neorealism, but also other theoretical paradigms and frameworks commonly applied in IPE and International Relations (IR). As a theory of IPE and IR, it is familiar to the discipline, though applied in an unfamiliar way (i.e., to a topic often considered beyond the bounds of the disciplines). Similarly, the research aims to be interdisciplinary not only topically but methodologically by applying definitional concepts, theoretical frameworks, and modes of analysis beyond the disciplines of IPE and IR—borrowing from Medical Sociology, Public Health, and Public Policy. This includes, for example, Critical Social Theory, Public Goods Theory, Feminist theorems of the commodification of bodies and labor, Marxist and Weberian theorems of modes of production and class-elite dialectical relations, Public Health concepts of power in global health governance, and the analytical models of Walt, Gilson, Kentikelenis, and Rochford, which are themselves interdisciplinary, multifactorial, and dynamic.

Reflecting the Critical Constructivist theorem; typologies of ‘ideas’ and ‘consciousness’ from Constructivism; Critical Theory and Feminism as contextualizing factors; and typologies of power and actors from Realism, the research applies a Critical Constructivist analysis of the power and politics of medicines. Specifically, the ‘four factors’ of ideas, content, context, and process (as described on page 18) is applied to descriptive case studies (‘accounts’) that are analyzed in the second part of the analysis (Chapter 6). This multifactorial conceptual framework that the Four

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<sup>42</sup> Walt and Gilson, “Reforming the Health Sector in Developing Countries: The Central Role of Policy Analysis,” 354.

<sup>43</sup> Op. cit., Hopf, 185.

Factors model imparts is informed by the findings of the first portion of the analysis, the critical review of the literature, as found in Chapters 3-5.

### 1.2.2 Four Factors Model of Power Expression in Governance and Policymaking: Description of the Novel Analytical Framework

The research applies Ted Hopf's (1998) Critical Constructivism<sup>44</sup> theoretical framework, which is rooted in Alexander Wendt's (1992) Constructivism and the co-production of health frameworks developed by Vicente Navarro (1976). The analysis itself, however, reflects the application of a novel analytical framework reflecting the amended adaptation of Gill Walt and Lucy Gilson's (1994) Policy Triangle Model for Health Policy Analysis<sup>45</sup> that has been informed by Alexander Kentikelenis and Connor Rochford's (2019) Integrative Levels of Analysis framework for evaluating power asymmetries in global health governance.<sup>46</sup> Specifically, the Walt-Gilson model, which was developed primarily for sub-system or domestic application, posits that policy research needs to consider not just the *content* of policies, but also the *context* and *processes* to explain outcomes and assess implementation. The Policy Triangle model by Walt and Gilson outlined a simple analytical model that incorporates four preconceived thematic categories for examining health-related policies, rules, and standards and processes of policy change: content, context, process, and actors.

This research adapts and amends the Walt-Gilson model by incorporating ideational factors (ideas) as a factor of analysis in addition to content, context, and process, and placing actors as an independent variable or subject of the factors; see Figure 1.2-A and Table 1.2-A. Specifically, the proposed model, called the Four Factors Model of Power Expression in Governance and

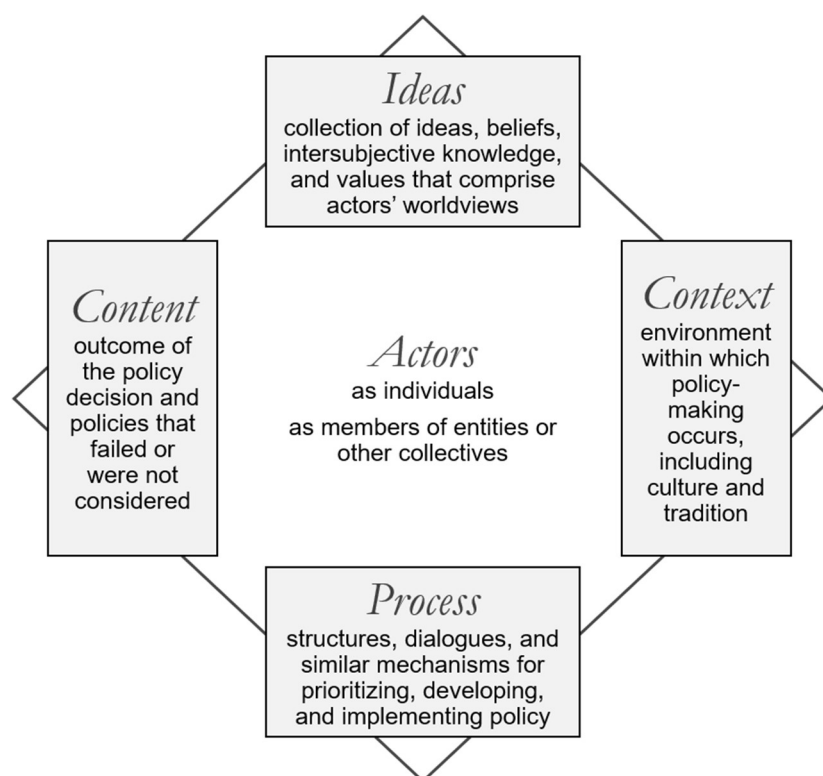
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<sup>44</sup> Op. cit., Hopf, 185. See also Weber, "Constructivism and Critical Theory."

<sup>45</sup> Walt and Gilson, "Reforming the Health Sector in Developing Countries: The Central Role of Policy Analysis."

<sup>46</sup> Kentikelenis and Rochford, "Power Asymmetries in Global Governance for Health: A Conceptual Framework for Analyzing the Political-Economic Determinants of Health Inequities."

**Figure 1.2-A. Four Factors Model of Power Expression in Governance and Policymaking**



Author-generated illustration of novel model for analysis of power and global health in the international system. For the Triangle Model of Health Policy Analysis, see Walt and Gilson, “Reforming the Health Sector in Developing Countries: The Central Role of Policy Analysis.”

Policymaking, shifts actors from a factor of analysis (i.e., dependent variable) to the agent under analysis (independent variable), resulting in a model that posits:

Actors involved in policymaking and governance are informed by the outward display and codification of their policy preferences and interests in the form of the policy outcome and the exclusion of failed or alternative policy options (content); the normative *ideas* that comprise actor’s individual worldviews and frame the collective discourse; the systemic context; and the processes that govern decision-making, often serving as a pre-negotiated mechanism for sharing or dividing power in policy decision-making.<sup>47</sup>

<sup>47</sup> The other three concepts are processes, actors, and context, which remain though, naturally, we have operationally defined each for the purposes of this research, as articulated on the subsequent pages.

**Table 1.2-A. Components of the Four Factors model**Dependent Variable

Actors	Who are the actors typically considered powerful on the global stage, and across the health system who may be powerful in national contexts? What are their motivations and interests? How do they express power, and is their power conditioned on the actor's role in the global economy or their political salience? <sup>48</sup>
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Independent Variables (Four Factors)

Content	How are policy preferences and interests outwardly displayed (in terms of preferred policy choices) and codified (policy outcome), as compared to those policies excluded from consideration, failed, or were unfavorable alternatives? What is the content of the policy and the content of other policies or alternative priorities not considered?
Context	What is the environmental context within which policymaking occurs, including the political culture, institution, style of engagement and intersubjective power dynamics between actors, the (contextualizing) influence of other policymaking or priorities, and historical traditions (e.g., policy negotiation with an ally on nuclear weapons is contextually different from negotiations with a threat or competing power).
Idea	What are the internalized, intersubjective, and pre-existing clusters of beliefs," cognitive short-cuts, mental aids, heuristic devices, and principles—the "cognitive maps"—held by individual actors or adopted by a group of actors to understand the human condition in its environment, including social relations and systems of power relations. <sup>49</sup> May be heuristic <sup>50</sup> or subjective. Range from the specific to the programmatic, diagnostic to philosophical, including 'understandings' <sup>51</sup> akin to those that form social consciousness <sup>52</sup>

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<sup>48</sup> The research defines actors using a composite definition reflecting that of Michael Reich (2002) and Hideki Kan (2010). Actors are the entities in the global political economy, including states and other individual and collective entities, that have the following features: "should have the autonomous capacity to determine their own purposes and interests;" "should have the capability to mobilize resources to achieve these purposes and interests;" and "their actions should be significant enough to influence state-to-state relations or the behavior of other non-state actors in the international system." May be applied to sub-system levels of analysis, referring to entities with the aforementioned features whereas the third refers to involvement in the relevant policymaking "process and might enter the debate over the policy's fate." Kan, "Actors in World Politics," 179–80, and Reich, "The Politics of Reforming Health Policies," 139.

<sup>49</sup> Quotations refer to Holsti, "Foreign Policy Formation Viewed Cognitively," 20. The conceptual definition, however, refers primarily to Béland and Cox, *Ideas and Politics in Social Science Research*, 6. The extant literature on what comprises ideas is extensive; see also Brummer, "Fiasco Prime Ministers: Leaders' Beliefs and Personality Traits as Possible Causes for Policy Fiascos;" Burdein, Lodge, and Taber, "Experiments on the Automaticity of Political Beliefs and Attitudes;" Foyle, "Public Opinion and Foreign Policy: Elite Beliefs as a Mediating Variable;" Radaelli and O'Connor, "How Bureaucratic Elites Imagine Europe: Towards Convergence of Governance Beliefs?" and Renshon, "When Public statements Reveal Private Beliefs: Assessing Operational Codes at a Distance." For an extensive review of the literature on ideas, see Swinkels, "How Ideas Matter in Public Policy: A Review of Concepts, Mechanisms, and Methods"

<sup>50</sup> Jones, "Behavioral rationality as a foundation for public policy studies," 2017.

<sup>51</sup> For literature exploring specific and programmatic ideas, see Kingdon, *Agendas, Alternatives, and Public Policies* and Schmidt, "Discursive Institutionalism: The Explanatory Power of Ideas and Discourse." For diagnostic beliefs and principles, see op. cit., Jervis, and Van Esch and Snellens, "From Belief to Behavior. Using Cognitive Maps to Test Ideational Policy Explanations."

<sup>52</sup> Robertson, "Glocalization: Time-Space and Homogeneity-Heterogeneity."



**Table 1.2-A, Continued**Independent Variables (Four Factors), Continued

Process	How do issues get on the policy agenda, and are they on the agenda for formal or informal policymaking? How far does a particular issue get once policy space is created for it? Is the process visible to the public, transparent, and articulated in advance with decision-making terms negotiable by actors not exclusively regulating authorities? Besides the visible processes open to public engagement and attendance, how are the pre-event decisions negotiated and whom may be involved?
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Author-generated explanation.

In addition to the retention of the original contextualizing factors of *policy* content and the decision-making or governance *process*, including the concept of *ideas* improves the Walt-Gilson model and better reflects the authors' intent to move policy analysis, whether of health or otherwise, from "wrongly focus[ing] attention on the content of reform," meaning the policy itself, to broader analyses of "the processes which explain why desired policy outcomes fail to emerge" (emphasis added).<sup>53</sup> The inclusion of macro-meso-micro indicators (e.g., values, norms, interests, choices, and preferred behaviors) and the adjustment to focus on the broader category of ideas strengthens the model's ability to examine the ex-ante drivers of "policy content," versus the *post hoc* focus on policy choices and outcomes, which – this research argues – are themselves the product of power-informed processes, actors, and ideas occurring *ex-ante*. Essential to this model is a mutual understanding of power. For Critical Theorists, power is "exercised in every social exchange, and there is always a dominant actor in that exchange."<sup>54</sup>

Power can take multiple forms, also called taxonomies (Table 1.2-B). For example, productive or discursive power refers to how meaning is produced, fixed, lived, experienced, and

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<sup>53</sup> Op. cit., Walt and Gilson, 354.

<sup>54</sup> Op. cit., Hopf, 185.

**Table 1.2-B. Barnett and Duvall's taxonomy of power, with Critical Theory overlay**

		<u>Operational Definition</u>	
		Direct	Diffuse
<u>Power works through:</u>	Interactions with specific actors	Compulsory <i>Coercive/ constraining or Incentive:</i> direct control over another actor, á la Weber, Dahl, <sup>55</sup> and Waltz, which employs material <i>and ideational</i> factors to 'balance' the power of stronger actors	Institutional <i>Regulatory or Governance:</i> indirect power over socially distant others, which should empower weaker actors through institutionally facilitated collective action, but often strengthens already-empowered actors
	Social relations of constitution <sup>54</sup>	Structural <i>Representative:</i> direct and mutual constitutions of the capacities of actors, which may legitimize and fortify embedded social relations and hegemonic positions	Productive <i>Discursive:</i> the "production of subjects of power through diffuse social relations" <sup>55</sup> (self-regulation, redefinition of traditions <sup>56</sup> ), which may similarly leverage change to benefit already-powerful actors

Author-generated examples based on Barnett and Duvall, "Power in International Politics."

transformed, which produce social identities, boundaries, and capacities—the intersubjective knowledge and ideas that form consciousness. This research adopts Barnett and Duvall's (2005) definition: "The production, in and through social relations, of effects that shape the capacities of

<sup>55</sup> Dahl's concept of power implies nothing about the preferences of B, is not zero-sum, does not necessitate compulsion, may or may not be subtle or visible, is not confined to material resources, and may be either direct and immediate or indirect and long term. See Dahl, "The Concept of Power"; Dahl, Robert, *Who Governs? Democracy and Power in an American City*.

<sup>56</sup> Refers to the constitution of an actor (e.g., their capacities, interests), which affects their ability to shape the circumstances of their own existence, or a 'power to' concept as it defines the actor's ability to perform an action and as such its effects are generally seen in terms of the identity of the subject of power. See op. cit., Barnett and Duvall.

<sup>57</sup> Institutional power refers to the power of global institutions to create a conceptual starting point for addressing complex issues, including through rulemaking, treaty making, and other forms of governance or rulemaking that allows for the sharing, dividing, or exclusion of power, and may permit certain actors to dominate others. While some institutions are self-generating, the 'great powers' long have had the ability to establish international institutions that enable them to maintain their positions of advantage by guiding global rule establishment. The Bretton Woods Institutions are such an example.

<sup>58</sup> Moon, "Power in Global Governance: An Expanded Typology from Global Health."

actors to determine their circumstances and fate.”<sup>59</sup> It is relational and relative, interactive and constitutive, and produces effects relative in their specificity.<sup>60</sup> Perhaps use of this form of Constructivism – the Critical Theory offshoot of Constructivism – is unconventional regarding its application to IR and IPE scholarship. Critical Constructivism, also sometimes termed Post-positivism or Pragmatism, views historical knowledge as socially constructed, as compared to dominant IR theorems that treat history as an independent store of events, actors, and consequences. As Jonathan B. Isacoff (2002) has argued, “if the assumptions upon which historical knowledge within IR scholarship is constructed were found to be flawed,” meaning that historical accounts reflect constructed or imagined narratives about events, actors, and consequences, “then explanations that appear to successfully account for historical cases might not be as accurate as we would like to believe.”<sup>61</sup> Because this research implicitly aims to examine whether power asymmetries in global health reflect hegemonic ideational factors, the selection of this un-‘conventional’<sup>62</sup> form of Constructivism is intentional. Critical Theory<sup>63</sup> offers a unique complementary lens through which to consider the normative and historical properties of identity, power, and ideas relating to health. Critical Constructivism’s theoretical orientation is a better approximation of the hypothesized processes and inputs than more quantitative or positivist models that presume human behavior in idealized scenarios.

### 1.2.3 A Mixed-methods Approach

Employing a mixed-methods approach, the research then has two parts. Part I of the research is a critical review of the literature that aims to examine how and why *power shapes global*

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<sup>59</sup> Barnett and Duvall, “Power in International Politics,” 39.

<sup>60</sup> Navarro et al., “Politics and health outcomes.”

<sup>61</sup> Isacoff, “On the Historical Imagination of International Relations: The Case for a ‘Deweyan Reconstruction,’” 603.

<sup>62</sup> Cho, “Conventional and Critical Constructivist Approaches to National Security.”

<sup>63</sup> Reynolds, “Building Theory From Media Ideology: Coding for Power in Journalistic Discourse.”

*health* and, as an instrument of and influence on power, *ideas make health*. Taken together, the existing interdisciplinary literature on health, globalization, and power reflects the collective ‘imagining’ of pharmaceuticals and their role in the global political economy. This first analysis draws on the extant literature and richness of theoretical, conceptual, analytical, and evidentiary frameworks from IR, IPE, the interdisciplinary scholarly community of the London School of Economics’ *BMC: Globalization and Health* journal, Macroeconomics, Microeconomics, Medical Sociology, Public Health, and Public Policy.<sup>64</sup>

Employing the Critical Constructivist theoretical framework, the first set of findings inform the assumptions and approach represented by the Four Factors model, which is applied in the second analysis of descriptive accounts of political influence along the pharmaceutical lifecycle – from prioritization of a disease for pharmacological research to the pricing of a drug. This secondary analysis intends to practically contextualize the ‘imagining’ of pharmaceuticals as operational influence points, whether exemplified by a particular policy, policy outcome, or decision-making structures that drive or reflect policies. Specifically, influence points refer to demonstrations and implications of the areas of intersect between power, ideas, and actors in global health governance to pharmaceuticals.

#### 1.2.4 Organization of the Descriptive Accounts

Following Part I’s critical review of the extant literature, the research examines the theoretical and conceptual findings of Part I against a differential range of policy expression, which is intentionally varied and inclusive of multiple levels of analysis to validate the explanatory power of such an approach. Specifically, within Part II, the Four Factors model is applied to a series of brief,

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<sup>64</sup> the relevant actors; their ideas, preferences, and degrees of influence; the continuum of known and unseen policymaking processes; policy as *content* with *context*; and the complex array of practical outcomes resultant of both adopted policies and the system of power relations from which they are derived and operate.

descriptive accounts spanning the pharmaceutical lifecycle. The accounts have been chosen to intentionally reflect multiple potential pathways of influence and levels of political action<sup>65</sup> relating to and involving pharmaceuticals, a proxy for health.

Each descriptive account—of strategic R&D decision-making rooted in geopolitical considerations, of patients funding their own drug development, of offshoring clinical trial research to the ‘global South,’ of pharmaceutical policy harmonization-turned-hegemony, of the devaluation of cures lacking a commercial market, of taxpayers acting against their own interests (to insulate drug markets from price-lowering competition), of price-negotiation schemes that internationalize certain concepts of value, of equity in protection against global pandemics—offers a situated perspective through which the hypothesis and model can be tested. Each case also affords a locus for observing the multitude of ways power influences making global health at distinct levels of political engagement.

The descriptive accounts of Chapter 6 are organized in four sections, which align with the major components of the pharmaceutical lifecycle (Figure 1.2-B). *First*, the early processes and mechanisms of state intervention for determining which therapeutic area (diseases), modality (delivery mechanism for the pharmaceutical), and geographies (states as markets) that pharmaceutical research and development (R&D) should prioritize are examined. *Second*, the rise of alternative research investment and financing of pharmaceutical R&D are examined, including venture philanthropy sponsored by patient advocacy groups (i.e., ‘co-production’) and state-appropriate grants and other research funding. *Third*, the systems and processes of power relations post-discovery and pre-market approval that influence the approval of pharmaceuticals are

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<sup>65</sup> Per Kentikelenis and Rochford (2019), the model incorporates a macro, meso, and micro levels of analysis framework through the intentional inclusion in the Research Design of case studies that enable the exploration of macro (i.e., “frames, scripts, and models”), meso (“type of actors involved; forms of decision-making; content of policy choices”), and micro (“values, interests, and choices; behaviors”) levels of pharmaceutical governance and related politico-economic actions and decision-making processes.

Figure 1.2-B. Visual depiction of the pharmaceutical lifecycle



Author-generated illustration of based on analysis of descriptions of pharmaceutical lifecycles by different national regulatory authorities and by multinational pharmaceutical corporations (MNPCs) themselves.

considered. These represent the midpoint of the pharmaceutical lifecycle.

This third collection of case studies does not address the *inputs and outcomes* of regulatory approval for a pharmaceutical to enter a market, as this area is well explored through existing health policy analysis. Reminiscent of Walt and Gilson’s critique, the endpoint of this midpoint in the lifecycle most often reflects the standard policy analysis questions of “what is the policy” (i.e., the standards for pharmaceutical approval or licensure in a particular market) and “what are the policy’s outcomes” (e.g., how many drugs were approved). Rather, the “distant proximities”<sup>66</sup> that inform the *processes* of actor interaction, the *ideas* informing available policy choices (*content*), and the (market) *context* preferencing the design (another form of *content*) of regulatory oversight of states’ domestic pharmaceutical approval and licensure policies are explored. Specifically, the somewhat-obscure

<sup>66</sup> Rosenau, *Distant Proximities: Dynamics Beyond Globalization*.

international regulatory coordinating forums that underpins many states' contemporary pharmaceutical regulation are examined, along with the geopolitical and historical legacy of the emerging contract research industry.

*Fourth*, what happens after clinical research trials and pharmaceutical approval or licensure is explored, including the processes for determining whether and how to bring a pharmaceutical to market (commercialization), pricing, and market access. The section also examines at least one potential endpoint to the pharmaceutical lifecycle: patient access to a medicine—, the Covid-19 vaccine. The closing case specifically examines mass purchasing and patient access.

Of the descriptive accounts in this five-part chapter, the majority could be considered deviant or semi-deviant, meaning ill-suited to the research's premise, analytical framework, or paradigm. The research seeks to examine the politics of health which, one could presume, are limited to the confines of *explicit* requirements under particular modes of regulatory governance, versus the independent decision-making of private actors, including firms. Contrary to this presumption, several cases focus directly or indirectly on industry- or firm-level decision-making processes and considerations, which is presumed to be outside the bounds of politics. Including these cases, however, is intended to test the hypothesis' application to actors, ideas, processes, and outcomes that may be considered 'apolitical,' including those wholly within the purview of private firms.<sup>67</sup>

### 1.2.5 Looking Beyond Pricing and Access: Evolution of the Research

From ideation, this research has evolved significantly, and for good reason. At the outset, the research intended to examine the questions before us through the lens of two particular

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<sup>67</sup> We hypothesize that these cases will demonstrate the interrelation and complex interdependence of firm- and state-level decision-making, or how state and global policy contextualizes the ideas, preferences, and available choices of market actors even in areas absent direct regulation.

pharmaceutical pricing and access (P&A) policies: external reference pricing (ERP) and health technology or value-based assessment. The analysis would have examined the policymaking process and policy outcomes to determine the range of influential actors and their motivations, hypothesizing that global governance for health was increasingly moving to policy negotiation between states and select market actors. While this approach is reasonable and interesting, as the research advanced, it represented a biased approach: it ignored the extensive inputs and implicit power struggles along the way.

Focusing exclusively on how, mostly, advanced economies negotiate select pharmaceutical prices implies that only then — at the proverbial ‘end of the line’ in terms of the pharmaceutical lifecycle — is power at play, which is antithetical. Again, it presumes that except for the ERP policy, the global pharmaceutical market is otherwise Pareto-level efficient and ‘free’ of political influence and consequence, and so government intervention at the point of pricing is problematic and counter to global norms.

However, this is simply untrue. The pharmaceutical market, both from a global lens and the perspective of national markets, is highly governed (regulated), often in ways that seek to preserve the safety and clinically efficacy of these products but also, and increasingly, in ways that seek to protect these products from competitive market forces. Besides these generally well-understood forms of pharmaceutical governance, the 21st century has introduced forms of governance and policymaking largely invisible to the average patient or global citizen, including international regulatory coordination, collaboration, and, occasionally, harmonization, which effectively streamline and globalize pharmaceutical governance approaches that largely originate in advanced economies. These frameworks for coordination between states’ regulatory authorities (RAs) often include industry representatives at the decision-making table and require prospective member states to adopt particular policy approaches—in a manner not dissimilar to the structural adjustment program (SAP)



and similar models of required policy adoption employed by other international institutions and intergovernmental organizations.

To guard against the implicit bias and exclusion of the spectrum of political intervention and better examine the role of power, actors, and ideas in the global pharmaceutical market, the analysis was amended and expanded. Rather than focusing solely on the role of power at the *end*, the research examines the potential influence of power on actors and outcomes through *context, content, ideas, and process*. The final form – of a mixed-methods analysis of literature and practice – allows for a more fulsome examination of the issues at hand, specifically, the constructing role of ideas as norms and the hypothesized *diversity* of influence points oriented to achieve *similar* outcomes.

### 1.3 *Cui bono?* Typologies of Power within Global Health Governance

Specific to IPE, health is examined only through the narrow lens of international regimes and multilateral trade agreements (e.g., World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1994); the contributions of international organizations (IOs) to anarchy-counteracting global governance (e.g., United Nations Millennium Development Goals (MDGs) and Sustainable Development Goals (SDGs); World Health Organization (WHO) International Health Regulations (IHRs), 2005); and implications for global economic growth and development priorities and the role of international financial institutions (IFIs), e.g., health system-related requirements of structural adjustment programs (SAPs)). Within International Relations (IR), health boasts a similarly narrow focus; it is rarely examined beyond the limited confines of security theory (“medicalization of security”<sup>68</sup>).

Within Political Science, health scholarship emphasizes issues of policy analysis in terms of policy outcomes over questions of actors’ roles, interests, salience, how power is expressed through

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<sup>68</sup> Elbe, *Security and Global Health*.

political processes, power-adjacent instruments, policy agenda-setting, and design as politically constructed. Though power and politics influence the policymaking continuum, Political Science scholarship of comparative health often favors analysis of late-stage policy adoption or outcomes. Specific to Public Health, power and politics may be broadly discussed but, historically, has “been off the radar of the global health research community.”<sup>69</sup> Rarely were such dynamics centered in scholarship on health promotion, evidence-based interventions, clinical policy, and health care system improvements for explicit assessment and rigorous evaluation.

The prior two decades, however, have borne witness to dramatic attempts to address this gap. The United Nations (UN) Commission on Macroeconomics and Health, 2001, chartered a course of evidence generation, research, and action within the broader Public Health community as evidenced by the 2005 launch of the new research journal, *BMC: Globalization and Health*. Public and Global Health researchers are developing theories, frameworks, and methods for examining power—its sources, workings, and effects—in health systems and policy research.

Often, the scholarship is interdisciplinary, an approach this research adopts, leveraging engagement with the social sciences and humanities, including IR theory, to thematically broaden the study of power and politics in health. More recent research analyzes the exercise of power by actors typically considered powerful in global settings, and actors, if different, demonstrating outsized power in national and local contexts, which may include certain actors, interest groups, and practices rarely viewed as politically salient.

One of the more notable developments in the literature of global health and power in Public Health is the identification of mechanisms for challenging or counteracting power asymmetries and concentrations, including through human rights-based frameworks. Collectively, the field of Public

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<sup>69</sup> Storeng and Mishra, “Politics and Practices of Global Health: Critical Ethnographies of Health Systems,” 860.

Health has deepened policy analysis of the *political* and the practical, which is meaningfully advancing a systems and structures-based approach to critically investigating global politics, or political determinants, of health. Mindful of IPE's and IR's rich tradition of power analysis, the fields are extraordinarily complementary to this effort—though within these two fields, there is far limited focus on *health*, as earlier discussed.

Despite the burgeoning study of power and the politics of health in Public Health, health remains on the margins of IR and IPE, while feasibility and economic analysis are squarely at the center. This paper argues that questions of power and politics should continue to complement Public Health's broader assessments, just as health itself should be centered in IR and IPE, and there should be more immediate and direct dialogue between the disciplines. Similarly, the influence of power, context, narratives, and norms in the actual policymaking process should complement policy design analysis in the fields of Political Science and Comparative Politics. Building on the important groundwork laid by the Public Health community, this intentionally interdisciplinary research intends to promote the intersectionality of health-adjacent disciplines by articulating the merit of properly centering this marginalized issue within each and in a manner well-reflecting health's outsized importance.

Examining why certain actors hold power; who those actors are and what influences them; how that power is used; and what differences exist in terms of wielding that power – the *cui bono* – can help to theoretically and practically ground collective understanding of the workings and effects of power on critical social and political questions, especially health and health equity. So, too, can such an approach inform contemporary thinking on the effects of power on global governance, including the potential for global social norms commodifying health to be reversed. Analyzing power disparities and asymmetries, actor types, and typologies of power in global health spanning the disciplines must be examined.

Specifically, the dissertation intends to contribute to the field by encouraging the centering of health in IPE, including through the recognition of health as a core issue area alongside trade, development, finance, and multinational actors. Health has not become part of the ‘high politics’ that dominate the global politico-economic agenda, but this is a *characterization*, a reflection of political priorities which are themselves intersubjective and subject to normative influence—not a reflection of the actual severity and significance of a particular issue. Globalization’s influence on health, and of health (as a good and as a human condition) on the global political economy, warrants a greater focus within IPE not limited by the bounds of securitization of disease, medicalization of international development aid, or the marketization of health.

The IPE discipline and its scholarship must reflect the global experience it seeks to examine. The discipline must not only incorporate health within its bounds, redefine its own ‘scholarship space,’ as it were, beyond the neoliberal bounds of health for trade’s sake, but center health – for health’s sake – as a core issue of the 21st century global political economy. To paraphrase Jeremy Youde (2016), “[t]he international community has increasingly come to recognize the importance and merit of global health as a *leading* political issue,”<sup>70</sup> not as a *security* or an *economic issue*, *but as a core issue*. Regarding the issues articulated in this research, it is long past time for IPE to do the same.

## 1.4 Defining Terms

Because of the interdisciplinary nature of the research, readers may be more or less familiar with some terms over others. The research includes a comprehensive Nomenclature (beginning on page ix) and Glossary of Terms (beginning on page 433). Within the Glossary, terms essential to the research are denoted (\*\*). Here is a brief accounting of those terms and their operational definitions, which have been denoted (*italics*) where they reflect an original definition. Of these essential terms,

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<sup>70</sup> Youde, “High Politics, Low Politics, and Global Health.”

terms relating to governance and regulatory coordination are extensively discussed in Chapter 5, so these terms have only been noted as a high level in Table 1.4. The operational terms relevant to the Four Factors model, however, will not be reiterated as they otherwise have been defined in Chapter 1.2.2: actors, content, context, ideas, power, and processes.

## **1.5 Organization of the Dissertation**

The dissertation is organized into two parts and a totality of seven chapters. This first chapter (Chapter 1) introduced the conceptual significance of the research to IPE and presented the corresponding research design and methodology. From here, the dissertation is divided, roughly, in two parts: Part I being the literature-based analysis, beginning with a validation of the research's working premises, and Part II analyzing select case studies.

Chapter 2 examines and seeks to validate or nullify a trio of premises foundational to the research question and its lines of inquiry, including the primary role of pharmaceuticals in the global production of health and also for global economic development, recovery, and growth. Serving as a literature review of concepts, the chapter also examines the rise of market-driven politics under neoliberal globalization (or, global capitalism, as the concepts are identical in their expression and intention herein) and the implications of pharmaceutical use, spending, and overall market growth. The emerging bioeconomy, within which the majority of tomorrow's highest-cost pharmaceuticals reside, reflects the complex, interconnected 'international political economies of medicine,'<sup>71</sup> which encourage the market creation and political valuation of pharmaceuticals in a manner reflexive of broader macro trends in assetization and commodification motivated by interest in capital

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<sup>71</sup> Cassier, "Value Regimes and Pricing in the Pharmaceutical Industry: Financial Capital Inflation (Hepatitis C) versus Innovation and Production Capital Savings for Malaria Medicines"

**Table 1.4. Defining terms**

Term	Operational Definition
Commodification	Processes whereby the practices of marketization “qualitatively reconstitute” health in ways it becomes understood as a commercial good or commodity under common economic metrics, “produced for sale,” and able to be traded-off in policymaking, <sup>72</sup> in the style of “fictitious commodities.” <sup>73</sup>
Critical Constructivism	The ontological status of actors “is an artefact of a continual process of reproduction that performatively constitutes its identity” <sup>74</sup> in relation to the “social constraints and cultural understandings” that create and reproduce social relations or systems of “hierarchy, subordination, or domination,” despite a “supreme human interest in enlightenment and emancipation.” <sup>75</sup>
Economy, Advanced	Pharmaceutical markets of high and upper-middle income countries. Excludes those economies with emerging pharmaceutical markets. Includes the 10 “developed markets,” which have domestic pharmaceutical spending greater than \$10 billion: Australia, Canada, France, Germany, Italy, Japan, South Korea, Spain, U.K., and the U.S.
Globalization	The consistent and inconsistent globalizing of the processes of modernity and rationality, which are simultaneously constructed and applied through politics that magnify power and resource asymmetries enhancing and lessening the costs, benefits, and trust-risk dynamics of complex interdependence and global consciousness. <sup>76</sup>
Governance	The way rules, requirements, norms, and actions are structured, sanctioned, sustained, regulated, and held accountable. Occurs within and across a variety of levels of political engagement, including the individual, local, national, regional, and supranational or global, and can be established by state and nonstate actors.

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<sup>72</sup> Fraser, “Can Society Be Commodities All the Way down? Polanyian Reflections on Capitalist Crisis;” Hoppania and Vaitinen, “A Household Full of Bodies: Neoliberalism, Care, and ‘the Political;” Vaitinen, Hoppania, and Karsio, “Chapter 27: Marketization, Commodification and Privatization of Care Services.”

<sup>73</sup> Polanyi, *The Great Transformation: The Political and Economic Origins of Our Time*.

<sup>74</sup> Campbell, “Cultural Governance and Pictorial Resistance: Reflections on the Imaging of War,” 57–58.

<sup>75</sup> For Critical Theorists, power is “exercised in every social exchange, and there is always a dominant actor in that exchange.” See Hopf, “The Promise of Constructivism in International Relations Theory,” 185.

<sup>76</sup> This research adopts an author-created combined version of Anthony Giddens’ (2012 [1990]) and Ethan B. Kapstein’s (1999, 2000, 2001) respective typologies of globality and globalization. See Giddens, *The Consequences of Modernity*; and Kapstein, “Distributive Justice as an International Public Good: A Historical Perspective;” “Winners and Losers in the Global Economy;” and Kapstein and Milanovic, “Responding to Globalization: Social Policy in Emerging Market Economies.”

Table 1.4, Continued

Term	Operational Definition
Health	“A state of complete physical, mental, and social well-being, and not merely the absence of disease or injury” <sup>77</sup> that is “a resource for everyday life, not the object of living. Therefore, health promotion is not just the responsibility of the health sector but goes beyond healthy life-styles to well-being.” <sup>78</sup>
Hegemony	A specific actor or entity (hegemon) that dominates in a system.
Ideational Factors* *Related to ‘Ideas’	The “distribution of ideas and knowledge” that establish “both actors’ identities and interests” <sup>79</sup> and therefore are important to systems of political relations in ways beyond constraining behavior because they “constitute the rules of the game, which define roles, identities, interests, and criteria of legitimacy and justification.” <sup>80</sup>
Internationalization	Actions or processes whereby an idea or belief, norm, policy, system, or structure is made international, or its implications or context become international (global).
Levels of Analysis	Methodology’s unit of analysis. This research employs the macro-meso-micro and system-state-individual scales interchangeably: system or world (macro), state or other system-level actor (meso), and individual or other state or sub-system actor (micro).
Marketization	Referring to the processes where health is governed by the market or market-like mechanisms. Under marketization, health is commodified, conceived in terms of quantifiable goods or service products, bought and sold at a market price, and constructed in terms of market efficiency.
Neoliberalism	Market-oriented policies and/or reforms including eliminating price controls, deregulating and creating new capital markets, lowering trade barriers, and, overall, reducing state influence and role in the economy.
Pharmaceuticalization	The “process of understanding and/or treating social, behavioral, [] bodily conditions,” including economic development priorities and other political priorities, “with pharmaceuticals; reducing public health strategies from a broad array of disease prevention efforts to one seeking to improve the health of populations with pharmaceuticals.” <sup>81</sup>

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<sup>77</sup> World Health Organization, Constitution of the World Health Organization (2006 [1948]).

<sup>78</sup> World Health Organization, Ottawa Charter for Health Promotion (1986).

<sup>79</sup> Wendt, *Social Theory of International Politics*, 24.

<sup>80</sup> Jackson, *Russian Foreign Policy and the CIS: Theories, Debates, and Actions*, 22–23.

<sup>81</sup> Figert and Bell, “Big Pharma and Big Medicine in the Global Environment”

Table 1.4, Continued

Term	Operational Definition
Pharmocracy	The global regime of pharmaceutical hegemony, which “operates to institute forms of governance across the world that are beneficial” <sup>80F</sup> <sup>82</sup> to increased sales volume, pricing, and exports, and reduced production costs, including through harmonization of national regulatory policy through interstate coordination or formal global governance processes (e.g., treaties). <sup>83</sup>
Policy Convergence, Coordination, and Harmonization	Forms of global governance that vary based on the level of alignment between states: policy convergence, or the “narrowing of national policy differentiations” <sup>84</sup> or gaps in national standards over time; policy coordination, or the mutual adjustment of national rules and regulations in recognition of other countries’ regulatory frameworks; and policy harmonization, or the convergence of standards, policies, or rules to the same harmonized regulatory practice and procedure, resulting in a single, global regulatory standard.
Power	“The production, in and through social relations, of effects that shape the capacities of actors to determine their circumstances and fate.” <sup>85</sup> It can be relational and relative, interactive or constitutive, and direct or indirect. <sup>86</sup> Can be coercive (e.g., physical, economic, capital), institutional (regulatory, expert), ideational (discursive), or structural (moral). <sup>87</sup>
Privatization	The state is made to withdraw or not occupy a particular space of human activity, as the provision of goods are opened up to, or deferred to, private firms to produce, sell, and profit from. Within the context of health, replaces the idea of health as a public good with the production of health as a form of commerce. <sup>88</sup>

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<sup>82</sup> Sunder Rajan, *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine*, 5.

<sup>83</sup> The research amends Sunder Rajan’s original definition to remove the centering of the pharmaceutical industry, as the embedding and reproduction of the underlying valuation of pharmaceuticals is rooted in fundamental global norms associated with neoliberal interests—not solely a result of the preferences of multinational firms.

<sup>84</sup> Drezner, “Who Rules? The Regulation of Globalization.”

<sup>85</sup> Barnett and Duvall, “Power in International Politics,” 39.

<sup>86</sup> Navarro et al., “Politics and health outcomes.”

<sup>87</sup> Barnett and Duvall, “Power in International Politics;” Dahl, “The Concept of Power;” Dahl, Robert, *Who Governs? Democracy and Power in an American City*; Moon, “Power in Global Governance: An Expanded Typology from Global Health;” and Bourdieu, “The Forms of Capital.”

<sup>88</sup> See Vaitinen, Hoppania, and Karsio, “Chapter 27: Marketization, Commodification and Privatization of Care Services;” Marchand and Runyan, *Gender and Global Restructuring: Sightings, Sites and Resistances*.



accumulation and compounded by the potential for financial inflation (instead of quantifiably better health), which devalue the individual, health, and the role of the state.

Beginning the Part I analysis, Chapter 3 provides topical framing to the dissertation, including a review of microeconomic theory about public goods. This section presents public goods scholarship alongside contemporary perspectives that help explain health's persistent exclusion from descriptions of the Global Commons and other public goods, which are rooted in constructed characterizations of health that have more to do with the underlying normative versus positive assumptions of the field and the alignment with neoliberal discourse, including privatization of health, than the actual, practical differences between health as a 'good' and other goods.

Chapter 4 discusses the contemporary politico-economic context of global health and pharmaceutical spending, and the proportion of public expenditures, including relative to leading drivers of global health expenditures. It then examines how health care, as a market, deviates from standard theories of how markets work. The chapter also expounds on two distinct but interrelated concepts: the pharmaceutical pricing, marketing, and regulatory "arms race" among and between firms and states; and the shifting international political economy of medicine.<sup>89</sup>

Chapter 5 further advances the dissertation's interdisciplinary approach by highlighting the essential conceptual frameworks and understandings of globalization and health, global governance and international regulatory coordination and convergence, power and politics amidst complex interdependence, and other theories and typologies for examining the role of power, actors, and ideas in the international political economy of medicines. The discussion of globalization and health, global governance, linkage politics, and contradictory dynamics is interdisciplinary. The chapter also examines the underpinnings of, and contemporary frameworks for, health in IPE scholarship, an

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<sup>89</sup> Ibid., Kay and Williams (2009), 1.

issue historically reserved to the margins despite its intimate relevance to every global citizen. This includes a historical accounting of the field's development and divergence, and the implications of normative versus positive approaches to the study of certain issues, like health, within IPE. It closes with a review of health in IPE scholarship.

Turning to the second part of the analysis, Chapter 6 presents descriptive accounts of the expression of power through actors and ideas as influence points across the pharmaceutical lifecycle: first, targeting, investment, and discovery; second, clinical trials and market approval; and third, marketing, pricing, and access. Last, Chapter 7 presents the collective findings, discusses the findings' implications, and presents both the limitations of the research and recommendations resulting from the research.

## CHAPTER 2

### THE POLITICAL ECONOMIES OF MEDICINE: DISCUSSION AND ANALYSIS OF HYPOTHESIZED SYSTEMIC FACTORS

“Historians, anthropologists and economists repeatedly point to the critical role pharmaceuticals have acquired in the dynamics of global health.”

— Jean-Paul Gaudillière, Kristin Peterson, and Kaushik Sunder Rajan (2016)<sup>1</sup>

“What should the modern doctor be doing? He should either prevent a disease, so it does not occur, or cures it if it does. What does the modern doctor, me included, do? He neither prevents, nor cures in any but a few conditions. He only controls spread of the disease and palliates while so doing.”

—Practicing physician Dr. Ajai R. Singh (2010)<sup>2</sup>

To begin this discussion, it is necessary to establish the working premises—the environmental factors and assumptions about the global political economy, health, and medicine (pharmaceuticals) that guide and inform this dissertation. This chapter aims not only to articulate these premises but also to validate them. The three premises are, first, that pharmaceuticals have a primary role in the global production of health (Chapter 2.1). Second, pharmaceuticals also play a primary role in contemporary models of global economic development, recovery, and growth because certain previously primary commodities and service sectors (e.g., electronics, machinery, agriculture, other forms of domestic manufacturing) are or have been on the decline (Chapter 2.2).<sup>3</sup> And, third, the emerging bioeconomy reflects complex and interconnected global-local “political

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<sup>1</sup> Gaudillière, Peterson, and Sunder Rajan, “Opening statement.”

<sup>2</sup> Singh, “Modern Medicine: Towards Prevention, Cure, Well-Being and Longevity.”

<sup>3</sup> In their exploration of the prioritization of the pharmaceutical industry in Brexit negotiations, Kazzazi et al. (2017) find that pharmaceuticals “is one of the few components of the U.K.’s manufacturing sector to have experienced fairly consistent growth in output, productivity, and employment over the last decade.” The study also finds pharmaceuticals are a driving component of total venture capital (VC) and, overall, protected from macroeconomic growths because of its adjacency to demand for health care, which “has been resilient to economic downturns with the sector’s growth remaining positive even during the 2008-09 crisis.” The research intensive component of the U.K. economy is responsible for 25% of all commercial R&D conducted. Kazzazi et al., “Evaluating the Impact of Brexit on the Pharmaceutical Industry.”

economies of medicine”<sup>4</sup> (Chapter 2.3).

The research hypothesizes that, and seeks to validate whether, these serve as *systemic factors* – individual ‘political economies’ – that give context to and serve as reflections of the value and role of pharmaceuticals in the contemporary global political economy. Collectively, if valid, these factors reflect an ‘international political economy’ of pharmaceuticals, or practical consequences of the ‘pharmaceuticalization’ of the global political economy.

The hypothesized implications and origins of these factors are examined through the fuller research but, as noted in Chapter 1, these factors encourage the market creation and political pricing of pharmaceuticals that drive capital overvaluation and financial inflation, instead of quantifiably better health, and perpetuate a political narrative that economic wellness, and also personal health and well-being, rely on bio-pharmaceutical innovation—the ‘medicalization’ of the global political economy built on the ‘marketization’ of individual and collective health.

This research rests on the extant literature establishing the strong influence of globalization<sup>5</sup> on health, which has driven select health gains (e.g., life expectancy at birth (LEB); reduction in the global prevalence of communicable, maternal, perinatal, and nutritional (CMPN) diseases; select pharmacological complete treatments (‘cures’); vaccines against certain infectious diseases), but also significant and often harmful consequences for global health (e.g., shift in the global disease burden to NCDs; dramatic slowing in LEB gains; potential reversal of overall health gains; sharp declines in personal income). This is explored at greater depth and within the context of the multitude effects of globalization on health (Chapter 5).

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<sup>4</sup> Cassier, “Value Regimes and Pricing in the Pharmaceutical Industry: Financial Capital Inflation (Hepatitis C) versus Innovation and Production Capital Savings for Malaria Medicines”

<sup>5</sup> For context, the influence of globalization – of politico-economic structures at the global level, which shape their peers at the national, regional, and local levels, and also ‘individual governance’ – informs the socio-political construction of rules and norms that govern the global-local distribution of health.

## 2.1 Begin Drug Treatment: The Preeminent Role of Pharmacological Treatment in Western Medical Practice

For communicable and noncommunicable diseases (CDs and NCDs), “the practice of medicine is centered on prescribing as first line of treatment” despite overwhelming evidence that the former, through standard public health measures, and the latter, through lifestyle modifications, can be prevented, thus negating the need for pharmacologic treatment.<sup>6</sup> Despite such evidence, including for pharmacologic-dependent disease states like diabetes,<sup>7</sup> the actual first line and often only form of treatment recommended in common medical practice is not primary care, prevention, or cure, but maintenance and symptom alleviation or reduction. Omar Israel González Peña, Miguel Ángel López Zavala, and Héctor Cabral Ruelas (2021) found global pharmaceutical consumption “continues increasing due to changes in clinical practice and growing demand for drugs,” resulting in an eight-fold increase in cholesterol-lowering drugs (Figure 2.1-A) and a doubling of antihypertensives (Figure 2.1-B) across Organization for Co-operation and Economic Development (OECD) member states between 2000 and 2017.<sup>8</sup>

Dr. Singh’s (2010) practical, if not unfortunate, observations in the opening quote are not without an upside: he praises the gains in longevity, reductions in infant mortality, and efficiencies in acute care heralded by biopharmaceutical innovation and the modern medical practice-as-prescribing that such innovation has enabled. His praise, however, stops there, noting that “we have not reduced the number of diseased, nor found cures for any diseases except the infectious,” because humanity will “struggle and strain to cope with emergencies.”<sup>9</sup> These emergencies do not merely

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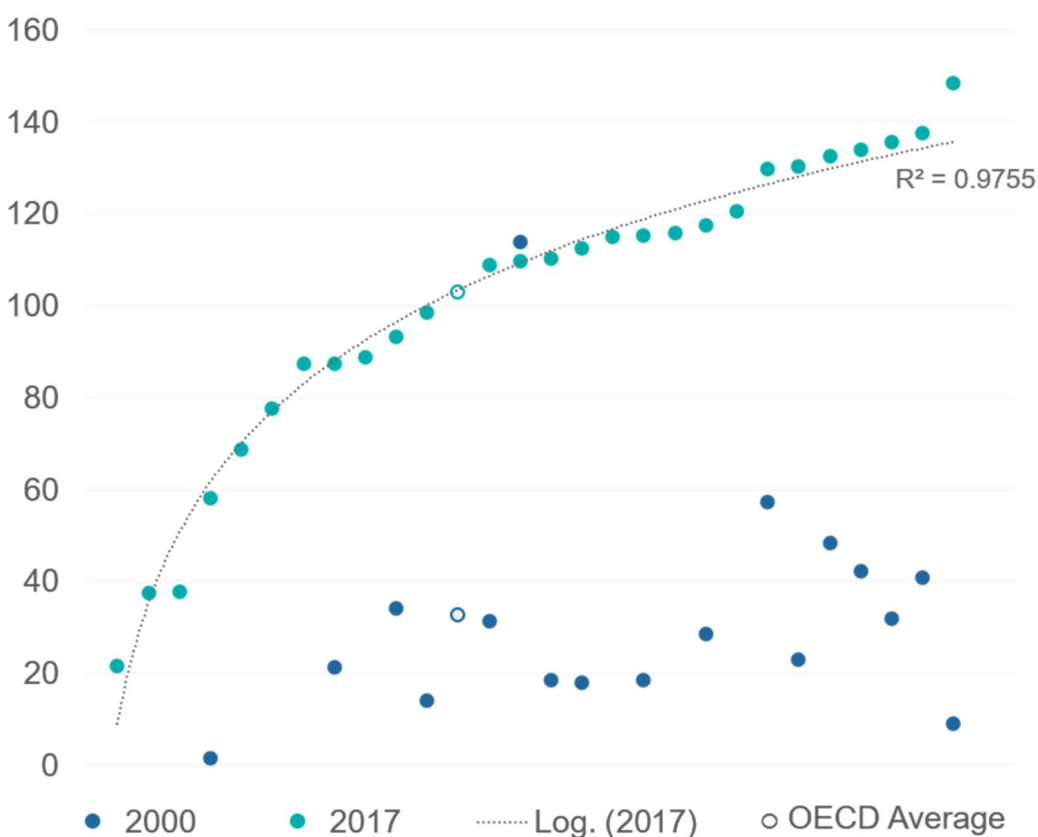
<sup>6</sup> Hartley, “Lifestyle Modification as First Line of Treatment for Chronic Disease.”

<sup>7</sup> Lerman et al., “Enhancement of a Modified Mediterranean-Style, Low Glycemic Load Diet with Specific Phytochemicals Improves Cardiometabolic Risk Factors in Subjects with Metabolic Syndrome and Hypercholesterolemia in a Randomized Trial.”

<sup>8</sup> González Peña, López Zavala, and Cabral Ruelas, “Pharmaceuticals Market, Consumption Trends and Disease Incidence Are Not Driving the Pharmaceutical Research on Water and Wastewater,” 2539 and Figure 7.

<sup>9</sup> Op. cit., Singh (2010).

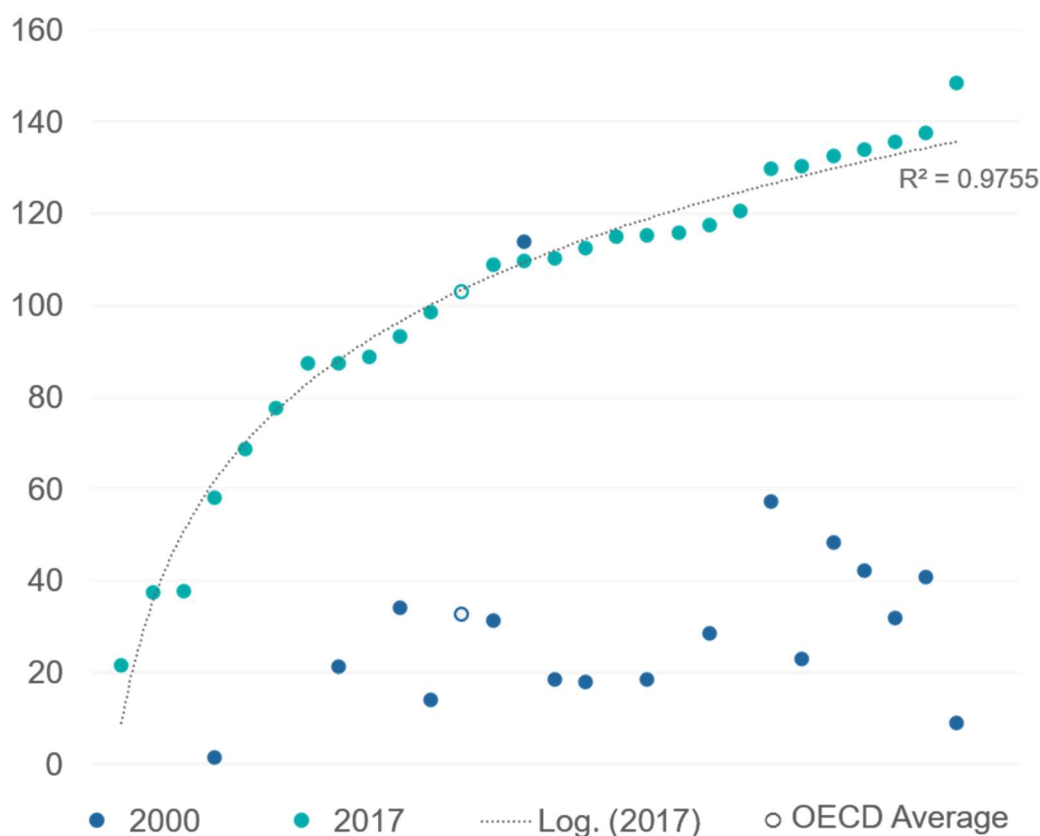
**Figure 2.1-A. Change in the global consumption of cholesterol-lowering drugs, Defined daily doses (DDD) per 1,000 in 28 OECD member states (2000 and 2017)**



Cholesterol-lowering drugs refer to C10 lipid-modifying agents. The data includes 28 OECD member states, including Chile, Turkey, Republic of Korea, Canada, and others. Author-generated figure using data from OECD, "Pharmaceutical Consumption."

generate cause for action. They generate significant market opportunity with potentially limitless demand and enduring profitability. But if the market allocates resources efficiently, optimizing price and demand—in the case of preserving health, is the market naturally incentivized? Or is the market incentivized to create long-term demand and global consumer relationships, which, in terms of pharmaceuticals, would not be achieved through prevention or cures but through the market production of quasi-health and quasi-sickness: the perfect partial treatment. As the 21st century's

**Figure 2.1-B. Change in the global consumption of anti-hypertensives, DDD per 1,000 in 28 OECD member states (2000 and 2017)**



Anti-hypertensives refer to the following drug classes: C02-antihypertensives, C03-diuretics, C07-beta blocking agents, C08-calcium channel blockers, and C09-agents acting on the renin-angiotensin system. Author-generated figure using data from OECD, “Pharmaceutical Consumption.”

emerging bioeconomy and biocapital industry have shown, new political economies of medicines are fast emerging, and it will be important to examine what the market is being incentivized to “produce” and whose interests such production, value regimes, and pricing models advance.

### 2.1.1 The “Indiscriminate Use” of Essential Medicines in Medical Practice

Consider the global burden of NCDs, which is increasing for advanced, emerging, and low-income economies. Heart disease, high blood pressure, diabetes, and other NCDs are projected to overtake communicable, maternal, perinatal, and nutritional (CMPN) diseases as the leading cause

guidelines include ‘begin drug treatment’ as a primary course of medical care. Building on Dr. Paul Farmer’s compelling 2003 critique of the intersection of conventional biomedical ethics, medical practice, and the pharmaceutical industry,<sup>10</sup> Sociologist Joan Busfield (2006) argues that medicines are “indiscriminately used” as part of modern medical practice in three ways.<sup>11</sup>

*First*, medicines are “frequently taken by those whose problems would be better dealt with by other means and for whom they have little or no benefit and may lead to unwanted side effects.”<sup>12</sup> The indiscriminate prescribing and use of opioids for acute pain management, and the resultant rise in misuse, abuse, and addiction is one example. The prevalence of psychotropics among older adults and children, youth, and young adults served through child welfare (‘foster’) systems are others. Busfield (2006) also notes, *second*, that medicines are “produced and prescribed in dosages that are far too high,” and, *third*, that even when clinically necessary, medicines are “prescribed for too long a period of time.”<sup>13</sup> Her argument rests on the concept of medicine-as-commerce, originated by Dr. Farmer, which assumes the marketization of health (“in the business of meeting health needs”) creates a “culture” in which the use and sale of the product is “encouraged even when this is unhelpful, counterproductive, and even harmful.”<sup>14</sup>

Though Busfield’s full contribution is in her examination of the industrial production and marketization of scientific knowledge, specifically, the “science on which judgements of the safety and effectiveness of drugs are made,” her premise can be evaluated in the practical context of national treatment guidelines and the increasingly prominent complement of essential medicines lists (EMLs). The Standard Treatment Guidelines and EML for the United Republic of Tanzania (2013)

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<sup>10</sup> Farmer, *Pathologies of Power*.

<sup>11</sup> Busfield, ‘Pills, Power, People: Sociological Understandings of the Pharmaceutical Industry.’

<sup>12</sup> *Ibid.*, Page 299.

<sup>13</sup> *Ibid.*

<sup>14</sup> *Ibid.*



is one such example.<sup>15</sup>

Besides the advisory role of the World Health Organization (WHO) in developing Tanzania's EML, formulary, and national treatment guidelines, the state also has received structural adjustment loans and associated requirements under a World Bank Group (TWB) country partnership framework.<sup>16</sup> For example, Tanzania has been advised by the International Monetary Fund (IMF)<sup>17</sup> to improve the state's "patterns of health expenditures in the public sector" in line with IMF and TWB global goals for "the country's future" by enhancing "industrialization... for development," "creating a conducive environment for private investment and growth," and "moderniz[ing] and improv[ing] efficiency of public institutions."<sup>18</sup>

Tanzania's Standard Treatment Guidelines are not only illustrative of Farmer's and Busfield's medicines-as-commerce concept in its title – conflating treatment and medicines at the onset – but also in its substance. The Guidelines include an EML "for the treatment of common disease conditions in Tanzania,"<sup>19</sup> noting "improvements" that "show more clearly the classification of medicines by level of health care within the treatment guidelines," and emphasizes in its Term of Use that "medicines will be used to treat the majority of public health problems and they should be available to health facilities at all times"<sup>20</sup> (Table 2.1-A).

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<sup>15</sup> Ministry of Health and Social Welfare, *Standard Treatment Guidelines and Essential Medicines Lists*, 4th ed. (Dodoma: United Republic of Tanzania, 2013), [https://www.who.int/selection\\_medicines/country\\_lists/Tanzania\\_STG\\_052013.pdf](https://www.who.int/selection_medicines/country_lists/Tanzania_STG_052013.pdf).

<sup>16</sup> Moritz Piatti-Funkirchen and Mariam Ally, *Tanzania: Health Sector Public Expenditure Review 2020*, Public Expenditure Review AUS0001650 (Washington, DC: World Bank Group, 2020); "Country Partnership Framework for the United Republic of Tanzania for the Period FY 2018 to FY 2022," International Development Association, International Finance Corporation, and Multilateral Investment Guarantee Agency, *Country Assistance Strategy Progress Report* (Washington, DC: World Bank Group, 2018).

<sup>17</sup> Piatti-Funkirchen and Ally, *Tanzania: Health Sector Public Expenditure Review 2020*; International Monetary Fund, "IMF Staff Completes 2020 Article IV Mission to Tanzania."

<sup>18</sup> The World Bank Group does not describe its Vision 2035 goals outside of country-specific contexts, but the country-specific goals appear in the Country Partnership Frameworks and Country Assistance Strategy Progress Reports for multiple low-income countries receiving SAP support from TWB. See Juma and Piatti-Funkirchen, *Cameroon - Public Expenditure Review: Aligning Public Expenditures with the Goals of Vision 2035*; Cameroon - Public Expenditure Review: *Aligning Public Expenditures with the Goals of Vision 2035*.

<sup>19</sup> *Ibid.*, Foreword and How to Use the Document (Pages i-iv).

<sup>20</sup> The WHO also maintains an EML; see. See Abegunde, "Essential Medicines for Non-Communicable Diseases."

**Table 2.1-A. World Health Organization essential medicines list for non-cancer NCDs**

<u>NCD</u>	<u>Drug Category</u>	<u>Active Ingredient</u>	<u>Patent Protection Expired</u>
Asthma and Chronic Obstructive Pulmonary Disorder	Short-acting beta-agonists	Epinephrine	Yes
	Long-acting beta-agonists	Salbutamol	Yes
	Inhaled corticosteroids	beclomethasone budesonide	No: Patent on delivery
	Vagolytics	Ipratropium	Yes
	Systemic corticosteroids	prednisolone dexamethasone	Yes
Diabetes	Oral hypoglycemic	glibendamide metformin	Yes
	Short-acting insulins	(various)	No: Patent on delivery
	Depot insulin	(various)	No: Patent on delivery
	Insulin antagonists	Glucagon	Yes
Heart Disease	Anti-platelet drugs	acetylsalicylic acid	Yes
	Nitrates	glyceryl trinitrate isosorbide dinitrate	Yes
	Beta-blockers	Bisoprolol	Yes
	Lipid-lowering drugs	Simvastatin	Yes
	Calcium channel blockers	verapamil amlodipine	Yes
	Other antihypertensive drugs	Methyldopa	Yes
Heart Failure	Diuretics	hydrochlorothiazide furosemide amiloride spironolactone	Yes
	ACE inhibitors	Enalapril	Yes
	Anticoagulants	Warfarin	Yes
	Inotropic agents	Digoxin	Yes
	Other vasodilators	Hydralazine	Yes

Author compiled based on Abegunde, “Essential Medicines for Non-Communicable Diseases.”

Reviewing the Guidelines for treatment of heart disease (systolic heart failure, heart attack), high blood pressure (hypertension), and diabetes (Type 2, gestational diabetes), the treatment guidelines are divided between “Non-pharmacological” and “Pharmacological,” instead of based on the severity of the disease’s presentation, patient preference, or other factors. For each NCD (and all conditions in the Guidelines), there is a pharmacological treatment option consistently present, even for first-line treatments. The broader Guidelines list a “drug of choice” under treatment “Management” for 34 conditions, including “not excessive” cases of nausea and vomiting in pregnancy and paronychia, a skin infection around the fingernails commonly caused by nail biting.<sup>21</sup>

Reflecting on the role of intergovernmental organizations (IOs) and international institutions on health, at the state actor level, TWB “disseminates knowledge products and training tools” for “strengthening the pharmaceutical sector in order to improve health outcomes” and promoting “convergence toward [pharmaceutical policy] models that work to reduce fragmentation of policies and enhance regulatory and economic efficiencies” (Table 2.1-B).<sup>22</sup> The examples of nausea and vomiting in pregnancy and paronychia are not suggested to be non-serious; for those patients with extreme nausea and vomiting or skin infections, neither of which improve on their own, medicines are important components of medical treatment. In this way, skepticism of the role of pharmaceuticals in modern medical practice “is not grounded in any general claim that modern therapeutic drugs have little value” (emphasis added). Rather, and returning to Busfield (2006), they are examples to probe whether, despite their value, pharmaceuticals are “frequently used indiscriminately,”<sup>23</sup> which is not accidental but an intentional outcome reflecting the practical processes and construction of global norms preferencing market growth and expansion.

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<sup>21</sup> Ibid., Pages 88 and 119.

<sup>22</sup> Seiter, *A Practical Approach to Pharmaceutical Policy*. Pages 54-55.

<sup>23</sup> Busfield, “Pills, Power, People: Sociological Understandings of the Pharmaceutical Industry.”

**Table 2.1-B. World Bank Group-recommended objectives for national pharmaceutical policy objectives, by level of national income**

<u>High-income Country</u>	<u>Middle-income Country</u>	<u>Low-income Country</u>
<ul style="list-style-type: none"> <li>• Access to essential medicines and all other “important treatments”</li> <li>• Access to innovative, costly treatments for a population covered by health insurance</li> <li>• Control growth of health expenditures, which presents a macroeconomic risk factor for economic growth</li> <li>• Maintain economic incentive for pharmaceutical industry to develop treatments to address “unmet medical needs”</li> </ul>	<ul style="list-style-type: none"> <li>• Access to “essential medicines” for basic public health programs for the poor</li> <li>• Access to a broader range of medicines, including innovative and more expensive drugs</li> <li>• Balance pressures from domestic pharmaceutical industry development, multinational corporations, and patient advocacy groups</li> <li>• Explore pooled financing mechanisms for cost containment</li> </ul>	<ul style="list-style-type: none"> <li>• Access to “essential medicines” necessary to achieve major public health goals</li> <li>• Balance “pressure to ensure the prosperity of” domestic pharmaceutical industry</li> <li>• Avoid “conflicts with policy objectives that are based on public health goals,” including overprescribing and use of more expensive medicines, which are “good for profitability [] but bad for public health and public budgets”</li> </ul>

Author compiled based on Seiter, A Practical Approach to Pharmaceutical Policy.

Tanzania’s Standard Treatment Guidelines and complementary EML are products not only of the marketization of health, but also of its internationalization. At the macro or system level, the role of politico-economic processes to sustain health marketization norms within states by requiring the design and structuring of a state’s health care system (e.g., guidance from IOs, conditions of structural adjustment programs (SAPs)). These results suggest it may be worth examining whether the commodification of health also drives the overuse of pharmaceuticals.

### 2.1.2 Polypharmacy and the Rise of Medication Overload

For some, pharmacological treatment leads to using multiple medicines or more than are clinically necessary, also called polypharmacy. A 2014 systematic review of observational studies from Canada, Italy, and the United States of America (U.S.) found broad, documented evidence of high rates of polypharmacy in adults ages 65 and older that spanned clinical settings of care (e.g., ambulatory, hospital, nursing facility) and pharmaceutical classes, including medicines for heart disease, diabetes, pain, nervous system disorders, mental health conditions, gastrointestinal issues, and even vitamins.<sup>24</sup> In three such studies, 41.4% of hospitalized older adults and 40% of older adults living in a nursing facility were taking nine drugs.<sup>25</sup>

The results of an updated systematic review of studies conducted between 2003 and 2018 suggest the trends are not abating and the trends are global, with the prevalence of polypharmacy ranging from 11.8% (Switzerland) to 86.4% (Republic of Korea) in different patient populations around the world.<sup>26</sup> Polypharmacy also is not limited to older adults. According to Shannon Brownlee and Judith Garber (2019), the number of Americans of any age taking five or more medicines, which Brownlee and Garber call “America’s other drug problem,” increased significantly between 2000 and 2012, from 8.2% to 15%.<sup>27</sup>

Though studies acknowledge that, for some patients, “polypharmacy and poor outcomes could simply represent that polypharmacy is the marker of increased risk and not the primary cause of it.”<sup>28</sup> When studies control for the effect of NCDs and other chronic conditions, however, observed associations between the two persist. The extant literature, including these studies, detail the negative consequences associated with polypharmacy, including: adverse drug events (ADEs);

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<sup>24</sup> Maher, Hanlon, and Hajjar, “Clinical Consequences of Polypharmacy in Elderly.”

<sup>25</sup> Hajjar et al., “Unnecessary Drug Use in Frail Older People at Hospital Discharge;” Nobili et al., “Polypharmacy, Length of Hospital Stay, and in-Hospital Mortality among Elderly Patients in Internal Medicine Wards. The REPOSI Study;” Dwyer et al., “Polypharmacy in Nursing Home Residents in the United States: Results of the 2004 National Nursing Home Survey.”

<sup>26</sup> Khezrian et al., “An Overview of Prevalence, Determinants and Health Outcomes of Polypharmacy.”

<sup>27</sup> Brownlee and Garber, “Medication Overload: America’s Other Drug Problem.”

<sup>28</sup> Khezrian et al., “An Overview of Prevalence, Determinants and Health Outcomes of Polypharmacy.”

drug-drug interactions, reduced functional capacity (e.g., cognitive impairment<sup>29</sup> such as delirium and dementia), reduced ability to perform instrumental activities of daily living (IADLs, e.g., dressing, toileting),<sup>30</sup> falls and urinary incontinence,<sup>31</sup> hospitalization,<sup>32</sup> malnourishment,<sup>33</sup> medication nonadherence,<sup>34</sup> and higher costs.<sup>35</sup> Many of these consequences drive further pharmacological treatment, higher polypharmacy rates, and hospitalization. Rather than consistently being value additive to health and wellness, “too often more prescriptions simply mean more serious harm.”<sup>36</sup>

Why is this happening, increasingly, within the context of standard medical practice? The literature is varied, but findings often point to disconnects “perpetuated by external factors,”<sup>37</sup> including communication failures where de-prescribing<sup>38</sup> plans are not followed through by the prescriber; patient perception of their own care needs, which drive medicine-seeking behaviors (e.g., direct-to-consumer advertising of pharmaceuticals); clinical practice guidelines based on trials, which are designed and run by drug-makers,<sup>39</sup> and guidelines themselves written by experts with financial ties to manufacturers;<sup>40</sup> and prescriber awareness of evidence-based guidelines but failure to incorporate corrective practices related to polypharmacy mitigation.

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<sup>29</sup> Nobili et al., “Polypharmacy, Length of Hospital Stay, and in-Hospital Mortality among Elderly Patients in Internal Medicine Wards. The REPOSI Study;” and Aljeaidi and Tan, “The Association between Polypharmacy and Cognitive Ability in Older Adults: A National Cohort Study.”

<sup>30</sup> Dwyer et al., “Polypharmacy in Nursing Home Residents in the United States: Results of the 2004 National Nursing Home Survey.”

<sup>31</sup> We would note that urinary incontinence, or urinary tract infections, often require additional pharmacological treatment and, sometimes, hospitalization.

<sup>32</sup> Lu et al., “Effect of Polypharmacy, Potentially Inappropriate Medications and Anticholinergic Burden on Clinical Outcomes: A Retrospective Cohort Study.”

<sup>33</sup> Malnourishment often includes reduced soluble fiber intake and higher intake of cholesterol, glucose, and sodium, all of which are correlated with other comorbidities, including heart disease and Type 2 diabetes.

<sup>34</sup> Nonadherence, including as a result of multiple unwanted side effects, has been associated with higher risk of cardiovascular outcome events, including death and major bleeding. See Millenaar et al., “Cardiovascular Outcomes According to Polypharmacy and Drug Adherence in Patients with Atrial Fibrillation on Long-Term Anticoagulation (from the RE-LY Trial).”

<sup>35</sup> Santibáñez-Beltrán et al., “Economic Cost of Polypharmacy in the Elderly in Primary Health Care.”

<sup>36</sup> Brownlee and Garber, “Overprescribed: High Cost Isn't America's Only Drug Problem.”

<sup>37</sup> Nguyen et al., “A Qualitative Exploration of Factors Contributing to Non-Guideline Adherent Antipsychotic Polypharmacy.”

<sup>38</sup> Payne, “Polypharmacy and Deprescribing”

<sup>39</sup> Rasmussen et al., “Collaboration between Academics and Industry in Clinical Trials: Cross Sectional Study of Publications and Survey of Lead Academic Authors.”

<sup>40</sup> Norris et al., “Conflict of Interest Disclosures for Clinical Practice Guidelines in the National Guideline Clearinghouse.”

### 2.1.3 Overprescribing, Overuse, and a Sustained state of ‘Quasi Health’

Returning to Busfield (2006), she poses a broader structural explanation for these practical examples of indiscriminate use and overuse of medicines. The free market, seeking to maximize efficiency, will naturally drive pharmaceutical development and use. When health is marketized, it is not only the research and development priorities and resultant product that are shaped:

For the pharmaceutical industry, preferred drugs are those that can be patented and sold at a high profit relative to the cost of production. It is also ideal if the drugs are designed to treat ongoing conditions affecting a significant portion of the population. It is for these reasons that many pharmaceutical companies choose to invest in drugs marketed to treat chronic conditions in richer countries instead of infectious diseases in poorer countries.<sup>41</sup>

As Priscilla J. Lefebvre (2015) notes, it also is the production of “scientific fact making,” referring to the construction of facts and reality. This may include what is health versus illness and the primacy of the individual in health attainment, preservation, and risk creation (i.e., individualization of health). It may also include and reflect the evidence and standards that govern the practice of medicine, including standard treatment guidelines, EMLs, and pharmacological mechanisms for “secondary prevention.”<sup>42</sup>

When patients are primed to ask their doctors for medicines, doctors are primed to respond first with medicines, and global society is primed to rely on medicines, health, when marketized, reflects a “pill for every ill” mindset and a reality of “medication overload.”<sup>43</sup> Combining the theoretical (of Farmer, Busfield, Latour and Woolgar, and many other Public Health and Medical Sociology scholars) and the practical (of standard treatment guidelines, EMLs, how patients and doctors receive their information, and polypharmacy), there are larger forces at work. The market-

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<sup>41</sup> Lefebvre, “Medicating the Crisis: Investigating the Links between Precarious Employment, Mental Health Issues, and the Reliance on Antidepressants as Treatment.” Page 7.

<sup>42</sup> Latour and Woolgar, *Laboratory Life*.

<sup>43</sup> Brownlee and Garber, “Overprescribed: High Cost Isn’t America’s Only Drug Problem.”

based production and preservation of mass ill health is socially and politically constructed by market and state actors *and also* sustained in practice by care providers and recipients.

In this way, the actual practice of modern medicine and the political choices that structure it are themselves a product of the pharmaceutical market—recreating the narrative that biopharmaceutical ‘band-aids’ are actually innovative health care. In this way, pharmaceuticals, which are (mostly) palliative, have been structurally reconstituted and reframed as preventive (“secondary prevention”<sup>44</sup>), implicitly accepting and sustaining as a global norm their essential role in medical practice and for the global political economy.

## **2.2 Rx for Global Economic Growth: More and More Medicine**

All medicines have side effects but not all are clinical. Some are economic and political, and often global, not only personal. While taking too much is a disorder (like substance misuse) and taking too many compromises the health and quality of life for patients around the world, taking modern medicines at all also leaves extraordinarily little incentive to prevent or reverse underlying global sickness—as the bioeconomy illustrates. Overreliance on pharmaceuticals also underpins the economic valuation of multinational corporations (MNCs) and the geopolitical competitiveness and relevance of states. In this way, pharmaceuticals are a growing mechanism for industrialization, participation in global trade, attraction of foreign direct investment (FDI), demonstration of global status as an engine of innovation, and the achievement of economic development, recovery, or growth.

The intersection of conventional biomedical ethics, medical practice, pharmaceutical industry, and – also – the international political economy is intentional, reflecting the power, interests, and preferences of leading global actors (including the U.S.) effectuated through

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<sup>44</sup> Matke et al, “Improving Access to Medicines for Non-Communicable Diseases in the Developing World.”



international institutions and other instruments of economic and political power. As Kean Birch and David Tyfield (2013) explain, “In the policy discourses of the OECD and EC, modern biotechnology and the life sciences are represented as an emerging ‘bioeconomy,’ in which the latent value underpinning biological materials and products offer the opportunity for sustainable economic growth.”<sup>45</sup> The relationship between pharmaceuticals, national economies, national health policymaking, and the global governance of health, including pharmaceuticals, reflects a compelling case of the interdependence of states and markets under a neoliberal economic model, and the powerfulness of leading actors in terms of other states’ political priorities and policymaking.

This section examines the role of pharmaceuticals in national and global economic growth. It also discusses how global economic development and trade advisory bodies, including the Bretton Woods Institutions (BWIs) and IOs like the United Nations (UN) and European Commission (EC), have prioritized national health care and pharmaceutical policy within the context of economic development, recovery, or growth, specifically, as a vehicle for industrialization and global trade. These priorities are not executed solely at the global level, however; they are reinforced through domestic policymaking.

2.2.1 “A substantial proportion of the world economy today revolves around the commercialization of biological products and processes”<sup>46</sup>

Increasingly, pharmaceuticals are a leading component of global economic activity and output, totaling an estimated 400 billion USD in global exports in 2019, up from 337 billion USD in 2015, representing a 17% five-year increase.<sup>47</sup> Often called the bioeconomy, the research and development (R&D), manufacturing, export, and import of pharmaceuticals represent a major

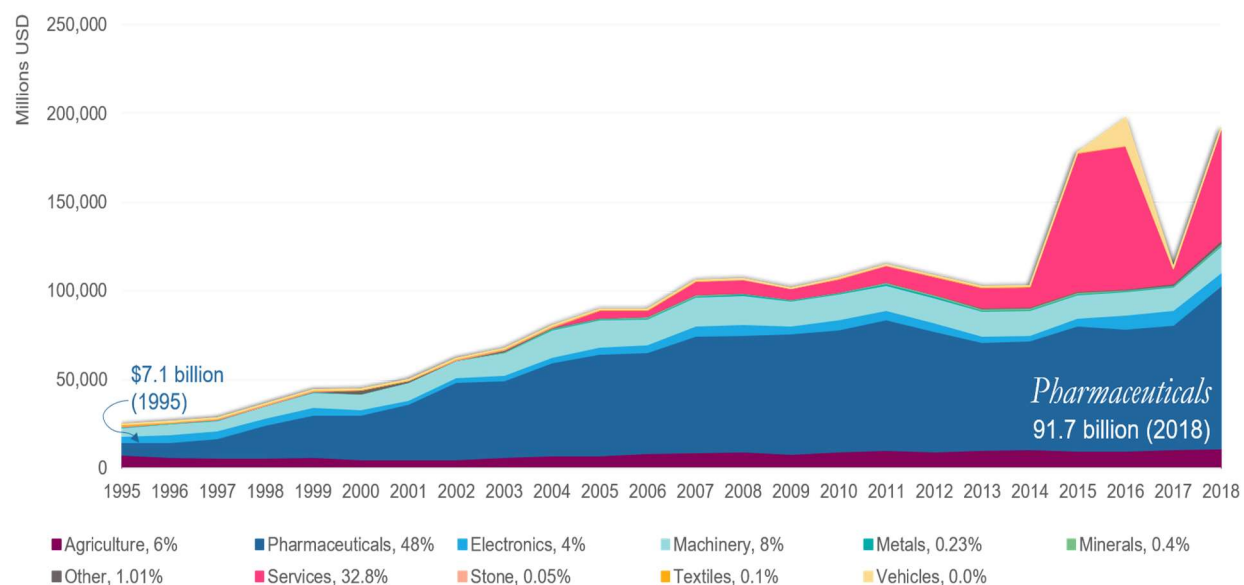
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<sup>45</sup> Birch and Tyfield, “Theorizing the Bioeconomy: Biovalue, Biocapital, Bioeconomics or . . . What?”

<sup>46</sup> Elbe and Long, “The Political Economy of Molecules: Vital Epistemics, Desiring Machines and Assemblage Thinking.”

<sup>47</sup> Department of Commerce (U.S.), “Pharmaceuticals, A Market Assessment Tool for U.S. Exporters,” Workman, “Drugs and Medicine Exports by Country,” Harvard Growth Lab, The Atlas of Economic Complexity.

**Figure 2.2-A. Irish pharmaceutical exports grow  $\approx 1,200\%$  to 92 billion USD; Total net exports from Ireland and share of total, by Category, Millions USD (1995-2018)**



“Chemicals” includes the overall HS4 Product Class, “Pharmaceuticals” and the specific HS2, “Pharmaceutical products,” which includes vaccines, serums, and packaged “medicaments” (medicines). Author-generated image using data from the Harvard Growth Lab, “Atlas of Economic Complexity,” Product code 5 HS1 (Chemicals), inclusive of 30 HS2 (Pharmaceuticals) (2021)

source of net inflows of foreign direct investment (FDI), which historically has been an essential component of states’ economic development, industrialization, and balance of trade growth strategies, regardless of their phase of development or national income. For example, FDI in the form of pharmaceuticals represents a significant and growing component of Ireland’s international trade balance.

According to Neave O’Clery (2015), Ireland’s pharmaceutical exports grew steadily between 1996 and 2018 to represent 10% of overall trade and over 14% of exports.<sup>48</sup> Estimates suggest the

<sup>48</sup> O’Clery, “A Tale of Two Clusters: The Evolution of Ireland’s Economic Complexity since 1995.”

pharmaceutical market now comprises between 35 billion USD<sup>49</sup> and 52 billion USD, held constant, of gross Irish exports,<sup>50</sup> from 3 billion USD in 1995.<sup>51</sup> The case of Ireland is not unique. In the case of Ireland, pharmaceuticals have played a primary role in the state's strategy for economic growth and recovery because growth in the Irish pharmaceutical industry has compensated for declines in previously primary commodities and service sectors, especially electronics, machinery, agriculture, and other forms of domestic manufacturing (Figure 2.2-A).

The Irish experience is not an aberration. In their exploration of the prioritization of the pharmaceutical industry in Brexit negotiations, Fawz Kazzazi et al. (2017) find that pharmaceuticals are “one of the few components of the United Kingdom’s (U.K.’s) manufacturing sector to have experienced fairly consistent growth in output, productivity, and employment over the last decade.”<sup>52</sup> Kazzazi et al. also note the geopolitical significance of the U.K. pharmaceutical industry:

The U.K. Pharmaceutical Industry is arguably one of the most important industries to consider in the negotiations following the Brexit vote. Providing tens of thousands of jobs and billions in tax revenue and research investment, the importance of this industry cannot be understated. At stake is the global leadership in the sector, which produces some of the field’s most influential basic science and translation work. ... The U.K. is a reference internationally in the life sciences industry, having discovered and developed 25 of the top 100 prescription medicines globally. Nevertheless, to sustain the status of global leadership in the sector, it is essential to guarantee long-term funding, the brightest talent and the ability to collaborate at scale.<sup>53</sup>

The study also finds the U.K. pharmaceutical industry is a driving component of total venture capital (VC) and, overall, a useful area of economic focus given it is inherently protected from

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<sup>49</sup> European Commission, “International Trade in Medicinal and Pharmaceutical Products.”

<sup>50</sup> Though the EU estimates pharmaceutical exports from Ireland totaling 35 billion USD (2020), the Harvard Growth Lab estimates 52 billion USD (2018). Regardless of the figure, the proportional impact of the global pharmaceutical market in Ireland is a striking example.

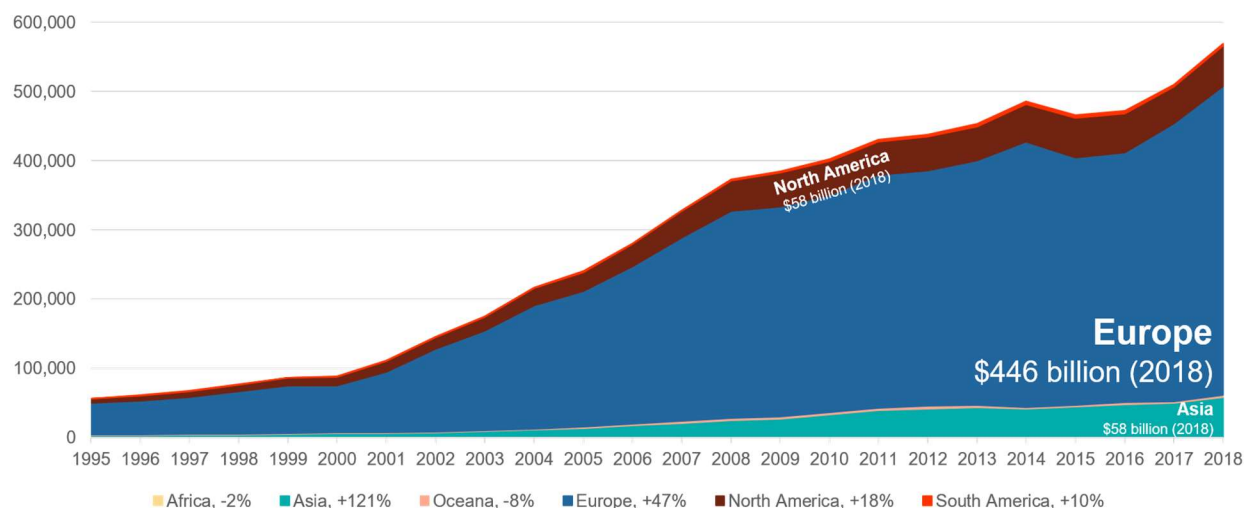
<sup>51</sup> “What did Ireland export between 1995 and 2018? Share of constant gross trade flow for HS4 Product Class,” from Harvard Growth Lab, The Atlas of Economic Complexity.

<sup>52</sup> Kazzazi et al., “Evaluating the Impact of Brexit on the Pharmaceutical Industry.”

<sup>53</sup> Ibid., 32.

**Figure 2.2-B. Global pharmaceutical market has grown more than 900% to 569 billion USD;**

**Gross pharmaceutical exports, by Region (2018 and 1995-2018)**

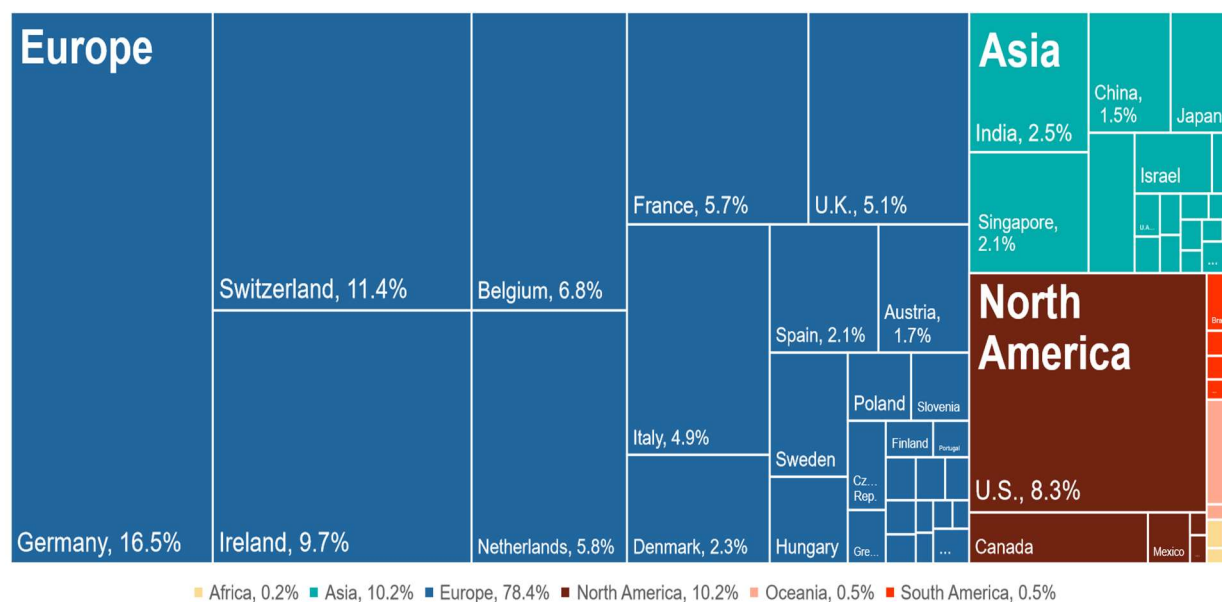


Reflects 568.6 billion of 570 billion USD total gross exports for “Pharmaceutical Products” (20 HS2) for 2018 or most current year available. For the surveyed countries in 2018, gross exports without country origin totaled 1.42 billion USD; these have been excluded from the overall data. Author-generated image using data from the Harvard Atlas of Economic Complexity for “Pharmaceutical products (20 HS2),” 2021.

macroeconomic growths because of its relationship to health and the ‘recession-proof’ demand for health care: “[Health sectors have] been resilient to economic downturns with the sector’s growth remaining positive even during the 2008-09 crisis.”

As the examples of Ireland and the U.K. illustrate, pharmaceuticals are a growing source of trade and economic activity for states all over the world, accelerating since 2002 (Figure 2.2-B). These gains, however, are distributed unevenly, with particular concentrations in the global North and also among leading advanced and select pharmerging economies. The top 15 states, by share of gross pharmaceutical exports, comprise over 86% of the global market. The leading exporters include in the top five: Germany (16.5%), Switzerland (11.4%), Ireland (9.7%), U.S. (8.3%), and Belgium (6.8%). The Netherlands (5.8%), France (5.7%), the U.K. (5.1%), Italy (4.9%), and India

**Figure 2.2-C. *Rx* for European economic growth: The ‘Competition Region,’ Gross pharmaceutical exports, by Country (2018)**



Reflects 568.6 billion of 570 billion USD total gross exports for “Pharmaceutical Products” (20 HS2) for 2018 or most current year available. For the surveyed countries in 2018, gross exports without country origin totaled 1.42 billion USD; these have been excluded from the overall data. Author-generated image using data from the Harvard Atlas of Economic Complexity for “Pharmaceutical products (20 HS2),” 2021.

(2.5%) round out the top 10, while the balance of the top 15 include Denmark (2.3%), Singapore (2.1%), Spain (2.1%), Austria (1.7%), and China (1.5%).

While the U.S. and three pharmerging Asian economies (China, India, and Singapore) make the list, the true global market leaders (in terms of gross export value) are amongst the advanced economies of the ‘competition region’ of Europe (Figure 2.2-C). Despite the narrative<sup>54</sup> that

<sup>54</sup> As the Council on Foreign Relations (2019) has noted, “we could have overestimated our dependence on Chinese-made pharmaceutical products.” See Huang, “U.S. Dependence on Pharmaceutical Products From China.” In 2019 testimony before the U.S.-China Economic and Security Review Commission, Food & Drug Administration (U.S.) Associate Commissioner for Global Policy and Strategy Mark Abdoo advised that China is the second-ranked pharmaceutical exporter to the U.S. by import line (13.4%). Of these U.S.-

pharmaceutical production is concentrated in China and India,<sup>55</sup> Asia as a region is a far smaller player than Europe and the Americas. Europe exported over 78% of pharmaceuticals, while Asia and North America each exported approximately 10%, with the U.S. comprising the vast majority (81%) of gross North American exports. Smaller percentages came from pharmaceutical exporters based in Latin America (0.8%), excluding Mexico but including the Caribbean; Oceania (0.5%) led by Australia and New Zealand; and Africa (0.2%). European economies exported the highest dollar-value worth of pharmaceuticals in 2018, exceeding 446 billion USD as compared to 58 billion USD each for Asia and North America and approximately 8.5 billion USD for Africa, Oceania, and South America combined.<sup>56</sup>

Within Europe, Germany is the leading and largest exporter, representing 16.5% of gross exports in 2018 and extra EU exports exceeding 49 billion USD in 2020. Pharmaceuticals represent a significant share of European and other leading states' trade activity and have facilitated favorable trade balances amidst declines in other sectors and industries. As the EU experiences decline in total trade, driven by losses in other sectors, pharmaceuticals have preserved total trade growth, represented as a favorable trade balance over time (Figure 2.2-D). European trade of pharmaceuticals (in terms of exports and imports) has grown 47% since 1995 into a primary driver

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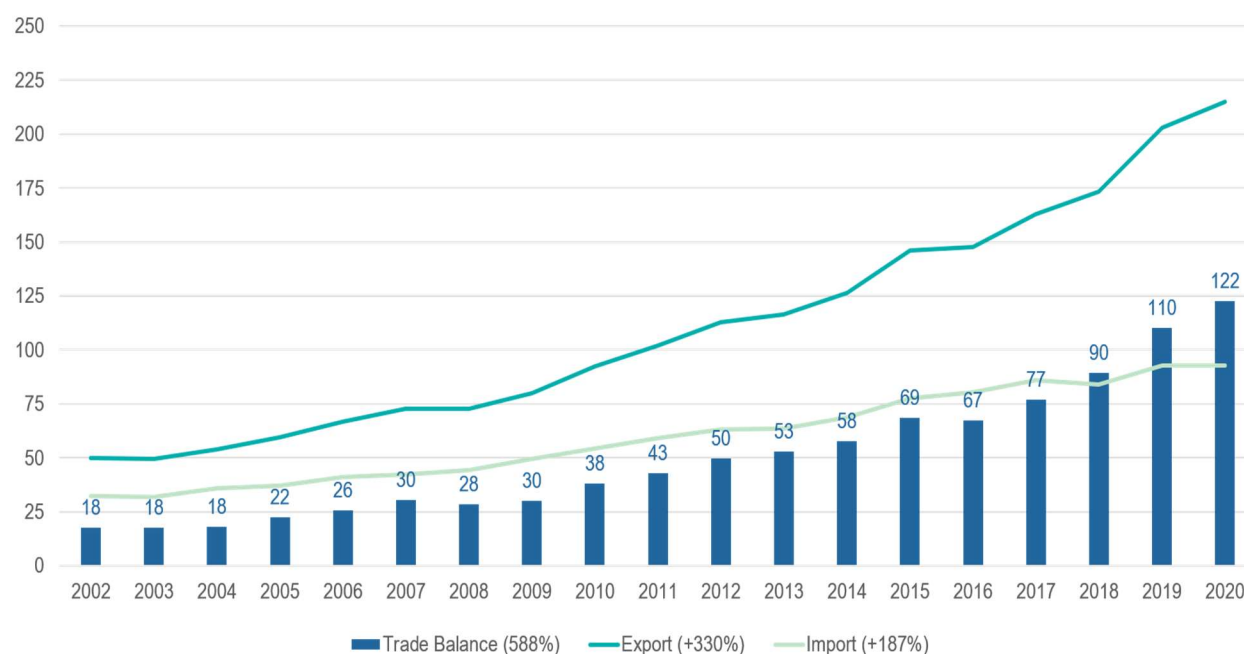
imported pharmaceuticals from China, however, less than 8% were API and, naturally, both figures exclude the context that the U.S. itself is the fourth largest pharmaceutical exporter in the world behind Germany, Switzerland, and Ireland. See U.S.-China Economic and Security Review Commission, Hearing, "Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products" See also Abdoo, Testimony Before the U.S.-China Economic and Security Review Commission.

<sup>55</sup> The Biden-Harris Administration (U.S.) released a report on "critical" U.S. supply chains and their interaction with global supply chains on June 8, 2021. An accompanying fact sheet on the reported noted two datapoints: first, generic pharmaceuticals represent approximately 90% of total pharmaceuticals by volume in the U.S.; and second, approximately 87% of active pharmaceutical ingredients (APIs) – referring to the underlying chemicals and other components of unfinished pharmaceutical products – are "located outside of the U.S.," though particular countries (like India or China) are not specified. The fact sheet goes on to note that "[t]he drive toward lower costs, as well as unfair trade practices, have led to a hollowing out of domestic production. A new approach is needed to ensure more resilient supply chains that include improving transparency, building emergency capacity, and investing in domestic production." See White House (U.S.), "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth;" "Fact Sheet: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-Term Supply Chain Discontinuities" (June 8, 2021); and Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products.

<sup>56</sup> Op. cit., Harvard Growth Lab.

**Figure 2.2-D. Pharmaceuticals help preserve favorable trade balance in Europe:**

**Pharmaceuticals trade in the European Union, in Billions EUR (2002-20)**



Author-generated image using data from the European Commission, “Eurostat,” Online data code DS-018995 (2021).

of trade surplus for the region. Even the financial crisis associated with the global Covid-19 pandemic did not mute these trends, with the pharmaceutical-related trade surplus (trade balance) growing 536% from 22 billion to ≈140 billion EUR between 2000 and 2020.<sup>147F57</sup>

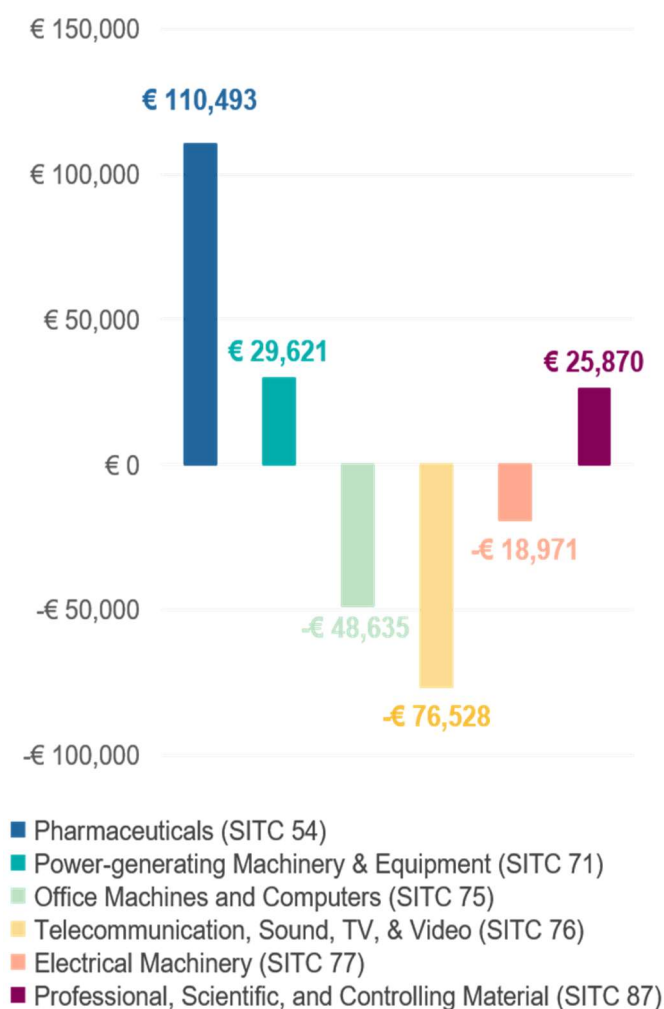
Pharmaceuticals are estimated to comprise approximately 12% of extra-regional trade—up from 5% in 2002<sup>148F58</sup>—and ≈795,000 jobs across the Euro-region.<sup>149F59</sup> Increasingly, pharmaceuticals are Europe’s top-performing sector (Figure 2.2-E).

<sup>57</sup> European Federation of Pharmaceutical Industries and Associations (EFPIA), “The Pharmaceutical Industry in Figures: Key Data 2020,” 2.

<sup>58</sup> Op. cit., European Commission (April 7, 2021).

<sup>59</sup> Op. cit., EFPIA.

**Figure 2.2-E. Comparison of trade balance among European Union high technology sectors, Millions EUR (2019)**



European Federation of Pharmaceutical Industries and Associations, “The Pharmaceutical Industry in Figures.”

Projections of global economic growth are directly reliant on pharmaceuticals and the success of the so-called bioeconomy (in terms of sales and sales growth, meaning greater prescribing and patient use), regardless of the implications for improved health and reduced sickness in absolute terms. And when global health goals are reconstituted in the context of health care expenditures (reduced via a shift to pharmaceutical care instead of acute care), access to care (improved via



increased use of and adherence to pharmaceuticals), and diagnosis and treatment (goals associated with improved rates of diagnosis and timely pharmacological therapy initiation, plus long-term adherence), it is the proverbial win-win-win.

Similarly, the global marketplace finds common ground in its reliance in terms of medical treatment, reliance on pharmaceutical innovation to advance global health, and to preserve workforce productivity and sustain economic gains. But such gains are not independent of costs.<sup>60</sup> Medicines are one of the fastest growing components of health spending, which is crowding out other budget priorities. Calls for regulation are strong,<sup>61</sup> and none more loudly than for changes at the international financial institutions (IFIs) whose support of health reform have led us here.

## 2.2.2 From Economic Reconstruction to the Marketization of Health in the New World Order:

### American Post-war Power and the Neoliberal Transformation

Accelerated since the turn of the century, IFIs, including the BWIs (the World Bank Group<sup>62</sup> and IMF<sup>63</sup>); other global economic development and trade advisory IOs (like the World Trade Organization (WTO)); and IGOs (like the EC and Organization for Economic Co-operation and Development (OECD)<sup>64</sup>) have taken a meaningful interest and role in the development and reform

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<sup>60</sup> Aseem Malhotra, “Why Modern Medicine Is a Major Threat to Public Health,” *The Guardian*, August 30, 2018, sec. Society.

<sup>61</sup> National Academies of Sciences Engineering, and Medicine (U.S.), *Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators*, Consensus Study Report, 2019.

<sup>62</sup> See, for example, Diack et al., “Assessment of Governance and Corruption in the Pharmaceutical Sector: Lessons Learned from Low- and Middle-Income Countries”; Guislain, *The Privatization Challenge: A Strategic, Legal, and Institutional Analysis of International Experience*; Juma and Piatti-Funkirchen, *Cameroon - Public Expenditure Review: Aligning Public Expenditures with the Goals of Vision 2035*; Piatti-Funkirchen, *Namibia - Health Sector Public Expenditure Review*; Tandon et al., *Intertemporal Dynamics of Public Financing for Universal Health Coverage: Accounting for Fiscal Space Across Countries*; *Cameroon - Public Expenditure Review: Aligning Public Expenditures with the Goals of Vision 2035*; World Bank Group, *Driving Sustainable, Inclusive Growth in the 21st Century*.

<sup>63</sup> Andritzky, Munkacsi, and Wang, “Ghana - IMF Staff Mission Concludes 2021 Article IV Discussions”; Clements, Coady, and Gupta, *The Economics of Public Health Care Reform in Advanced and Emerging Economies*; Grigoli and Kapsoli, “Waste Not, Want Not: The Efficiency of Health Expenditure in Emerging and Developing Economies”; Clements, “Healing Public Health Care Finances: Budget Reforms That Work”; de Bidegain et al., “Managing the Impacts of the Coronavirus: Guidance on Health Spending Policies”; International Monetary Fund, “World Economic Outlook Update, January 2021: Policy Support and Vaccines Expected to Lift Activity.”

<sup>64</sup> Tompson, “Healthcare Reform in Russia: Problems and Prospects,” Organization for Economic Co-operation and Development, “Public Funding of Health Care,” Organization for Economic Co-operation and Development, “Pharmaceutical Innovation and Access to Medicines.”

of national health care systems across the world, particularly, in middle-income and low-income countries and, increasingly, regarding national pharmaceutical policies. This remarking of health in market terms (whether economic valuation or labor productivity) is consequential to the role of IFIs and, in particular, a reflection of the *raison d'être* of the BWIs: the neoliberal (styled as democratic capitalism) transformation of the global economies and state societies.<sup>65</sup>

Sarah Babb (2003) helpfully notes that “organizations like the IMF tend to be influenced by the dominant ideas and interests in their environments.”<sup>66</sup> While implicitly accurate, this sociological perspective ignores the global political and economic context within which the BWIs but also other IFIs, were constructed. The World Bank Group, IMF, WTO, and OECD, among other international organizations established in the wake of World War II are strategic politico-economic instruments of mid-20th century U.S. hegemonic power and global interest. They are the political tools of Pax Americana, “the imperative of continued U.S. world leadership:” a U.S. dominated world order, which American policymakers historically interpret as requiring a “favorable international environment” built on the foundation of capitalism-as-security (i.e., “a global capitalist economy”).<sup>67</sup>

As Ruth Felder (2009) describes, the U.S.-driven and styled neoliberal transformation of global society, economics, and politics “involve the liberalization of trade and finance, the creation of opportunities for accumulation through the privatization and commodification of public goods, the protection of foreign direct investments and the building of domestic institutional structures of

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<sup>65</sup> Ruth Felder, “From Bretton Woods to Neoliberal Reforms: the international Financial Institutions and American Power,” Chapter 9 in Panitch and Konings, *American Empire and the Political Economy of Global Finance*.

<sup>66</sup> Babb, “The IMF in Sociological Perspective: A Tale of Organizational Slippage.”

<sup>67</sup> Schwarz, “Capitalism Is the Cold War Winner.”

accountability to international financial markets.”<sup>68</sup> Since the Asian financial crisis of 1997-98,<sup>69</sup> the role of IFIs, the IMF and World Bank Group in particular, “has extended from the enforcement of these reforms” through the requirements of structural adjustment programs “to the management of their adverse effects.”<sup>70</sup>

Paul Cammack (2002, 2004) similarly critiques the “Unholy Trinity” of the IMF, World Bank Group, and WTO, particularly, their enhanced engagement in national policymaking, which these IFIs style as a “new focus” on poverty, public services like health and education, governance, and transparency to address the widely held perception of IFI illegitimacy (“international crisis of legitimacy” arising from IFI’s response to the Asian financial crisis<sup>71</sup>):

Its attention to institutional and social issues has been driven primarily by the aim to establish the structural conditions for the global governance of capitalism, especially the creation and maintenance of an exploitable and disciplined global proletariat.<sup>72</sup>

Cammack and others, including Babb (2003), Michael Barnett and Raymond Duvall (2005),<sup>73</sup> and Leonard Seabrooke (2007),<sup>74</sup> note such engagement has been intended to close the “legitimacy gap” by demonstrating IFIs’ ability to transparently “manage the conflictual and contradictory development of neoliberal globalization and contain the spread of the disruptive effects of crises.”<sup>75</sup> (The legitimacy gap refers to “the space between claims to the fairness and rightfulness of policy actions by those who seek to govern, and the conferral of legitimacy on these claims through belief-

<sup>68</sup> Page 175 in Panitch and Konings, *American Empire and the Political Economy of Global Finance*.

<sup>69</sup> There is broad agreement that the IMF misdiagnosed the roots and causes of the Asian financial crisis and, as a result, recommended policy reforms that were inappropriate. In this case, the IMF and its partner IFIs recommended policies better suited to an export earnings problem versus the actual liquidity crisis that certain south-east Asian states faces in the mid-to-late 1990s. See Independent Evaluation Office, *The IMF and Recent Capital Account Crises* (Washington, D.C.: International Monetary Fund, 2003).

<sup>70</sup> Ibid. Such “adverse effects,” as noted by Felder, are broadly discussed elsewhere in the International Political Economy discourse, as well as beyond it, particularly, by Global Health scholars. These include impoverishment, social dislocation, expropriation of public goods (our particular focus, of course), inequitable health and loss of health gains (another focus), regressive distribution of wealth, environmental degradation, and thinning societal cohesion.

<sup>71</sup> Cammack, “What the World Bank Means by Poverty Reduction, and Why It Matters.”

<sup>72</sup> Cammack, “Attacking the Global Poor.”

<sup>73</sup> Barnett and Duvall, “Power in International Politics.”

<sup>74</sup> Seabrooke, “Legitimacy Gaps in the World Economy: Explaining the Sources of the IMF’s Legitimacy Crisis.”

<sup>75</sup> Page 175 in Panitch and Konings, *American Empire and the Political Economy of Global Finance*.

driven acts by those being governed (such as policy implementation).”<sup>76</sup>) As Cammack (2002) describes, IFIs’ contemporary global engagement is styled as advancing “a world free of poverty.”<sup>77</sup> It is IFI global ‘social responsibility,’ which is intended to sustain neoliberal globalization against the global headwinds of public discontent.<sup>78</sup>

From post-war economic reconstruction to today’s marketization of health, the scholarship of Farmer, Cammack, and others suggest that contemporary IFIs continue to advance the post-war premise of a U.S.-led new world order through the power of political authorities expressed in various forms. These perspectives critique the IMF’s and World Bank Group’s “new focus” on the socio-political consequences of globalization as an exercise in discursive power: a conscious reframing of these global institutions *raison d’être* in the language of “inclusive development” and “empowering the poor.”<sup>79</sup> This is a form of power, a mechanism for coercing or inducing others to do something they otherwise may not do, with deep roots in International Relations (IR), though perhaps the innovation is its application to health systems, instead of the broader politico-economic systems related to development.

From Hans Morgenthau’s *Politics Among Nations* (2005 [1948])<sup>80</sup> to Robert O. Keohane and Joseph S. Nye, Jr.’s *Power and Interdependence* (2011 [1977]) to Alexander Wendt’s “Anarchy is what states make of it: The social construction of power politics” (1992), and beyond, questions of who holds power, how it is wielded (i.e., the forms or typologies of power), and what change it can or cannot bring about have long dominated scholarship in IR. Morgenthau, Keohane, Nye, Wendt, Barnett, Duvall, and others have extensively examined how powerful states use coercion – whether

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<sup>76</sup> Page 252 in Seabrooke.

<sup>77</sup> Granzow, “Our Dream: A World Free of Poverty.”

<sup>78</sup> For a discussion of the role of ideas and policy as a form of power reinforcing and sustaining global capitalism and its modes of production and capital accumulation, see “Part III: The Political Economy of Medical Care” in Navarro, *Medicine Under Capitalism*.

<sup>79</sup> Op. cit., Granzow.

<sup>80</sup> Morgenthau, *Politics Among Nations*.

acting on their own or through other actors or processes, and in forms that are direct (like military force) and indirect (like economic inducements) – to bring about preferred policy changes elsewhere in the world.<sup>81</sup>

The tools and forms of power are unchanged since the post-war period, including coercive-regulatory forms of power (e.g., hard-law treaties and trade agreements), coercive-economic forms of power (SAP requirements and credits tied to policy adoption), and indirect-discursive forms of power, including ideas and narratives that validate certain politico-economic policy choices. As with the SAPs of the 1980s and 1990s about political and economic system development, the forms of power, including regulatory, economic, and discursive, are employed by powerful actors through IFIs to systematically advance one-size-fits-all neoliberal policies—they just now include health and medicines, too, and are reinforced through domestic-level expressions of regulatory, economic, and discursive power.

State policymaking that practically and indirectly drives particular outcomes over others – including domestic investment in pharmaceutical research and development (R&D), known as Selection Mechanisms<sup>82</sup> – illustrate the multi-level influence of neoliberalism on states’ politico-economic policy choices. So, too, does the evolution in state policies under the competition state<sup>83</sup> rubric: particularly the shift from a focus on interest rates, exchange rates, corporate tax rates, and economies of scale to strategic public-private partnerships (PPPs), regulatory coordination and harmonization, facilitated industry collaboration, and direct investment in the research and development (R&D) of innovation. The accelerated growth of the global pharmaceutical market and

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<sup>81</sup> See, for example, Barnett and Duvall, “Power in International Politics;” Iber, “Worlds Apart: How Neoliberalism Shapes the Global Economy and Limits the Power of Democracies;” Keohane and Nye, Jr., *Power and Interdependence*; Holsti, “The Concept of Power in the Study of International Relations;” Wendt, “Anarchy Is What states Make of It: The Social Construction of Power Politics.”

<sup>82</sup> Navarro, *Medicine Under Capitalism*.

<sup>83</sup> Michael E. Porter, “The Competitive Advantage of Nations.”

dominance of the global market by select actors (i.e., those typically considered powerful) is not accidental, but intentional and exemplar of the downstream effect (on domestic policy) of power asymmetries, neoliberalism, and the marketization of health.

### 2.2.3 The Competition State: Forms and Rationale for the Use of State Power in Pursuit of Economic Priorities

The global pharmaceutical sector is not only an engine for economic development, growth, or recovery but also what Michael E. Porter (1990) describes as a source of “national prosperity” and, geopolitical prestige. States’ economic growth and prosperity are the products of competitive advantage, which are “created, not inherited... as classical economics insists.”<sup>84</sup> And a state’s competitiveness depends on the *capacity of its industry to innovate and upgrade*” (emphasis added), just as a state’s.<sup>85</sup> Take, for example, contemporary Sino-U.S. relations, which are described in terms of economic growth *and* national prosperity by U.S. President Joe Biden in remarks on the Senate’s passage of the U.S. Innovation and Competition Act (June 8, 2021):

We are in a competition to win the 21st century, and the starting gun has gone off. As other countries continue to invest in their own research and development, we cannot risk falling behind. America must maintain its position as the most innovative and productive nation on Earth.<sup>86</sup>

Amidst increasing globalization and technology diffusion in the 21st century, so-called competition states’ geopolitical relevance relies on the capacity of its respective industries to innovate to meet the challenge of the new ‘bio-century.’<sup>87</sup> For this research, competition state refers to states securing and sustaining national competitive advantage in the global political economy by leveraging market

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<sup>84</sup> Op. cit., M. E. Porter.

<sup>85</sup> Op. cit., M. E. Porter.

<sup>86</sup> White House (U.S.), “statement of President Joe Biden on Senate Passage of the U.S. Innovation and Competition Act.”

<sup>87</sup> For Competition state literature, see Porter, “The Competitive Advantage of Nations.” For an example of a great power leveraging domestic institutions to advance international power, see 117th Congress (2021-2022) - 1st Session, “U.S. Innovation and Competition Act (USICA)”; White House (U.S.), “statement of President Joe Biden on Senate Passage of the U.S. Innovation and Competition Act,” “Major Scientific and Technological Investments Sought to Better Compete against China,” Elbeshbishi and Behrmann, “Senate Passes Bill to Boost U.S. Science and Tech Innovation to Compete with China,” Lobosco, “What’s in the China Competitiveness Bill?”

investment, production, exports, and imports to sustain its competitive edge economically and, politically.

Contextualized through the lens of strategic competition, pharmaceuticals represent the prized, high Science of innovation that sets competition states apart, with clear ramifications for a suite of power and competition-oriented trade-as-technology geopolitical issues. Pharmaceuticals also practically demonstrate the mechanisms of power leveraged to create and preserve a ‘competition state,’ including Selection Mechanisms for Allocative Intervention (Vicente Navarro, 1976) and economic policies that act as incentives or determinants of national competitive advantage (Porter 1990).

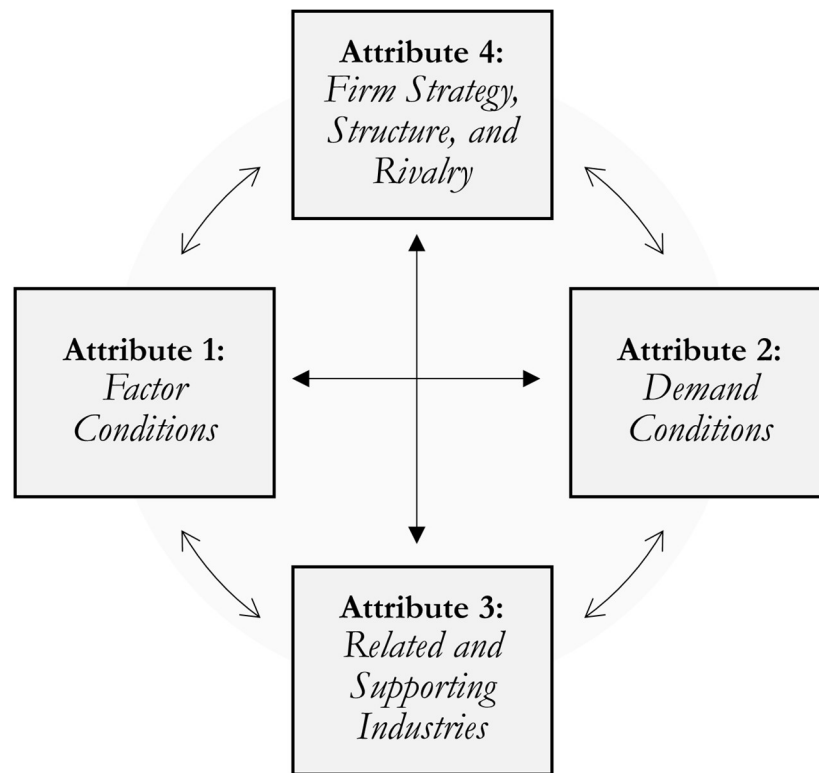
Beginning with Porter, he describes a global political economy of the late 20th century where states “ha[d] become more, not less, important” and geopolitical prominence associated with their relative national competitive advantage.<sup>178F88</sup> The Diamond of National Advantage (Figure 2.2-F) describes the determinants of national competitive advantage, or what sets ‘competition states’ apart, as the rate and efficiency with which factors of production are created, upgraded, and deployed (factor conditions); the composition and character of the domestic market—not the size (demand conditions); the advantage of close working relationships between related and supporting industries, and the ability to mutually benefit from downstream efficiencies; and the convergence of firm strategy, structure, and practices with the modes favored by the state because of their alliance with the state’s sources of competitive advantage. Akin to contemporary concepts of assetization,<sup>179F89</sup> contemporary competition between firms and between states is rooted in turning scientific

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<sup>88</sup> Op. cit., M. E. Porter.

<sup>89</sup> Birch and Muniesa (2020) define assetization as how assets are constructed and how anything “that can be controlled, traded, and capitalized as a revenue stream has become the primary basis of technoscientific capitalism.” For example, assetization can describe when knowledge is turned into a capital asset or market good. See Birch and Muniesa, *Assetization: Turning Things Into Assets in Technoscientific Capitalism*.

**Figure 2.2-F. Porter's Diamond of National Advantage: Determinants of national competitive advantage**



Author-generated figure based on Michael E. Porter, "The Competitive Advantage of Nations" (1990).

innovation and knowledge into market goods.

The critical finding of Porter's analysis is that states can facilitate national advantage by incentivizing the sources and drivers of innovation, specifically, the accumulation of capital and acquisition of modes of production, including technical expertise, necessary for innovation. National economic and market policies, including rules coordinated with other states' regulatory authorities, that favor specialized factors of production, avoiding intervention in factor and currency markets, enforcing strict standards in product safety and quality, limiting direct cooperation among industry rivals (e.g., cooperative pharmaceutical research and development (R&D) through public-private



partnerships (PPPs)), enforcing antitrust policies, and rejecting policy devices that divide markets artificially, among others, which are acutely relevant to the accelerated growth in the pharmaceutical markets of advanced economies. These approaches differ vastly from the economic policies that promote firms' competitiveness in the global political economy through interest rates, exchange rates, corporate tax rates, and economies of scale. These approaches, however, are not necessarily new—even from the 1990s standard—and represent what Vicente Navarro called selection mechanisms in the 1970s.

In *Medicine Under Capitalism* (1976), a collection of papers applying the Marxist paradigm to the U.S. and select other health care systems, Navarro builds on a rich Medical Sociology and Public Health legacy of exploring the political economy of health (e.g., Friedrich, 1845; Virchow, 1847). In the conclusion (“The Modes of State Intervention in the Health Sector”), Navarro introduces the concept of state intervention “in capitalist societies” to capture the continuous interplay between the state and the capitalist class. Selection mechanisms refer to state action through direct and *indirect* expressions of power—or political mechanisms (e.g., formal policy and rules, influence of international priorities, public statements), “that generates, stimulates, and *determines* a positive response favorable to overall capital accumulation, as opposed to a negative selection which excludes anticapitalist possibilities.”<sup>90</sup>

Navarro uses selection mechanisms to describe types of state intervention in markets (i.e., policies or rules), can be divided into two categories: positive selection and negative selection (Table 2.2). Negative selection can be structural, whereby the state as a domestic and international actor (“political decision-making entity”)<sup>91</sup> discourages other actors from considering changes in policy or in practice (including the practices of private firms) that are noncomplementary. Specifically,

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<sup>90</sup> Navarro, *Medicine Under Capitalism*, 209–11.

<sup>91</sup> Waitzkin, “The Marxist Paradigm in Medicine,” 695.

**Table 2.2. Navarro's Selection Mechanisms with health care examples**

<u>Negative Selection Mechanisms</u>	<u>Positive Selection Mechanisms</u>
<p>Structural Selection</p> <ul style="list-style-type: none"> <li>• The “breaking of class structure” to nationalize British health care under the National Health Service (1948) without the support of British physicians</li> <li>• Implied assumption that all health system reforms must involve the role of private capital to secure efficiency in service delivery</li> </ul>	<p>Allocative Intervention Policies</p> <ul style="list-style-type: none"> <li>• Requirements for the reporting of infectious disease, vaccination rates, and other surveillance components of the International Health Regulations, 2005</li> <li>• Statutory inclusion of certain populations in universal health coverage</li> <li>• Favorable tax and policy treatment of certain private products</li> </ul>
<p>Ideological</p> <ul style="list-style-type: none"> <li>• Proliferation of medical and other scientific research examining individual causation of disease and responsive treatment<sup>92</sup></li> <li>• Lack of public funding or goal setting to examine the political origins of disease, including work-place policies,<sup>93</sup> family-friendly labor policies, active employment policies involving training and support<sup>94</sup></li> <li>• Disproportionately smaller public investments in public health than in private forms of health care delivery (e.g., tax deductibility of private insurance, limited state commitments to the World Health Organization)</li> </ul>	<p>Productive Intervention Policies</p> <ul style="list-style-type: none"> <li>• Shift from national insurance schemes, which are allocative (i.e., subsidies, tax benefits), to national health services, which are productive (i.e., nationalization of health services so the state is actually producing health)</li> <li>• Growth in the health expenditures of states, and associated employment in industries, which promotes the accumulation of private capital (which simultaneously is the financial basis for modern states, thus imparting an interdependence between health and pharmaceutical sector growth, fiscal stability, and gains in gross national income (GNI) or gross domestic product (GDP))</li> </ul>

<sup>92</sup> For example, ‘precision medicine,’ diet, exercise, genetic inheritance), including through public funding (e.g., market exclusivity for pharmaceutical products that treat ‘rare’ or ‘orphan diseases.’

<sup>93</sup> For example, Navarro notes that a 1973 report of the then-Secretary of the Department of Health, Education, and Welfare (HEW, U.S.), the precursor of today’s Department of Health and Human Services (HHS), found that the *strongest predictor of “longevity,”* according to a 15-year study on healthy aging, was “work satisfaction” and the second top predictor was “happiness” concluding that “other factors are undoubtedly important—diet, exercise, medical care, and genetic inheritance. But research findings suggest that these factors may account for only 25% of the risk factors in heart disease.” Special Task Force to the Secretary of Health, Education, and the Welfare, *Work in America*, Boston: MIT Press (1973): 77-79.

<sup>94</sup> Solar and Irwin, *A conceptual framework for action on the social determinants of health*, Geneva: WHO (2010), 25.

Table 2.2, Continued

<u>Negative Selection Mechanisms</u>	<u>Positive Selection Mechanisms</u>
Decision-making Processes	
The establishment of public decision-making bodies, but the representatives are privately appointed and less powerful actors without a priori political relationships are excluded.	

Author-generated figure based on author analysis of Navarro, *Medicine Under Capitalism* (1976), 209-213; and Solar and Irwin, “A conceptual framework for action on the social determinants of health” (2010).

Navarro describes noncomplementary policies and practices as those which may invite “alternatives that threaten the capitalist system.”<sup>95</sup> Negative selection mechanisms may be *ideological* (i.e., the state discourages other actors from considering *ideas* that would conflict with the fundamental ideas and norms of the system) or *decision-making* in nature (i.e., the leveraging of weighted or otherwise limited decision-making processes by powerful actors with aligned interests to the exclusion of other actors and alternative or undermining interests). Conversely, positive selection can be *allocation intervention policies*, whereby the state uses its rulemaking authority to “influence, guide, and even direct [] the main activities of society,” through laws and regulations that “make certain behavior mandatory” or “certain claims legal;” and *productive intervention policies* refer to when the state directly participates in the *production* of a resource.

Intellectual property (IP) protections, including patents; market and data exclusivity policies; and expedited pre-market regulatory approval processes are examples of positive selection mechanisms (i.e., the *incentives* for pharmaceutical R&D). However, recall Navarro’s conceptual point that every positive incentive creates a dichotomy—what is *not* being valued? What is indirectly being

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<sup>95</sup> Op. cit, Navarro, 210.

discouraged? Navarro and Porter suggest such mechanisms are *designed* to generate a response by nonstate actors, including market actors such as firms and industry, complementary to state priorities, which increasingly are aligned with neoliberal goals associated with global capitalism.

Navarro has since been joined by other researchers, including Chung and Muntaner (2006), Mackenbach et al. (2008), Navarro and Li (2001), Raphael (2006), Raphael and Bryant (2006), and Solar and Irwin (2010), who have explored the intersection between positive and negative policy, decision-making mechanisms, or informal state preferences on determinants of health and influences on nonstate actors, including firms and individuals.<sup>96</sup> Such an approach implicitly relies on application of the Four Factors model: actors involved in policymaking and governance are informed not only by, *first*, the outward display and codification their of policy preferences and interests (*content*), but also, *second*, the normative *ideas* (e.g., Flexnerianism, neoliberalism, commodification of health, individualization of health risks); *third*, the systemic *context* (e.g., global capitalism, sub-system level democratic capitalism); and, *fourth*, using *processes* as a mechanism for sharing or dividing power.

Reflecting on Porter's Diamond of National Advantage and Navarro's Selection Mechanisms, as Table 2.2 illustrates, there appears to be meaningful alignment between contemporary economic policies and the leading markets of advanced economies—pharmaceuticals being one such example. Through this lens, one particular area ripe for exploration goes into the so-called 'drug development pipeline,' or what areas of *potential* pharmaceutical innovation are prioritized and funded for R&D exploration over others, as well as which 'innovations' make it to market, who has access to the innovation, and what is its market price. Recent evidence by Gaessler and Wagner (2018) suggests a "causal effect of the duration of market exclusivity," which is a form

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<sup>96</sup> Raphael, "Social determinants of health: present status, unanswered questions, and future directions."

of positive selection (allocative) that extends public benefits – in government-sanctioned monopoly pricing – to certain types of pharmaceutical innovation over others.<sup>97</sup> Gaessler and Wagner find that “a reduction in the expected duration of market exclusivity upon drug approval significantly reduces the likelihood of successful drug commercialization,” meaning the manufacturer – most often “medium/large originators, whereas small originators seem much less affected” – elects *against* introducing the otherwise researched, developed, and approved product to the *market*.<sup>98</sup> If globalization has altered the basis of competitive national advantage, it is unlikely that high-innovation markets are not otherwise being politically shaped and sustained.

#### 2.2.4 The Entanglement of all Health in the Web of the Global Market: Implications for the Global and Local Governance of Pharmaceuticals<sup>99</sup>

A key component of this crisis-driven focus on the negative externalities of globalization has been IFIs’ increasing interest in, and engagement of, global health. One of the key functions of the BWIs has been surveillance of states’ economic development and growth in accord with U.S. promulgated and supported “world’s best practice” in economic policy. Besides surveillance, IFIs’ increasing engagement in global health also incorporates the active advancement of particular national health policies, some customized but more often homogeneous (by relative country development status), including through the creation of global health goals (Vision 2035), national health reform strategies, sharing of health policy ‘best practices,’ and sector-based recommendations—pharmaceuticals and pharmaceutical policy included. These efforts employ

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<sup>97</sup> Gaessler and Wagner, “Patents, Data Exclusivity, and the Development of New Drugs.” This paper also was presented to the 11th Annual Searle Center / U.S. Patent and Trade Office Conference on Innovation Economies (June 3, 2018), which suggests regulatory interest in understanding the relative success of such policies *within the context of advancing on-patent (i.e., protected) pharmaceutical innovation*.

<sup>98</sup> Op. cit., Gaessler and Wagner.

<sup>99</sup> The original quote is, “the entanglement of all peoples in the net of the world market,” per Marx, *Capital: A Critique of Political Economy*.

comparative reviews of public health sector expenditures in “overarching development”<sup>100</sup> goals, which primarily are oriented to increasing the “strong role of government in promoting private-sector development” and “increasing expenditure efficiency across multiple sectors of the public administration,” the majority of which is for “public health and education.”

Besides the IFIs, intergovernmental organizations (IGOs) like the United Nations (UN) and World Health Organization (WHO), international regulatory coordinating bodies (e.g., International Pharmaceutical Regulators Program (IPRP)), and other global organizations and actors have taken note. The WHO, for example, aims to have a central coordinating role in public health risk mitigation and management under the International Health Regulations of 2005. In part relying on the IHR’s efforts and progress, in 2015, the 193-member states<sup>101</sup> of the UN adopted the 2030 Sustainable Development Agenda. Known as the ‘global goals,’ the SDGs were designed to achieve three goals by 2030: protect the planet, end poverty, and create prosperity and peace for all.

The commitment reflects 17 goals and 169 goal-related targets that would build on the achievements and aspirations of the 2000-15 Millennium Development Goals (MDGs) by including ‘new’ global challenges like climate change and economic inequality, while retaining ‘old’ challenges

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<sup>100</sup> See, for example, the articulation of state-specific development goals within the content of broader global goals in Juma and Piatti-Funfkirchen, Cameroon - Public Expenditure Review: Aligning Public Expenditures with the Goals of Vision 2035.

<sup>101</sup> The most recently admitted member state, South Sudan, was admitted July 14, 2011. This figure reflects South Sudan’s inclusion and no other updates since July 2011. See United Nations, “Member states” (Updated July 2011).

**Figure 2.2-G. United Nations 2030 Agenda: 17 Sustainable Development Goals**



World Health Organization, “Health in the SDG Era.”

like health outcomes and access improvement (Figure 2.2-G).<sup>102</sup> Each of the 17 SDGs relates to health directly or else their achievement indirectly contributes to improved health. Health itself is the explicit focus of SDG 3 (“Ensure healthy lives and promote well-being for all at all ages”), and pharmaceuticals are implicitly referenced in several targets and indicators, including 3.4.1 (“Mortality

<sup>102</sup> The UN SDGs were adopted in September 2015 and officially came into force January 1, 2016. The SDGs include: (1) end poverty in all its forms everywhere; (2) end hunger, achieve food security and improved nutrition and promote sustainable agriculture; (3) ensure healthy lives and promote well-being for all at all ages; (4) ensure inclusive and equitable quality education and promote lifelong learning opportunities for all; (5) achieve gender equality and empower all women and girls; (6) ensure availability and sustainable management of water and sanitation for all; (7) ensure access to affordable, reliable, sustainable and modern energy for all; (8) promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all; (9) build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation; (10) reduce inequality within and among countries; (11) make cities and human settlements inclusive, safe, resilient and sustainable; (12) ensure sustainable consumption and production patterns; (13) take urgent action to combat climate change and its impacts; (14) conserve and sustainably use the oceans, seas, and marine resources for sustainable development; (15) protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation, and halt biodiversity loss; (16) promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable, and inclusive institutions at all levels; and (17) strengthen the means of implementation and revitalize the global partnership for sustainable development. See United Nations, 2030 Agenda for Sustainable Development; Sustainable Development Goals (Resolution).

rate attributed to cardiovascular disease, cancer, diabetes, or chronic respiratory diseases”) and 3.5.1 (“Coverage of treatment interventions for substance-use disorders (%)”); see Appendix.<sup>103</sup> Inclusion in the Global Goals demonstrates the continued,<sup>104</sup> preeminent role of pharmaceuticals in helping to achieve “a vision for a world free from poverty, hunger, and disease”<sup>105</sup> through universal “access to safe, effective, quality, and affordable essential medicines and vaccines for all” (3.8) and “development assistance and vaccine coverage” (3.b). The 2015 and prior global goals reflect the outsized importance of pharmaceuticals in development conversations and as a mechanism for advancing public health narratives (“improve health and saves lives”).<sup>106</sup>

Before a high-profile meeting of the UN General Assembly to discuss NCD prevention in the “developing world” – a component of SDG 3.4 that observers suggest is improving far too slowly<sup>107</sup> – the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the global trade association representing drugmakers, sponsored a report by the RAND Corporation on “promising ideas for improving” not the prevention of NCDs or identification of cures, but rather “access to medicines for NCDs.” The 2011 RAND report acknowledges that “prevention of NCDs through healthy lifestyles and risk factor control will be a critical component in containing this emerging challenge,” but “no matter how effective prevention efforts are, manifest

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<sup>103</sup> SDG 3 calls for achievement of universal health coverage, investment in research and development of medicines for communicable and noncommunicable diseases, and “access to safe, effective, quality, and affordable essential medicines and vaccines for all.” See, *op. cit.*, United Nations (2015) and also Tedros Adhanom Ghebreyesus, World Health Organization, *World Health Statistics 2020: Monitoring Health for the SDGs, Sustainable Development Goals*.

<sup>104</sup> The SDGs, adopted at the Sustainable Development Summit (of September 25-27, 2015), built on the prior UN Millennium Development Goals (MDGs), which were eight goals that UN member states adopted in September 2000 to achieve similar targets to combat poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women by 2015, which also included access to medicines. See “United Nations Millennial Declaration (Resolution),” General Assembly Resolution No. 55/2, Main Committee A/55/L2 (2000) and Inter-Agency and Expert Group on MDG Indicators, “The Millennium Development Goals Report.”

<sup>105</sup> World Health Organization, “Sustainable Development Goals.”

<sup>106</sup> Roth et al., “Expanding Global Access to Essential Medicines: Investment Priorities for Sustainably Strengthening Medical Product Regulatory Systems.”

<sup>107</sup> SDG 3.4 includes a target to “reduce by one-third pre-mature mortality from NCDs.” We explore progress toward this goal in the context of globalization and health in Chapter 4. To view all targets for SDG 3, see United Nations, “Goal 3: Ensure Health Lives and Promote Well-Being for All at All Ages - Goal 3 Targets.” See also Bennett et al., “NCD Countdown 2030: Pathways to Achieving Sustainable Development Goal Target 3.4.”



NCD will remain a significant challenge for years to come and ensuring access to medicines should remain a top priority.”<sup>108</sup>

The RAND report identifies the current “first line medications” that treat the four major non-cancer NCDs of diabetes, asthma, chronic obstructive pulmonary disease (COPD), and cerebrovascular disease (e.g., stroke), emphasizing these and other NCDs “will be responsible for losses to the national incomes of India, Russia, and China” and reductions in worker productivity. In premature mortality amongst “the working-age population,” RAND notes that “progress... has allowed the populations in poorer countries to achieve lifespans during which they experience chronic disease,” which, left untreated pharmacologically (because of limited access to medicines), will reverse contemporary health and economic and labor productivity gains.<sup>109</sup> The report does not, however, address similar policy opportunities or objectives relating to the “prevention of NCDs... and risk factor control.”

As an example of this narrative, in their recommendations for global leaders charged with advancing approaches to prevent NCDs, RAND instead focuses on what it calls “secondary prevention,” or preventing secondary comorbidities associated with an extant NCD or greater severity of the NCD. By clarifying clinical practice guidelines and treatment standards (for the prescribing of pharmacologic treatment), addressing affordability-related barriers, enhancing health care workforce capacity and diagnostic equipment, and broadening prescribing practices, it may be possible to prevent the worsening of NCDs through improved access to medicines:

At least one potent alternative in each therapeutic category for the first-line treatment of non-cancer NCDs and palliative care is likely to be available in generic form, implying that those medicines should be affordable in all but the poorest

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<sup>108</sup> Mattke et al., “Improving Access to Medicines for Non-Communicable Diseases in the Developing World.”

<sup>109</sup> Ibid, Page 12.

settings. Given the degree of under-treatment of NCDs... the most immediate gains in health can be achieved by improving access to existing medicines.<sup>110</sup>

Workers can still work, costly hospitals will not be overrun, state budgets will be protected from the fiscal risk of “untreated” NCDs—and all for the low price of a generic.

Part of the attractiveness of pharmaceuticals is that they promote a role for the private sector and market-based solutions to the challenge of ill health, which align well with the underlying economic development and global trade goals of TWB, IMF, OECD, and other Washington Consensus-styled IFIs, IOs, and ITGs. Pharmaceuticals also represent a compelling narrative that aligns with existing state motivations (to advance national interests, including economic and national income growth) and global norms asserting the primacy of the market. Plus, investing in expanded pharmaceutical access is comparatively cheaper than the scorable, longer-run costs of acute and emergency care for the same conditions, and far simpler than redesigning underlying politico-health systems toward prevention (instead of palliation). But these are imperfect fixes.

Pharmacological treatments for NCDs are neither preventive nor curative; they are palliative, maintaining a state of quasi-health. Should the projections of NCD prevalence hold, even “affordable” generics, when multiplied by hundreds of millions or even billions of patients, taken across the fullness of their lifespans, will be unaffordable and unsustainable. Considering the negative trade balance in the U.S. for pharmaceuticals as an example, when advanced and emerging economies respond to the “pressure to ensure the prosperity of” their domestic pharmaceutical industries, it quickly creates “conflicts with policy objectives that are based on public health goals” (e.g., overprescribing and use of more expensive medicines) and those rooted in fiscal austerity or sustainability, which are “good for profitability... but bad for public health and public budgets.”<sup>111</sup>

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<sup>110</sup> Ibid., Page 40.

<sup>111</sup> Seiter, A Practical Approach to Pharmaceutical Policy.

### 2.3 From Crisis to Promise: The Bioeconomy Narrative

All medicines have side effects but not all are clinical. Some are economic and political, and the preceding discussions illustrated the multitude of influences on health, including the power of the global neoliberal economic system to reconstitute health as a resource or commodity for the market to produce and distribute. The role of IFIs, IGOs, and other international organizations to motivate state and nonstate actors to adopt certain health policies also was presented, including actions related to the financing and organization of health as a public service and the guidelines and preferencing of pharmaceutical treatments in the practice of health care. The global politico-economic determinants of health that force, through economic policy choices, the preservation and preferencing of countervailing forces to health, including expansion of the global pharmaceutical market, also demonstrates the extensive influence of both power and politics on health. As Claire Bamba, Debbie Fox, and Alex Scott-Samuel (2005) note, “health is political because power is exercised over it as part of a wider economic, social and political system.”<sup>112</sup>

Health is amenable to political intervention, as demonstrated by the actions of the World Bank Group and other IFIs to impose politico-economic requirements on emerging economies; but actors can leverage power in different ways and, in terms of political action (or more usually, inaction), to influence health differently. Some typologies of power, including the concept of hard power, center on the role of force; but power is multifactorial. Other instruments and typologies of power include capacities to influence decision-making, frame or reframe discourse, and make or remake rules.<sup>113</sup> Discursive power, referring to discourse, includes the political tools of agenda setting and narrative construction, the latter of which can generate or reflect ideological alignment

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<sup>112</sup> Bamba, Fox, and Scott-Samuel, “Towards a Politics of Health.”

<sup>113</sup> Bas Arts, “Non-state Actors in Global Governance: Three Faces of Power,” Working Paper. Max Planck Institute for Research on Collective Goods, 2003.

between political actors. The narrative surrounding the bioeconomy is a compelling example of discursive power.

The bioeconomy narrative is premised on hope – the hope to cure disease and illness, to grow the global economy, to achieve “a world free of poverty.”<sup>114</sup> Whether true or not, creating issue linkages between public investment in and protection of the pharmaceutical industry (and its promise of innovation), and the growth or recovery of the global economy are compelling. They construct a public view on the need for the pharmaceutical industry not only to do well, but to innovate; policies that invest in the former to preserve the latter have the practical effect of furthering pharmaceuticals’ relevance and primacy in the contemporary global politics of health. Take, for example, the role of the bioeconomy in the global Covid-19 pandemic and “find the cure” narratives associated with national and transnational patient advocacy groups, including for cancer and Alzheimer’s disease (AD).<sup>115</sup>

The outsized importance of the global bioeconomy is a prime example through which not only the “the making of industrial and clinical knowledge” can be observed, but also how such “knowledge” shapes the practice of medicine (the individualization and global production of health). This knowledge – really, ideas constituting global norms – also shape the “regimes of intervention and capital accumulation” that create international political economies of medicine, herein defined in terms of systems, structures, and policies that advance the neoliberalization of health (i.e., health’s marketization, internationalization, and valuation as commodity).<sup>116</sup> It also is a lens through which to examine how those international political economies are created, the beliefs, ideas, and narratives that construct and sustain them.

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<sup>114</sup> Granzow, “Our Dream: A World Free of Poverty.”

<sup>115</sup> Maron, “Inventor of Hepatitis C Cure Wins a Major Prize—and Turns to the Next Battle.”

<sup>116</sup> Gaudillière, Peterson, and Sunder Rajan, “Opening statement.”

It demonstrates the ability of power and politics to preference the health goals of one actor or interest group over another (e.g., pharmaceutical market; wealthy countries); to shrink the policy space<sup>117</sup> to subordinate, or co-opt, health to other policy priorities (economic growth and security, enhancement of the private-sector);<sup>118</sup> and to spread beliefs and ideas in new ways that grant legitimacy to certain global social norms and systems (capitalism, marketization of health, valuation and assetization of bodies, and medical knowledge) and necessitate certain forms of political action. This section examines the bioeconomy as a mechanism of discursive power, in influence and narrative generation, related to the politics of health.

### 2.3.1 An Industry in Innovation Crisis

From the mid-1990s through the early 2010s, the pharmaceutical industry was reported to be in “innovation crisis,”<sup>119</sup> experiencing what the U.S. Government Accountability Office (2006) described as declines in “the productivity of its research and development expenditures,”<sup>120</sup> with investors, industry leaders and observers, policymakers, and the media collectively worried the industry had dried up, hit by a “research drought” that was only worsening.<sup>121</sup> And yet, less than a decade later, this same crowd touts not an innovation crisis but a promise—a bioeconomy that will solve it all: “improve the quality of life of our aging population,” “address the threat of disease outbreaks,” “correct genetic defects,” and “increase survival rates in cancer.”<sup>122</sup>

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<sup>117</sup> Radhika Gore and Richard Parker. “Analyzing Power and Politics in Health Policies and Systems” *Global Public Health* 14, no. 4 (April 3, 2019): 481–88.

<sup>118</sup> Labonté and Schrecker define “policy space” conceptually as those situations in which the international system constrains the ability of governments to adopt policies that promote a particular issue. Within the context of health, policy space is defined by “the extent to which national decisions for health and on social determinants of health can be made on the basis of health policy concerns and priorities as distinct from other priorities, such as economic growth, maintaining payments to external creditors, or complying with trade agreement disciplines.” See Page 53 of Ronald Labonté and Ted Schrecker. “Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution.” Final Report to the WHO Commission on Social Determinants of Health. University of Ottawa Institute of Population Health, June 29, 2007.

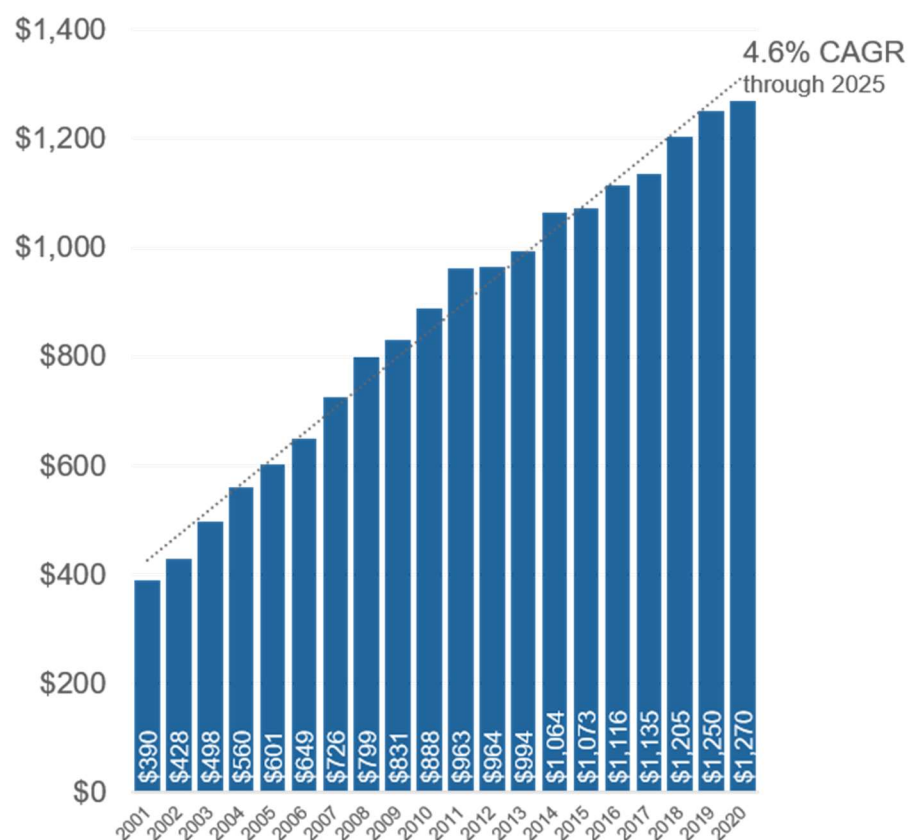
<sup>119</sup> Light and Lexchin, “Pharmaceutical R&D: What Do We Get for All That Money?”

<sup>120</sup> Government Accountability Office (U.S.), “New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts.”

<sup>121</sup> Cockburn, “Is the Pharmaceutical Industry in a Productivity Crisis?”

<sup>122</sup> Dogramatzis, “Healthcare Biotech: An Unfulfilled Promise?”

**Figure 2.3-A. Gross revenue of the global pharmaceutical market, USD Billions (2001-20)**



Author-generated image based on analysis of Mikulic, “Global Pharmaceutical Market Size 2001-2020.”

The pharmaceutical innovation crisis and similar industry narratives surrounding unsustainable research and development (R&D) costs represent a discursive expression of power complementary to state interests in the realm of generating competition national advantage. Using the U.S. as a proxy, actual pharmaceutical market approval or licensure trends do not suggest an industry recovering from crisis, but an industry like any other with peaks and also valleys. As illustrated by Figure 2.3-A, in 1996, the same year many of the “innovation crisis” claims materialized in trade journals and media statements, the U.S. Food & Drug Administration (FDA) approved a

**Figure 2.3-B. New drug applications approved by the Food & Drug Administration (U.S.), by Application Type (1992 to May 2021)**



Author-generated figure reflecting analysis of FDA annual “Novel Drug Approvals,” by year, from 1992 through 2021, plus an analysis of January-May 2021 drug approvals.

then-record 53 new drugs,<sup>123</sup> which was not exceeded until 2018’s record-breaking 59 approvals following an industry-wide 2016 decried as a “slump”—and also despite global revenues exceeding 1.1 trillion USD.<sup>124</sup> The claims and fears of 1996 and, again, in 2016 may be potent at particular point-in-times, but across three decades, the industry has averaged 30 novel drug approvals annually in the U.S. (Figure 2.3-B). Such consistent growth is far from an industry hit by “research drought” or in constant crisis.

Unlike other volatile sectors,<sup>125</sup> the pharmaceutical industry’s volatility is not only clearly recoverable – often in the following year – but their market share, profitability (or margins), and

<sup>123</sup> Owens, “New FDA Drug Approvals Hit an 18-Year High in 2014.”

<sup>124</sup> Mikulic, “Global Pharmaceutical Market Size 2001-2020.”

<sup>125</sup> Examples include the energy, commodities, financial, communication services, utilities, technology, health care sectors, which experience volatility often at greater levels. In terms of stock tracking in particular, the most volatile sector is oil services, followed by oil and gas exploration. Health care, consumer services, and utilities are among the least volatile, experiencing volatility ranges of 10% to 12%.

returns on investment are protected from competition, from those laissez-faire market forces that otherwise, would demand efficiency (“drug R&D would become more efficient, faster, less risky, and cheaper”),<sup>126</sup> granting it outsized market influence and power to set its own prices and to have its goods (and those profits) insulated for years, and often decades, in markets all over the world.

Rather, the cries of industry are calls to states and global economic leaders for greater public support,<sup>127</sup> whether through longer IP right protections, enshrined in WTO-enforced multilateral trade agreements (e.g., Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement),<sup>128</sup> longer data or within-market exclusivities, or more direct or indirect subsidies (e.g., tax deductibility of television advertisements) because, ultimately, the contemporary pharmaceutical market is actually not one of innovation. The approximately 1.3% of industry revenues devoted to discovering new molecules<sup>129</sup> compares with an actual estimated 25% spent on marketing and promotion,<sup>130</sup> or a ratio of 1:19.

The market’s leading products also are neither curative treatments nor preventatives, but examples of what Dr. Singh calls ‘palliation’: medical practice through medicines that manage the symptoms associated with noncommunicable diseases (NCDs) like heart disease. During a year marked by the global Covid-19 pandemic, the most important medicines (as measured by global revenue generation, or sales) were not Covid treatments or vaccines but NCD treatments, including: Humira (AbbVie, anti-inflammatory), which generated 20.4 billion USD in 2020, at least 16 billion

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<sup>126</sup> Dogramatzis, “Healthcare Biotech: An Unfulfilled Promise?”

<sup>127</sup> Light and Lexchin, “Pharmaceutical R&D: What Do We Get for All That Money?”

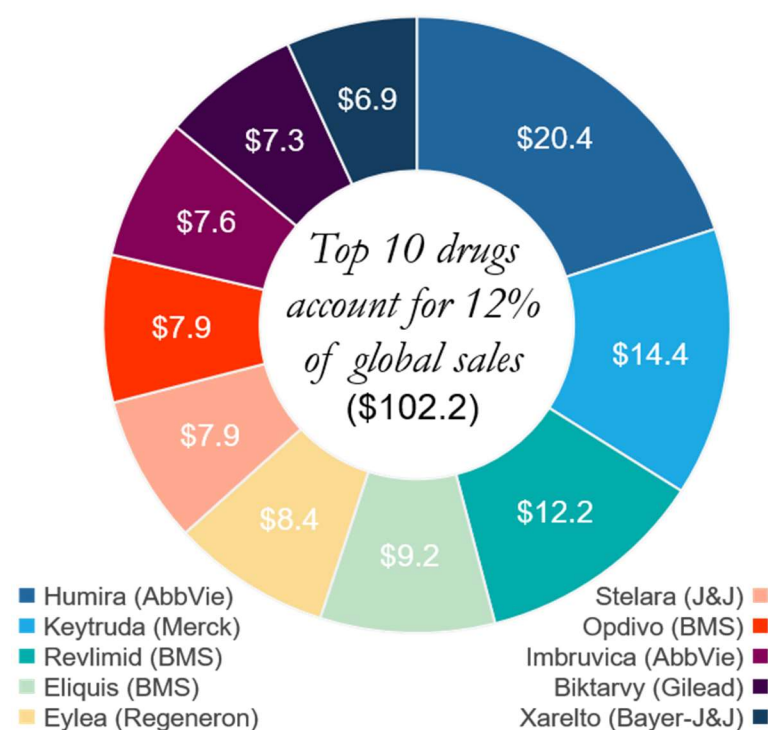
<sup>128</sup> The TRIPS agreement introduced IP law into the multilateral trading system for the first time and remains the most comprehensive multilateral agreement on IP to date. In 2001, low- and middle-income countries, concerned by high-income countries, where the pharmaceutical industry is a leading economic actor, reading of TRIPS, initiated a round of talks that resulted in the Doha Declaration. The Doha Declaration (November 2001) is a WTO statement that clarifies the scope of TRIPS, including that the Agreement can and should be interpreted in light of the goal “to promote access to medicines for all,” and allows for compulsory licensing.

<sup>129</sup> Light and Lexchin, “Foreign Free Riders and the High Price of US Medicines.”

<sup>130</sup> Gagnon and Lexchin, “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States.”



**Figure 2.3-C. Leading pharmaceutical products by global sales, Billions USD (2020)**



Author-generated figure based on data from Urquhart, “Top Companies and Drugs by Sales in 2020.”

of which reflects U.S., only sales;<sup>131</sup> Keytruda (Merck & Co., a treatment for melanoma, a skin cancer), which produced 14.4 billion USD; and Revlimid (Celgene, immunomodulator agent), which generated 12.1 billion USD (from 9.7 billion USD in 2018).<sup>132</sup> Figure 2.3-C presents the top 10 pharmaceutical products by global sales in 2020, which collectively represent 102.2 billion USD in sales, or over 12% of total global sales (of 1.3 trillion USD, 2020).<sup>133</sup> These pharmaceuticals generate significant global sales, and several have been ‘blockbuster drugs’ for many years now, representing a

<sup>131</sup> House of Representatives (U.S.), “AbbVie–Humira and Imbruvica,” i.

<sup>132</sup> Urquhart, “Top Companies and Drugs by Sales in 2020.”

<sup>133</sup> Mikulic, “Global Pharmaceutical Market Size 2001-2020.”

revenue-generating product with broad ‘market appeal’ neither novel nor new.<sup>134</sup>

For example, AbbVie’s Humira® (adalimumab), a treatment for rheumatoid arthritis and other autoimmune diseases, received its first U.S. patent in 1994 and first EU patent and marketing authorization in 2003.<sup>135</sup> While patent protection of Humira expired in most EU countries in October 2018, secondary patents remain active. In the U.S., though the primary patent expired in 2016, a collection of 100+ patents and exclusivities, including for this global blockbuster-drug being an “Orphan Drug”<sup>136</sup> means competitors are unlikely until secondary protection expires in 2033.

### 2.3.2 The BioCentury, or the Age of Slow and Incremental Technological Diffusion

Rather than an industry innovating in response to crisis, or revolutionizing to realize the BioCentury before us, the global pharmaceutical market, cloaked in a constructed narrative of bio-innovation, is “following a pattern of slow and incremental technology diffusion,”<sup>137</sup> seeking the market insulation only state actors can provide, particularly, market and data exclusivities for treatments for rare and orphan diseases and break-through innovation. For example, returning to the U.S. context, pharmaceutical governance evolved significantly between 1983 and 2020, including the enactment of laws, like the Orphan Drug Act, intended to spur generic drug and biosimilar competition, speed market access through faster approval and licensure pathways, and promote biopharmaceutical investment in rare diseases and curative therapeutics by granting protection from market competition.

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<sup>134</sup> Mukherjee, “Protect at All Costs: How the Maker of the World’s Bestselling Drug Keeps Prices Sky-High.”

<sup>135</sup> Moorkens et al., “The Expiry of Humira® Market Exclusivity and the Entry of Adalimumab Biosimilars in Europe: An Overview of Pricing and National Policy Measures.”

<sup>136</sup> The U.S. Orphan Drug designation, established under the Orphan Drug Act (ODA), aims to incentivize the development of medicines for the treatment of rare diseases and conditions. The ODA allows for accelerated approval and granting of a market exclusivity. Humira received eight ODA designations, despite the fact that the drug is not only the top-selling drug in the world, but also the highest grossing drug in the United States, with *net revenue* growing more than 770% between 2014 and 2020 alone (i.e., from 492 million USD in 2014 to 4.3 billion USD in 2020). Notably, “AbbVie also secured longer market exclusivity periods under the ODA by seeking separate, staggered market approvals and exclusivity periods for different age groups of patients affected by the same rare disease,” meaning, the combination of patents and staggered exclusivities may allow more than 39 years of protection from market competition. See House of Representatives (U.S.), “AbbVie–Humira and Imbruvica,” i–ii.

<sup>137</sup> Ibid.

The signing of the TRIPS Agreement by all WTO member states is also reflected during this period. The TRIPS Agreement internationalized and made enforceable – through a formal disciplining mechanism – pharmaceutical IP protections, representing the only hard-law global pharmaceutical governance paradigm. (And it is on terms favorable to both industry and economies with significant pharmaceutical exports—it also is a constant source of tension in questions of universal access to essential medicines.)

During this time of significant legal and regulatory action on behalf of the pharmaceutical industry, to preserve and encourage the industry's innovation, the actual rate of innovation has been relatively stable. From 1990 to 1999, following the signing of the TRIPS Agreement, the mean annual number of new drug approvals was 34. New drug approvals fell to 25 for the 2000-09 period and increased roughly in line with overall trend to 41 (for the 2010-19 period). Conversely, the area of most significant innovation – measured in terms of new products coming to market – has been among the generic manufacturers. The median annual approvals of generics were 420 from 1970 to the enactment of the Drug Price Competition and Patent Term Restoration Act (or Hatch-Waxman Act) in 1984<sup>138</sup> and enactment of the Generic Drug User Fee provisions of the Food & Drug Administration Safety and Innovation Act (FDASIA) of 2012,<sup>139</sup> or approximately 10 generic approvals per year. Following these policies' enactment, 588 generic applications were approved between 2013 and 2018—and 948 more in 2020 alone, including 72 first generics (Figure 2.3-D).<sup>140</sup>

The prior decade advanced select innovations in mechanisms of treatment, including RNA-based therapeutics (e.g., some Covid-19 vaccines represent messenger ribonucleic acid (mRNA) technology) and calcitonin gene-related peptide (CGRP) receptor antagonists for migraine treatment.

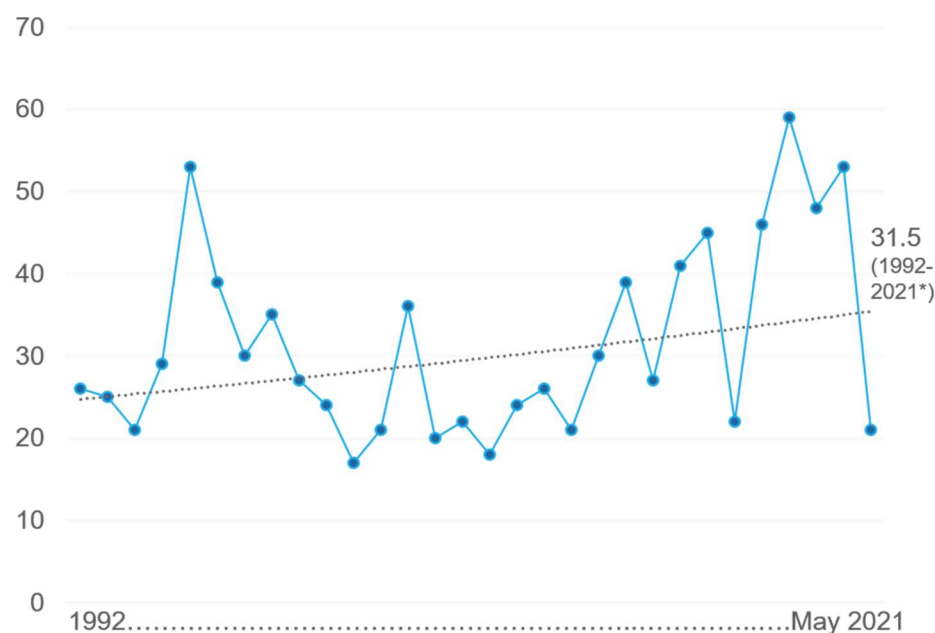
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<sup>138</sup> Congress (U.S.), Drug Price Competition and Patent Term Restoration Act of 1984.

<sup>139</sup> Congress (U.S.), Food and Drug Administration Safety and Innovation Act.

<sup>140</sup> Darrow, Avorn, and Kesselheim, "FDA Approval and Regulation of Pharmaceuticals, 1983-2018."

**Figure 2.3-D. New drug approvals average 31.5 between 1992 and May 2021 (U.S.)**



Author-generated image based on analysis of FDA annual “Novel Drug Approvals,” by year, from 1992 through 2021, plus an analysis of January-May 2021 drug approvals.

At least nine of the remaining drug products and vaccines relate to the SARS-CoV-2 virus and Covid-19 pandemic, which were the beneficiaries of significant public sector financing and support. Excluding new neurological treatments, including to treat pain, mental health conditions, and migraines, the balance comprises 2013’s DAA treatments for hepatitis C and neglected tropical diseases (NTDs) like malaria, tuberculosis, and Ebola, which IQVIA associates with “global philanthropy,” referring to the venture philanthropy of the Bill and Melinda Gates Foundation; the Chan-Zuckerberg Initiative; the Cystic Fibrosis Foundation, the latter which profited 3.3 billion USD after co-funding the development of Kalydeco® (ivacaftor);<sup>141</sup> and similar international and national nonstate actors and institutions. As Richard G. Frank, Leslie Dach, and Nicole Lurie (2021)

<sup>141</sup> Tozzi, “This Medical Charity Made \$3.3 Billion From a Single Pill,” Bloomberg (July 7, 2015).

have noted, the research, development, and commercialization of vaccines and treatments for select infectious disease reflect significant public support, including direct and indirect financing, and mediation of the same market forces the broader narrative – of market-based efficiency and innovation – seeks to reinforce:

In the case of vaccines in general, the government often plays an outsized role, but in the era of Covid-19 the government's role was even more central than usual. The government essentially removed the bulk of traditional industry risks related to vaccine development: scientific failures; failures to demonstrate safety and efficacy; manufacturing risks; and market risks related to low demand.<sup>142</sup>

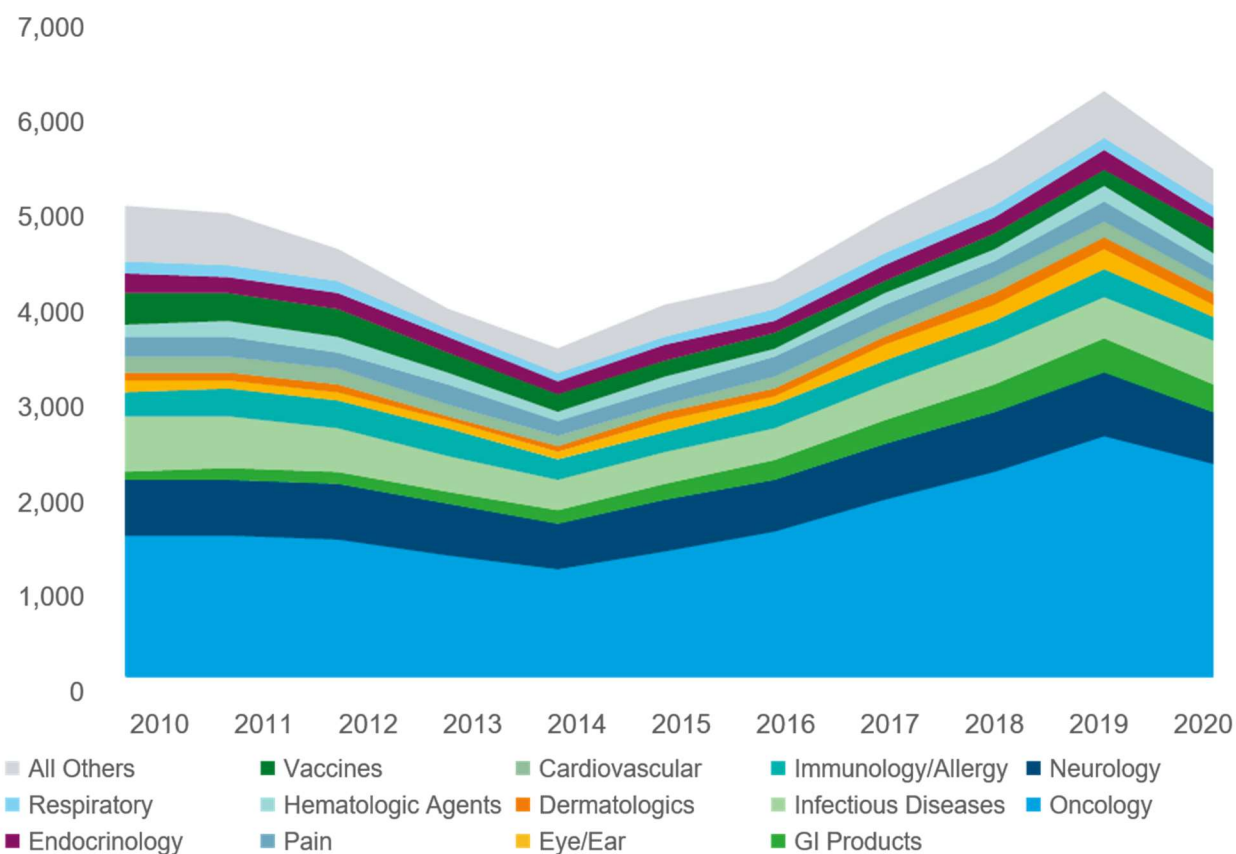
In terms of innovation, the global pharmaceutical industry's research and development (R&D) pipeline has grown in the volume of products, but neither in their scope and variation (in terms of therapeutic drug class) nor innovation (in terms of new active substances (NAS)), which have been net stable over the prior decade (2010-20); see Figure 2.3-E. Innovation in oncologics accounted for approximately half of all NAS filings across the decade (114 of 233), which is remarkable scientifically and for patients afflicted with cancers, but not a departure from prior pipelines. Using NAS as a proxy, the balance of the top three therapeutics classes includes 22 products, vaccines, or new mechanisms of action in neurology and infectious disease.

The promise of the new bioeconomy is made opaque, given the market's own relative stability versus innovation, the role of other actors to shoulder the risks associated with innovation, and post-patent exclusivity protections intended to generate innovation but being used to extend firms' product monopolies and design R&D pipelines fit-to-protective-purposes. Rather, the

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<sup>142</sup> The full reference follows: "With Covid-19, the government's role was even more central than usual. The government essentially removed the bulk of traditional industry risks related to vaccine development: a) scientific failures, b) failures to demonstrate safety and efficacy, c) manufacturing risks; and d) market risks related to low demand... In response to the Covid-19 pandemic, the government leveraged investments in those platforms in three ways. First, it supported additional preclinical studies. Second, it absorbed the bulk of human testing costs and risk through a set of contracts that paid for the various phases of vaccine development and manufacturing. And third, it reduced manufacturing risk by underwriting capacity investments. The government also largely eliminated market risks through advance purchase commitments. These contracts involved negotiation over price and quantity that ended in mutually agreeable contract terms between the government and industry." See Frank, Dach, and Lurie, "It Was The Government That Produced Covid-19 Vaccine Success."

**Figure 2.3-E. Late-stage pharmaceutical pipeline dominated by diseases of advanced economies: Oncology, neurology therapeutic drug classes (2010-20)**



Aitken and Kleinrock, “Global Trends in R&D: Overview through 2020,” 29, Exhibit 23.

narrative of innovation is socially constructed—a form of discursive power to generate good will with select power centers, including the state actors of advanced economies. The literature is extensive in illustrating the endpoints of the marketization of health, including pharmaceutical R&D: profit maximization.

With this awareness, what is most important now is to understand how effective the perception of an innovation-driven bioeconomy is for changing the hearts and minds of leading political-economic actors. Considering the ideas, beliefs, and interests involved in the creation and

management of “commodities all the way down”<sup>143</sup> – the marketization of health and bodies – the preservation of the bioeconomy, and its constructed narrative tying private-sector innovation to the end of poverty and sickness, is necessary for the political maintenance of the global social norms and endemic systems that commodify health despite its costs. The costs being the economic harms and harms to those with less power and market-determined value within the global political economy. Acceptance of this narrative is not inherent. These systems of marketization are not inherent. Each is a political choice rooted in power and interest.

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<sup>143</sup> Fraser, “Can Society Be Commodities All the Way down? Polanyian Reflections on Capitalist Crisis.”

## CHAPTER 3

### HEALTH AS A GLOBAL PUBLIC GOOD: REVIEW OF THE MICROECONOMICS LITERATURE

“The history of civilization is a history of public goods... The more complex the civilization, the greater the number of public goods that need to be provided. Ours is by far the most complex civilization humanity has ever developed. So, its need for public goods – and goods with public goods aspects, such as education and health – is extraordinarily large.”

—Martin Wolf, chief economics commentator, *Financial Times* (2012)<sup>1</sup>

The evolution of public goods theory and the emergence of, and opportunities and challenges for, global public goods, are essential starting points for this research’s conversation on the international political economy of health. Ideational factors, or a society’s intersubjective beliefs, underpin the comparative value of what is considered ‘public’ versus ‘private.’ These beliefs form a shared collective understanding and also “construct actors’ identities and interests,”<sup>2</sup> which are realized through the meta systems, processes, interests, actions, and typologies (including those that implicitly defer relative powerfulness and political saliency on select actors over others) that structure modern life—including the marketization of individual health. Even where health is publicly financed, the role of the individual in health and sickness, how health services and goods are priced and purchased, the opportunities for “better care” through adjacent private sources, and the collective investment (or go-it-alone approach) to global health each are built on ideas constructed and sustained based on the “ontological reality of intersubjective knowledge” and the “epistemological and methodological implications of this reality.”<sup>3</sup>

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<sup>1</sup> Wolf, “The World’s Hunger for Public Goods.”

<sup>2</sup> Finnemore and Sikkink, “Taking Stock: The Constructivist Research Program in International Relations and Comparative Politics,” 393.

<sup>3</sup> Adler, “Seizing the Middle Ground: Constructivism in World Politics.”



Scholarship, theoretical formulation, and modeling that seek to generate quantifiable evidence of natural phenomena and their properties and relations – to ask and answer the why-and-what questions objectively (a positivist approach) – are extraordinarily beneficial, particularly, for the study of finite phenomena. For scholars of the human experience, however, the particular connection to the subject is neither positivist nor faultlessly objective. Though it may appear simpler and more precise to quantify human existence and experiences, the formulation of contemporary public goods theory by mid-century American Economists Paul Samuelson and Richard A. Musgrave demonstrate that positivist approaches can prove inadequate, impractical, and ill-fitting (Chapter 3.1). Since the mid-20th century, public goods theory has continued to evolve, including through scholarly reexamination of Musgrave’s and Samuelson’s intent to achieve a normative model of optimal public expenditure, and the introduction of ethical, political, and global perspectives in the qualities of public and private goods (Chapter 3.2). The fast-growing literature on global public goods for health is explored in particular depth (Chapter 3.3). Such literature is expanding the contemporary bounds of considered the global commons versus global public goods and encouraging a reexamination of the relevance and application of public goods theory.

This chapter concludes by articulating the mischaracterization of health as a private good, and this mischaracterization is rooted in socio-politically constructed beliefs, identities, and interests that prefer positivist and rationalist answers to the inherently subjective, normative, and constitutive “how-possible” questions that comprise everyday life (Chapter 3.4).<sup>4,5</sup> This research is premised on the characterization that health, and components of health like pharmaceuticals, is a fundamental public good that consistently has been recharacterized through global systems, processes, and the interests and actions of powerful actors as a private or quasi-private good for which the market

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<sup>4</sup> Doty, “Foreign Policy as Social Construction: A Post-Positivist Analysis of U.S. Counterinsurgency Policy in the Philippines”

<sup>5</sup> Jung, “The Evolution of Social Constructivism in Political Science: Past to Present.”

should have a role. The marketization of health is explored further in Chapter 5; for now, assert the constructivist premise that the individualization and marketization of health is created, shaped, and sustained by positivist ideational factors tied to the neoliberal discourse, not the actual socio-economic characteristics of the good itself (e.g., relative market efficiency).

### 3.1 What Are Public Goods? Classical and Contemporary Understandings

Oft-cited examples of public goods, sometimes called ‘merit goods,’ include physical security, a resilient food supply, regulations to protect environmental resources, and shared knowledge of how to prevent and treat disease and illness. The basic concept of public goods was understood by classicist thinkers such as David Hume and Adam Smith. Hume’s *Treatise of Human Nature* (1739) discusses the difficulties inherent in providing for “the common good,” whereas Smith analyzes similar questions through a distinctly economic lens in *Inquiry into the Nature and Causes of the Wealth of Nations* (1776). Italian economists of the mid-19th century, including Francesco Ferrara, also were forerunners.<sup>6</sup> Conceptualizations also were advanced in the late 19th century and during the interwar period by economists Knut Wicksell and Erik Lindhal (*Die Gerechtigkeit der Besteuerung*, 1919),<sup>7</sup> particularly the Wicksell-Lindhal model of optimal public goods consumption. Contemporary public goods theory, however, reflects Samuelson’s (1954) “rigorous economic expression.”<sup>8</sup>

Although Samuelson’s definition and associated mathematical model are often credited, the

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<sup>6</sup> Many of these early classics were translated and introduced in Musgrave, *The Theory of Public Finance: A Study in Public Economy*; see also Musgrave and Peacock, *Classics in the Theory of Public Finance*; Samuelson, “The Pure Theory of Public Expenditures;” Buchanan, *The Demand and Supply of Public Goods*.

<sup>7</sup> For a comprehensive accounting of the contributions of Wicksell and Lindahl to public goods theory, see Silvestre, “Wicksell, Lindahl and the Theory of Public Goods.”

<sup>8</sup> Bodansky, “What’s in a Concept? Global Public Goods, International Law, and Legitimacy.”

two-criteria definition first articulated by Musgrave (1959)<sup>9</sup> and the pedagogical device<sup>10</sup> for classifying different families of goods he developed serve as the preeminent contemporary definition in public economics and microeconomics.<sup>11</sup> Taken together, Samuelson's and Musgrave's contributions form contemporary public goods theory, which are defined and discussed below.

### 3.1.1 Public Goods are Non-rival and Non-excludable

For Musgrave and Samuelson, public goods have two specific traits: it is difficult, if not impossible, to exclude others from having access to, or profiting from, such a resource (excludability); and the benefits that accrue to one do not diminish the benefits left for others (rivalry).<sup>12</sup> Public goods are non-rival, as they are goods that “all enjoy in common in the sense that each individual's consumption of such a good leads to no subtraction from any other individual's consumption of that good,” and are non-excludable, as others cannot be prevented from consuming or benefiting from it.<sup>13</sup> For an illustration of Musgrave's and Samuelson's definition of public goods, employing the pedagogical device that Musgrave made famous (i.e., two-by-two matrix describing different goods), see Table 3.1.

Private goods are goods where consumption by one individual, market, state, or other actor

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<sup>9</sup> Samuelson's distinction between public and private goods based on rivalry alone was not novel. Hammond (2015) notes that Samuelson himself built on the scholarship of Musgrave and others.<sup>9</sup> Indeed, Musgrave's scholarship on public goods begins in 1937—a decade prior to Samuelson's *Foundations of Economic Analysis*. Samuelson's analytical innovation, rather, was incorporation of the ethical status of the distribution of public goods. In “The Pure Theory of Public Expenditures,” Samuelson describes the model's inclusion of a “social welfare function” as necessary for modeling optimal public expenditure. See Hammond, “Paul Samuelson on Public Goods: The Road to Nihilism.”

<sup>10</sup> For origins of the four-square pedagogical device often used to compare public and private goods, see Musgrave and Musgrave, *Public Finance in Theory and Practice*.

<sup>11</sup> Musgrave's definition is used in public economics and microeconomics textbooks, including: Cornes and Sandler, *The Theory of Externalities, Public Goods, and Club Goods*; Hindriks and Myles, *Intermediate Public Economics*; Gruber, *Public Finance and Public Policy*; Varian, *Microeconomic Analysis*; Nicholson and Snyder, *Microeconomic Theory: Basic Principles and Extensions*.

<sup>12</sup> For Musgrave, see Musgrave, *The Theory of Public Finance: A Study in Public Economy*; Musgrave, “Provision for Social Goods”; Musgrave and Peacock, *Classics in the Theory of Public Finance*. For Samuelson, see Samuelson, “The Pure Theory of Public Expenditures”; Samuelson, *Foundations of Economic Analysis*; Samuelson, “Diagrammatic Exposition of a Theory of Public Expenditure.”

<sup>13</sup> Samuelson, “The Pure Theory of Public Expenditures.”

**Table 3.1. Traits and examples of public goods**

<u>Excludability</u>	<u>Rivalry in Consumption</u>	
	Non-Rivalrous	Rivalrous
Non-Excludable	Pure public goods <ul style="list-style-type: none"> <li>• Environmental protection</li> <li>• National defense</li> <li>• Public infrastructure</li> <li>• Rule of law</li> </ul>	Common-pool resources (aka, the “tragedy of the commons”) <ul style="list-style-type: none"> <li>• Air quality</li> <li>• Fisheries</li> <li>• Minerals</li> </ul>
Excludable	Club goods and monopolies (the “tragedy of artificial scarcity”) <ul style="list-style-type: none"> <li>• Childcare facilities</li> <li>• Education of a student</li> </ul>	Private goods <ul style="list-style-type: none"> <li>• Cars</li> <li>• Housing</li> <li>• Luxury items</li> </ul>

Author-generated and compiled examples.

prevents consumption by another (i.e., rivalrous consumption), and one actor can prevent directly or indirectly the other from consuming the good or service (excludability). Conversely, where consumption is non-rivalrous and non-excludable, such goods are considered pure public goods, though this qualifier (i.e., ‘pure’) may itself be impure, unrealistic, and impractical.

Examples of public goods may include maritime laws, traffic rules, and common knowledge, each of which are non-rivalrous, meaning that for each good, consumption by one ship captain, driver, or student, respectively, does not diminish the good’s availability for others. These examples also are non-excludable because other captains, drivers, or students are not excluded from benefiting from the good. While rivalry is implicitly binary, excludability is far more layered, encompassing characteristics of divisibility, transferability, scarcity, and participation.

While some members of a collective may benefit more or less from a system of national defense, participation is largely non-voluntary, meaning individual members could only be excluded

at great cost (through system exit). National defense is an oft-cited example of an ideal-type public good: a ‘pure’ public good fully and extremely non-rivalrous and non-excludable. In comparison, some public goods, like global fisheries, are regarded as ‘impure’ public good as they pass muster regarding one measure (e.g., non-excludability) but not the other (rivalrous). Herein they are common pool resources, also called the global commons, whereby the consumption of such goods are rivalrous (i.e., there may be a limited supply, use by one actor diminishes availability for another), but it is difficult to exclude actors from consuming the good.

Impure public goods can also be non-rivalrous but excludable of a bridge, which are called club goods, monopolies, or the ‘tragedy of artificial scarcity.’ Because club goods are excludable, inefficiencies due to external effects, including lack of collective action, can often be addressed by charging users for access to the good, whether by toll, tax, membership fee, or market price. In some ways, however, such club goods need not be excludable but are socially constructed to be limited or scarce, anyhow; Covid-19 vaccines and some quasi-public spaces, like botanical gardens, are examples.

Returning to the example of national defense, such public services also could be examples of club goods. As Daniel Bodansky (2012) notes, “if one part of the United States – say, Alaska – failed to contribute to the national defense by paying taxes, the federal government could choose not to defend it against attack.”<sup>14</sup> This constructed scarcity can also be observed with health goods, including pharmaceuticals, because such pharmaceuticals when patented can be excludable through limited production, regulatory barriers, and pricing – all of which economic and politics forces construct – but their benefit, whether in terms of good or improved health or reduction in infectious disease prevalence, are non-rivalrous.

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<sup>14</sup> Bodansky, “What’s in a Concept? Global Public Goods, International Law, and Legitimacy.” Page 653.

Though non-rivalry and non-excludability distinguish public goods from private goods, these same characteristics also complicate the role of markets in financing, producing, and/or allocating public goods. Both pure public goods and common pool resources are situations where the market cannot allocate resources efficiently. Markets tend to under-produce public goods relative to socially optimal; because of non-rivalry, nonstate actors usually cannot capture the full societal benefits of their production. State actors traditionally provide public goods, though neoliberal economic systems and their policies favor outsourcing.<sup>15</sup>

### 3.1.2 The Negative and Positive Externalities of Public Goods

In a critique of Samuelson's theory of public goods, Julius Margolis (1955) cited public education as an example of another essential nuance of excludability: externalities.<sup>16</sup> Externalities are the by-products of certain activities or actions, whether to the positive or the negative. An externality is present whenever the welfare of one actor or collective (e.g., the production capacity of a multinational manufacturer, the health of a community) are affected directly by the actions of another actor or collective in the economy – whether a state, multi-national corporation, other nonstate actor, or individual – and this interaction is not mediated by market forces, such as price. When an actor takes a particular course of action but does not bear all the costs, which directly affect or accrue to other actors, this is considered a negative externality; should the actor benefit, this is a positive externality.<sup>17</sup>

Public goods have large positive and negative externalities and diffuse benefits or harms unique as to “be thought of as special cases.”<sup>18, 19</sup> The education of a student in a school is a divisible

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<sup>15</sup> Smith and MacKellar, “Global Public Goods and the Global Health Agenda: Problems, Priorities and Potential.”

<sup>16</sup> Margolis, “A Comment on the Pure Theory of Public Expenditure.”

<sup>17</sup> Stiglitz, Economics.

<sup>18</sup> Kaul, Grunberg, and Stern, Global Public Goods: International Cooperation in the 21st Century.

<sup>19</sup> Cornes and Sandler, “The Simple Analytics of Pure Public Good Provision.”

benefit and, excludable, but the positive externalities of education to society are transferable and indivisible and, non-excludable. The education of women has positive externalities related to child health and survival and slowing population growth. Conversely, allowing trash to accumulate in oceans can harm global fisheries, the environment, and individuals, though neither a particular individual nor action may directly contribute to this accumulation.

The market is ill-suited to incorporate or account for externalities generated by specific goods and services. Pollution is an illustrative example, as Nolan Miller (2006) notes:

Suppose that a factory produces and sells tires. In the course of the production, smoke is produced, and everybody that lives in the neighborhood of the factory suffers because of it. The price consumers are willing to pay for tires is given by the benefit derived from using the tires. Hence at the market equilibrium, the marginal cost of producing a tire is equal to the marginal benefit of using the tire, but the market does not incorporate the additional cost of pollution imposed on those who live near the factory. Thus, from the social point of view, too many tires will be produced by the market.<sup>20</sup>

Health as a public good with positive and negative externalities is not dissimilar. Though individual components for individual or population health may be private goods (e.g., surgical equipment, syringes, over-the-counter pain relief medicine,) or even club goods operating under natural or artificial monopolies (e.g., patented pharmaceuticals, supply of a vaccine, health insurance), the positive and negative externalities of health to the society as a whole are transferable and indivisible, making the benefit (or harm) of the good non-excludable. All benefit from good individual or population health, just as all can be harmed by poor individual or population health.

Traditionally, microeconomic theory resolves the externality problem by imposing either quotas or taxes. While quotas impose a maximum or minimum amount of the externality-generating good that can be produced, taxes impose a cost of producing the externality on the good's producer.

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<sup>20</sup> Miller, Notes on Microeconomic Theory. Page 212.

The theory goes those positive taxes will decrease generation of negative externalities, while subsidies will promote the production of goods generating positive externalities. Under a marketized model of individual health, the problem of externalities would be solved by subsidizing ‘good’ health, including public health, primary and preventative care, and other determinants of wellness, and taxing or imposing quotas on sickness, potentially through higher costs of health care services or limits on access to such services.

If “health and wellness follow a social gradient: the lower the socioeconomic position, the worse the health,”<sup>21</sup> it is difficult to imagine how taxing the poor and limiting their access to health care would generate anything other than lower socioeconomic status and sickness, rather than motivate the production of good health. Some estimates attribute 10% to 20% of health outcomes to medical care, 30% to genetics, 40% to 50% to personal or individual behavior, and 20% to the social and physical environment. Individual behavior and the environment are often studied together as the non-medical determinants of health.<sup>22</sup> In studies that evaluated only modifiable determinants of health and ignored personal genetics, the non-medical factors accounted for 80% to 90% of a person’s health, and the contribution of medical care remains 10 to 20%.<sup>23</sup> Considering the realms of health personally modifiable and those that are not, and the significant grey between, the individualization of health, including of health-related risk via quotas, taxation, and other penalties – if intending to curb the individual production of negative health externalities – is mathematically doomed to fail.<sup>24</sup>

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<sup>21</sup> Commission on Social Determinants of Health and Organization, *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health*.

<sup>22</sup> Hood et al., “County Health Rankings: Relationships Between Determinant Factors and Health Outcomes.”

<sup>23</sup> Bradley et al., “Health and Social Services Expenditures: Associations with Health Outcomes.”

<sup>24</sup> Adler and Stewart, “Preface;” Hood et al., “County Health Rankings: Relationships Between Determinant Factors and Health Outcomes;” Bradley et al., “Health and Social Services Expenditures: Associations with Health Outcomes;” Commission on Social Determinants of Health and Organization, *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health*; Braveman and Gottlieb, “The Social Determinants of Health: It’s Time to Consider the Causes of the Causes.”



### 3.1.3 Positivism Meets Neoliberalism: Other Influences on Public Goods Theory

Though perfect examples of public goods ('pure' public goods) are rare, Musgrave's and Samuelson's characteristic properties of public goods (as non-rival and non-excludable) continue to serve as the foundation for contemporary public goods theory and underpin theoretical examination of issues of the global commons, global public goods, and new perspectives on public goods themselves. Musgrave's and Samuelson's definitions, however, are not neutrally contrived; contemporary public goods theory is rooted in (neoliberal) economic assumptions. Mid-century scholarship on public goods sought to establish an economic theory of public expenditures to optimize government intervention in markets, including if some optimization meant shifting the provision of public goods to the markets. Public goods, then and now, are regarded as peculiarities of suboptimal market conditions,<sup>25, 26</sup> contributors to shortfalls of collective action,<sup>27</sup> and "troublemakers" to be constrained or restricted.<sup>28</sup> Samuelson's normative model<sup>29</sup> for Pareto-optimal public expenditures is an example.<sup>30</sup> Even at the time, however, Samuelson himself was critiqued, by fellow economist Stephen Enke (1955), for generating a model that was inadequate, impractical, and ill-fitted to address issues not solely economic in nature.<sup>31</sup>

Samuelson responded both to his critics and his model's own limitation by acknowledging that "much expenditure on education, hospitals, and so on, can be justified by the feasibility

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<sup>25</sup> Little, *Ethics, Economics and Politics: Principles of Public Policy*.

<sup>26</sup> Tullock, Brady, and Seldon, *Government Failure: A Primer in Public Choice*.

<sup>27</sup> Olson, *The Logic of Collective Action*.

<sup>28</sup> Kallhoff, "Why Societies Need Public Goods."

<sup>29</sup> Normative economic models focus on the value of economic fairness or what the economy should be, whereas positive economic models are descriptive and explanatory of various economic phenomena and behavior.

<sup>30</sup> Pareto optimal allocation refers to the market acting acts to make sure that those who value goods the most receive them, and those that can produce goods at the least cost produce them, so that there is no way that everybody in society could be made better off. It is peak efficiency in the allocation and production of goods and services by the market. For an approachable discussion of this phenomenon and other aspects of microeconomic theory, see "Externalities and Public Goods," Chapter 8 (Pages 211-232) in Miller, *Notes on Microeconomic Theory*.

<sup>31</sup> Enke argued that not only are many goods provided through public expenditure divisible, in service to private ends, and, therefore, not public goods, but also that economic models have a responsibility to inform public policy rather than merely engage in the "elegant manipulation of highly abstract models." See Enke, "More on the Misuse of Mathematics in Economics: A Rejoinder."

consideration that, even if these are not 100% efficient in avoiding avoidable dead-weight loss, they may be better than the attainable imperfect tax alternatives.”<sup>32</sup> Samuelson would go on to express reservations for economic theory, on its own, to contribute to understandings of the optimal role of government versus the market in matters of public concern.<sup>33</sup> In less than a year, the leading author of contemporary public goods theory moved away from his own normative economic model of what optimally should be public expenditure to “a mixture of positive and normative conclusions arrived at from outside the model.”<sup>34</sup>

Musgrave’s descriptions of his own model and intent reflect the same inherent challenge as Samuelson: economics, on its own, cannot account for political processes (like public expenditures) or their ethical optimization. Like many theoretical frameworks and positivist analytical models, “the concept of public goods is an ideal type. Few, if any, goods are fully non-rivalrous and non-excludable.”<sup>35</sup> How can public goods theory evolve to account for these known weaknesses and limitations, while also proffering substantive, actionable insights for the very contemporary challenge of optimally distributing necessary though scarce (or limited) resources, like health?

### **3.2 Reexamining Public Goods: Critical Theory and Emerging Perspectives**

The potential answer rests in emerging scholarship by Angela Kallhoff (2014) and others that are critical of the beliefs and ideas foundational to mid-century public goods theory and apply fresh perspectives, including of social justice and global civil society, to inform a post-positivist evolution. Analyzing both Samuelson’s and Musgrave’s scholarship, Maxime Desmarais-Tremblay (2017) argues that Musgrave’s public goods theory intended to justify the role of the state, rather than seek market alternatives to it, in providing goods and services:

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<sup>32</sup> Samuelson, “Diagrammatic Exposition of a Theory of Public Expenditure.”

<sup>33</sup> Ibid.

<sup>34</sup> Hammond, “The Economist as Social Physician: Stigler’s Thesis Revisited.”

<sup>35</sup> Bodansky, “What’s in a Concept? Global Public Goods, International Law, and Legitimacy.” Page 653.

Musgrave's definition highlights his lifelong concern for a comprehensive, realistic, and useful normative theory of the public sector... Musgrave wanted to contribute to a better society by designing a normative model of the public economy that would help to elaborate rational public policies and facilitate public debate on the role of government in society. With growing public expenditures, the state became increasingly important in the lives of the citizens. In this context, upholding democracy required that public policies be framed in clear language, to which Musgrave contributed with his definition of social goods.<sup>36</sup>

The fathers of contemporary public goods theory themselves observed weakness in the premise that public goods must be substituted by private goods to prevent inefficiency and market failures. Such theories, however, have persisted in scholarship and, more important, in practice across the over seven decades since Samuelson and Musgrave first published. Alternative perspectives have emerged in recent years that introduce interdisciplinary approaches sought by Musgrave and Samuelson and build on the public goods as “special cases of externalities,” per Richard Cornes and Todd Sandler 1985).<sup>37</sup>

Two such perspectives must be examined closely: *first*, the reassessment of public goods in political philosophy through the lens of Critical Social Theory, whereby public goods can balance power asymmetries through social justice; and *second*, the recognition of GPGs as a necessity for social cohesion. It is important to introduce Critical Theory, Critical Social Theory, and Critical Discourse Analysis (CDA) as a means by which to examine contemporary *critical* perspectives on Public Goods Theory, the differentiation in concept and practice of public and private goods, and whether the practical of health governance reflects a misunderstanding of the public health literature.

### 3.2.1 A Brief Note on Critical Theory

Critical Theory, including Critical Social Theory and Critical Discourse Analysis (CDA),<sup>38</sup>

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<sup>36</sup> Desmarais-Tremblay, “Musgrave, Samuelson, and the Crystallization of the Standard Rationale for Public Goods.”

<sup>37</sup> Cornes and Sandler, “The Simple Analytics of Pure Public Good Provision.”

<sup>38</sup> Reynolds, “Building Theory From Media Ideology: Coding for Power in Journalistic Discourse.”

offer a unique lens through which to examine the dynamism of identity, power, and ideas in social relations, including of the politico-economic variety. Because this research intends to examine the role of power, actors, *and ideas* in the production, governance, and provision (making) of global health, it is essential to examine why and how the stories we tell ourselves, the beliefs and concepts that premise our awareness and consciousness, the values that form our interests, and the interests that underpin our preferences, motivations, and choices—or knowledge and ideas. Within International Relations and International Political Economy Constructivism offers a theoretical framework through which to explore the role of knowledge and ideas in systems of power relations (i.e., politics).

With its roots in Sociology, Constructivism asserts that knowledge and ideas (i.e., “intersubjective knowledge”<sup>39</sup> or consciousness, ideas,<sup>40</sup> and “knowledgeable agents”<sup>41</sup>) should be dependent variables in political analyses because they have mutually constitutive effects on systems and power relations. Knowledge and ideas have a dynamic, reciprocal relationship with social systems; change in world politics reflects changes in the accumulation of knowledge and dominance of certain ideas about the world. Whether analyzing social relations at the global or local levels, these interactions reflect a collection of “understandings, subjective knowledge[,] material objects,” structures, and processes that “*only acquire meaning for human action through the structure of shared knowledge* in which they are embedded” (emphasis added).<sup>42</sup> In this way, political interactions are ‘top-down’—the top being “social wholes and internal relations rather than individual[ actors].”<sup>43</sup>

Constructivism’s centering of knowledge and ideas in political analysis introduces factors of

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<sup>39</sup> Adler, “Constructivism and International Relations,” 96.

<sup>40</sup> As Emanuel Adler (2005 [2002]) explains, “interests are ideas; that is, they are ontologically intersubjective [knowledge] but epistemologically objective interpretations about, and for, the material world.” See op. cit., Adler, 102.

<sup>41</sup> Op. cit., Adler, 102.

<sup>42</sup> Wendt, “Constructing International Politics,” 73.

<sup>43</sup> Fearon and Wendt, “Rationalism v. Constructivism: A Skeptical View,” 58.

analysis (variables) that enrich our ability to examine and explain the social world. On their own, however, knowledge and ideas suggest neutrality and post hoc consequence (i.e., normative relevance, or values, only once applied through the processes and actions they inform). Conversely, Critical Theory assumes knowledge, ideas, and beliefs—collectively, discourse<sup>44</sup>—are normative and have a structuring influence on power itself and powerful (‘hegemonic’) actors<sup>45</sup> that is not dissimilar to the expectations of Realism and Neorealism, in particular.

Where Critical Theory distinguishes itself, however, is in its theoretical agenda, which orients the interrogation of the social practices, ideas, and norms that produce and reproduce power relationships normatively and toward issues of justice, equity, and fairness, per Ted Hopf (1998):

Unmasking these power relations is a large part of critical theory’s substantive agenda... Critical theory’s assumption that all social relations are instances of hierarchy, subordination, or domination ironically appears similar to the expectations of realists and neorealists about world. The different conceptualizations of power imply different theoretical agendas. Whereas conventional constructivism is aimed at the production of new knowledge and insights based on novel understandings, ‘critical theory’ analyzes social constraints and cultural understandings from a supreme human interest in enlightenment and emancipation.<sup>46</sup>

For critical theorists, *power* is “exercised in every social exchange, and there is always a dominant actor in that exchange,”<sup>47</sup> whether it is expressed as discourse, or narrative, or otherwise. This theoretical paradigm brings the normative back into the Constructivist conversation, into the scholarly examination of discourse’s role in systems of power. Here is where the critical perspectives introduced in the section begin: what control the narrative(s) surrounding public goods, and what

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<sup>44</sup> Per John S. Dryzek (2013 [1997]), discourse represents “a shared way of apprehending the world[]” through language that “enables those who subscribe to it to interpret bits of information and put them together into coherent stories or accounts[ which] construct meanings and relationships, helping define common sense and legitimate knowledge.”<sup>44</sup> Reflected in Dryzek’s definition is the essentiality of discourse to social relations, and systems of power in particular, defined by David Howarth (2010) as “representations and systems of meaning”

<sup>45</sup> For Critical Theorists, power is “exercised in every social exchange, and there is always a dominant actor in that exchange.” See Hopf, “The Promise of Constructivism in International Relations Theory,” 185.

<sup>46</sup> Howarth, “Power, Discourse, and Policy: Articulating a Hegemony Approach to Critical Policy Studies”

<sup>47</sup> Hopf, “The Promise of Constructivism in International Relations Theory,” 185.

ideas are they responding to, reflecting, and embedding or diminishing? And what does this mean for the processes and actors relating to public and private goods—perhaps those actors involving the global and national policymaking on health, for example?

A theoretical combination of Constructivism and Critical Theory, Critical Constructivism is etymologically oriented to examine these types of questions: the didactic, interactive, historical- and system-based social questions rooted in and reflecting back systems of power relations that often are unevenly constituted. Specifically, Critical Constructivism considers the inherent nature (ontology) of actors to be “an artefact of a continual process of reproduction that performatively constitutes its identity”<sup>48</sup> in relation to the “social constraints and cultural understandings” that create and reproduce social relations systems of “hierarchy, subordination, or domination,” despite a “supreme human interest in enlightenment and emancipation.”

By interrogating the ideas, knowledge, and beliefs, but also social practices and norms, that produce and reproduce power relationships normatively, the issues of justice, equity, and fairness can be examined within the *context* of the world as it is, not as an ideal à la Musgrave or Samuelson.<sup>49</sup> In these ways critical theorems like CDA, Critical Social Theory, and Critical Constructivism acknowledge “the prevailing social and power relationships... as the given framework for action,” and engage in modes of analysis that reflect the “inseparable unity between [the] normative and analytical.”<sup>50</sup>

### 3.2.2 Political Perspectives: The Social Justice Value of Public Goods

Through the application of Critical Social Theory and ethical and political philosophical

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<sup>48</sup> Campbell, “Cultural Governance and Pictorial Resistance: Reflections on the Imaging of War,” 57–58.

<sup>49</sup> Ira Shor (1992) defines Critical Constructivism as the “habits of thought, reading, writing, and speaking which go beneath surface meaning, first impressions, dominant myths, official pronouncements, traditional clichés, received wisdom, and mere opinions,” which are explored so as “to understand the deep meaning, root causes, social context, ideology, and personal consequences of any action, event, object, process, organization, experience, text, subject matter, policy, mass media, or discourse.” See Shor, *Empowering Education: Critical Teaching for Social Change*, 129–30.

<sup>50</sup> Rexhepi and Torres, “Reimagining Critical Theory,” 697–98.

frameworks, Angela Kallhoff (2014) finds that public goods have a “double face,” referring to the *social normative construction* of public goods as either “troublemakers” to be restricted or “an essential ingredient in democracies,” though the latter is far less common and further less well articulated.<sup>51</sup> Kallhoff further distinguishes public goods from private goods based on the former’s inherent *normative value*—finding that public goods support “the values of a well-ordered society,” inclusive of ‘democratic’ values of fairness, justice, equity, civic engagement, and social cohesion.<sup>52</sup> To Kallhoff, public goods are better suited than private goods “to support civic patterns of exchange” because, by their non-excludable and non-rival nature, they reduce or eliminate barriers to entry and engender conditions favorable to civil society and social justice.<sup>53</sup>

Specifically, public goods may impart *three positive externalities* that “contribute to social inclusion” (as *solidarity goods*), “support the generation of the public” (as *connectivity goods*), and “strengthen a shared sense of citizenship” (as *identification goods*).<sup>54</sup> Specifically, solidarity goods are public goods that strengthen social inclusion and promote social justice particularly through immediate anti-segregational and community-building effects.<sup>55</sup> For example, Kallhoff notes solidarity goods may include goods that once were exclusive, like a segregated public school, and were “transformed into a public good.” Kallhoff also notes the transformation of a private street to a public road. Solidarity goods, in this way, represent a social commitment to the shared good, whether by means of public finance or other way to ensure the “burdens of provision have also been shared.”<sup>56</sup>

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<sup>51</sup> Kallhoff, “Why Societies Need Public Goods.”

<sup>52</sup> Kallhoff notes that “even though most agree that the sustenance of some public goods is part of the noblest endeavors of the nation-state, many authors also agree that the range needs to be restricted . . . to some core functions of the nation-state because public goods are particularly costly and need support through tax policies and because normative ideas about the freedom and liberties of citizens.” See Kallhoff, *Why Democracy Needs Public Goods*.

<sup>53</sup> *Ibid.*, Page 648.

<sup>54</sup> *Ibid.*, Page 636.

<sup>55</sup> *Ibid.*, Pages 640-641.

<sup>56</sup> *Ibid.*, Page 641.

Public goods that are connectivity goods create a “shared realm” or equitable public forum necessary for mutual awareness, understanding, conflict mitigation, and collaboration across civil society, what Kallhoff describes as “realms of intersecting activity.”<sup>57</sup> Examples of public goods as connectivity goods include public spaces, national and state parks, print media, the Internet, and other goods that promote or facilitate a system or space of connectivity. The final of Kallhoff’s three positive externalities are identification goods, which are public goods that help generate and sustain the idea of the common good and foster a sense of self-identification with a larger community of equal citizenship. Such goods encourage substituting questions of fairness (i.e., is it fair, is it good for the general public) in place of efficiency (i.e., is it efficient).

In *Ill Fares the Land* (2010), historian Tony Judt articulated the dangers associated with the post-modern interpretation of public goods: rather than “simply assum[ing] that there were public goods and goals for which the market was just not suited,” as dominated the sociopolitical construct of public goods in the post-war era (and its high public expenditures), the late 20th and early 21st century have redefined public goods based solely on a particular good’s economic properties:

If we had to identify just one general consequence of the intellectual shift that marked the last third of the 20th century, it would surely be the worship of the private sector and, in particular, the cult of privatization. Some might say that the enthusiasm for dispensing with publicly owned goods was purely pragmatic. Why privatize? Because, in an age of budgetary constraints, privatization appears to save money.<sup>58</sup>

As identification goods, public goods are non-rivalrous and non-excludable, but also may serve as “visual representations of collective identity,”<sup>59</sup> of a society’s shared interests and values, which “used to matter a lot,” according to Judt.<sup>60</sup> Because identification goods are public goods that

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<sup>57</sup> Ibid., Page 642.

<sup>58</sup> Judt, *Ill Fares the Land*. Page 107

<sup>59</sup> Judt. Page 123.

<sup>60</sup> Ibid., Page 62



contribute to the interest of citizens, their construction as a public good may conflict with the interests of other groups (e.g., special interest groups, nonstate actors, multi-national corporations) about that good or the merits of another good's public construction. This can be problematic when such idea construction is within a postwar consensus that vacillates between "praiseworthy private freedoms and irritating public constraints."<sup>61</sup>

Using health as an example, it is possible to draw an analogy to health as an identification good, as health may be interpreted, understood, and civically advanced as a 'public good' or 'human right' by a particular group of interested citizens, but that claim may be countered by other citizens with contrary interests or interests advancing other goods' status as public goods. If there is limited policy space through which to make these decisions and also limited public resources to make real these decisions, interest group-driven identification goods may create significant politico-economic and social tensions.

Considering public goods through the lens of social justice and political cohesion, definitions and their application (or interpretation) matter. If health, for example, is considered a public good, it may be theorized as within the purview of public expenditure. If public goods are interpreted as peculiarities or an aberration of market norms to be corrected, they may be privatized, depoliticized, and commodified, as has been the case with health and health care. To the contrary, however, were public goods to be interpreted pursuant to their sociopolitical *and* economic value, a workable framework for Samuelson's "optimum *optimorum*" ("efficiency inclusive of equity") may yet be achievable.<sup>62</sup> Specifically, valuing and valorizing the positive externalities such goods generate for civil society, including their ability to contribute to social inclusion, generate the social construct of

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<sup>61</sup> Ibid., Page 91.

<sup>62</sup> Samuelson, "Aspects of Public Expenditure Theories." Page 338. See also Samuelson, "The Pure Theory of Public Expenditures." Page 387.

the Public, and create a shared sense of citizenship). Could such a framework, however, apply to GPGs for health?<sup>63</sup>

### 3.2.3 Global Perspectives: Public Goods as Necessary for Social Cohesion

A further complication of contemporary public goods theory is that public goods are not exclusive to domestic processes and social needs, where mature systems of public finance and expenditure can govern and address both their challenges and opportunities. While many public goods are inherently global, such as greenhouse gas emissions and population health, modern politico-economic processes associated with globalization have only furthered interconnections and interdependence across the globe, increasing the demand for GPGs in response to global social needs.<sup>64</sup>

The literature on GPGs and globalization features a range of definitions. For example, a public good may be a GPG if humanity determines it to be and agrees to collectively provide for it.<sup>65</sup> Other literature reinforces the contemporary definition of public goods, defining GPGs as global goods that are non-excludable and non-rival in consumption.<sup>66</sup> Variations on this more technical definition of GPG similarly begin with the Musgrave-Samuelson construct before turning to a qualification of global: GPGs are “marked by universality,” or the benefits are available to all of humanity, whether countries, population groups, or current and future generations.<sup>67</sup>

Global public goods often are not goods in the standard sense, but outcomes, rules, or systems relevant to the good’s place or role in the production chain. Global public goods can be final, which refers explicitly to global public goods that are outcomes; such outcomes can be tangible

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<sup>63</sup> As discussed in detail in the next section, GPGs are public goods for which the benefits are available to all of humanity, whether countries, population groups, or current and future generations. See Kaul, Grunberg, and Stern, *Global Public Goods: International Cooperation in the 21st Century*.

<sup>64</sup> *Op. cit.*, Kaul, Grunberg, and Stern.

<sup>65</sup> *Ibid.*

<sup>66</sup> Moon, Rottingen, and Frenk, “Global Public Goods for Health: Weaknesses and Opportunities in the Global Health System.”

<sup>67</sup> Page 2-3 and 11 in *op. cit.*, Kaul, Grunberg, and Stern, *Global Public Goods: International Cooperation in the 21st Century*.

(e.g., air quality, healthy environmental resource, or the common heritage of mankind) or intangible (peace or financial stability).<sup>68</sup> Global public goods also can be intermediate, referring to a set of rules, norms, standards of operating, decision-making processes, or other structure or system that contributes towards the provision of final global public goods (e.g., international regime). Just as public goods are not always this or that, so, too, are GPGs, which can arise from a mixture of public and private inputs and have qualities that span the spectrum of processes to outcomes.

Like other public goods, GPGs generate externalities, create incentives to free ride, discourage collective action, and, often, require governance (often public) to provide or guarantee. While GPGs impart similar characteristics and challenges as public goods, their global scale magnifies their inherent ethical and governance questions, and potential for social value. At its most simplistic, GPGs can “make people everywhere better off” and, alike some public goods, advance social justice.<sup>69</sup> Their absence also may generate significant negative externalities.

The trajectory of global social needs and GPGs aligns naturally with that of globalization itself. However, literature examining these interconnected phenomena have been far more disparate. As Inge Kaul, Isabelle Grunberg, and Marc A. Stern (1999) note, “while there is a rapidly growing literature on the globalization of economic activity and its implications for public policy, not much attention has been paid to the notion of global public goods.”<sup>70</sup> The global perspective on public goods has expanded significantly since the 1990s to account for a range of global issues and challenges that well define the present. While the literature has advanced since Kaul et al.’s assessment, the “growing recognition that societies need” GPGs in order to protect or promote particular priorities has not necessarily engendered the robust array of interdisciplinary and practical

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<sup>68</sup> Barrett, *Why Cooperate?: The Incentive to Supply Global Public Goods*.

<sup>69</sup> Page 648 in *op. cit.*, Kaul, Grunberg, and Stern, *Global Public Goods: International Cooperation in the 21st Century*.

<sup>70</sup> *Ibid.*, Page 2.

theorizing a challenge of this scale warrants.

By introducing ethical, political, and global perspectives, the public goods literature has become far more responsive to the fundamental question that Musgrave, Samuelson, and others sought to answer: how best to allocate limited public resources? Nevertheless, the question remains and the tension between ethics (a socio-political construct) and efficiency (an economic construct) persists. Public goods theory in practice remains embedded in mid-century liberal economics, tying the fate of public goods to their approximation to the market. There is no other public good, global or otherwise, for which this tension is most evident as global public goods for health (GPG-H).

### 3.3 Global Public Goods for Health

In “Medicines as Global Public Goods” (2008), Suerie Moon describes the 20th century rediscovery of *artemisinin*, a treatment for malaria that had become treatment-resistant in southeast Asia, as the transformation of private knowledge into a global public good, or GPG, for health, commonly called GPG-H:

Around the 4th century A.D., the Chinese physician Ge Hong recorded these instructions for curing intermittent fevers in his guidebook, *Emergency Prescriptions Kept Up One’s Sleeves*: ‘Qinghao: one bunch, take two shengs of water for soaking it, wring it out, take the juice, ingest it in its entirety.’ Sixteen centuries later during the Vietnam war, this simple text led Chinese government-sponsored researchers to identify artemisinin as a potent drug to treat malaria... Today, artemisinin-based combination therapies have become the gold-standard treatment and strongest line of defense against the malaria parasite’s uncanny ability to develop resistance to new drugs.<sup>71</sup>

Moon’s example provides a helpful narrative for imagining a GPG and a GPG-H in particular.

While other examples of GPGs commonly include nuclear nonproliferation (e.g., Non-Proliferation Treaty (1970), international environmental agreements (e.g., Vienna Convention for the Protection of the Ozone Layer (1985), Montreal Protocol on Substances that Deplete the Ozone Layer (1987),

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<sup>71</sup> Moon, “Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health.”

Geneva Convention on Long-Range Transboundary Air Pollution (1979)), and global maritime rules (e.g., Safety of Life at Seas (SOLAS) Convention (1974 [1914]); International Convention for the Prevention of Pollution from Ships (MARPOL) (1983 [1973]); Standards of Training, Certification, and Watchkeeping for Seafarers (STCW) (1978))—examples that spillover into the related realms of governance and the global commons—neater examples of GPGs, however, often center more acutely on questions of health, though the international legal regimes touch on issues adjacent to health and generally considered part of ‘public health’ or ‘global health.’<sup>72</sup>

Take, for example, the collective investment in vaccines or global standards to curb the overuse of antibiotics, which could preserve or prolong the efficacy of antibiotics for all.<sup>73</sup> It is tidier to construct a narrative akin to the Global Commons for the non-excludable and non-rivalrous value of antibiotic efficacy, herd immunity against communicable disease, community response and preparedness for health challenges (whether infectious or noncommunicable), and open access medical research and interventions—as Moon’s example of Ge Hong and artemisinin evokes. Other examples health include “norms and rules, standards and guidelines, research on the causes and treatments of disease, and comparative evidence” (Table 3.3-A and Table 3.3-B).<sup>74</sup>

Reflecting on the World Bank’s post-Ebola pandemic commitment, announced in May 2016, to providing a financial mechanism to support global pandemic preparedness, Felix Stein and Devi Sridhar (2017) suggest “creating a market for pandemic risk” is a global public good for health and an opportunity for international financial institutions to be active in global health governance.<sup>75</sup> Similarly, collective investment in vaccines and diagnostics (for infectious disease), “global rules to

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<sup>72</sup> Lincoln C. Chen, Tim G. Evans, and Richard A. Cash, “Health as a Public Good,” in Kaul, Grunberg, and Stern, *Global Public Goods: International Cooperation in the 21st Century*.

<sup>73</sup> See, for example, Moon, “Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health”; Balasegaram et al., “A Global Biomedical R&D Fund and Mechanism for Innovations of Public Health Importance.”

<sup>74</sup> Op. cit., Moon, “Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health.” Pages 196-197.

<sup>75</sup> Stein and Sridhar, “Health as a ‘Global Public Good’: Creating a Market for Pandemic Risk.”

**Table 3.3-A. Traits and examples of global public goods for health**

<u>Excludability</u>	<u>Rivalry in Consumption</u>	
	Non-rivalrous	Rivalrous
Non-excludable	Pure public goods <ul style="list-style-type: none"> <li>• Herd immunity (to infectious disease)</li> <li>• Open access medical research</li> <li>• Pandemic preparedness</li> </ul>	Common-pool resources (aka, the “tragedy of the commons”) <ul style="list-style-type: none"> <li>• Efficacy of antibiotics</li> <li>• Universal health care, where applicable</li> </ul>
Excludable	Club goods and monopolies (the “tragedy of artificial scarcity”) <ul style="list-style-type: none"> <li>• IP rights for medical devices</li> <li>• Health insurance, where applicable</li> </ul>	Private goods <ul style="list-style-type: none"> <li>• Hospital services</li> <li>• Patented vaccines</li> <li>• Syringes</li> </ul>

Author-generated and compiled examples.

curb the overuse of antibiotics,”<sup>76</sup> and “governance regimes for new product development,”<sup>77</sup> referring to pharmaceuticals, also represent opportunities for GPGs for health that may strengthen global health through collective action, investment, and decision-making.

A shared aspect of both public goods theory and the collective action problem is under-provision; this is no less the case for GPG-Hs. The rational is straightforward: state actors – acting rationally and in response to other near-term domestic political interests – may be unwilling or unable to provide such goods unilaterally or in concert, particularly, if it should detract from meeting a state’s domestic political or security needs. Covid-19 is a relevant example. Political Scientist Mancur Olson’s *The Logic of Collective Action* (1965) was the first to apply contemporary public goods

<sup>76</sup> Op. cit., Moon, Röttingen, and Frenk, “Global Public Goods for Health: Weaknesses and Opportunities in the Global Health System.” Page 197.

<sup>77</sup> Op. cit., Moon, “Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health.” Page 198.

**Table 3.3-B. Global public goods for health and their accompanying national or****international regime<sup>78</sup>**

<u>Category</u>	<u>Examples of GPGs for Health</u>	<u>Related National and Global Policies, Institutions, Rules, Legal Instruments, Standards, or Other Regime</u>
Research and Assessment	Health technology assessment	<ul style="list-style-type: none"> <li>• National Institute for Health and Care Excellence (NICE) (U.K.)</li> <li>• Institute for Comparative Effectiveness Research (ICER) (U.S.)</li> </ul>
	Pharmaceutical approval and post-marketing surveillance	International coordinating and information-sharing bodies for national and regional Ras (e.g., Australia-Canada-Singapore-Switzerland Consortium (ACSS) and International Generic Drug Regulators Program (IGDRP))
	Pharmaceutical approval and post-marketing surveillance, Continued	National pharmaceutical regulatory authorities (RAs) (e.g., FDA and EMA)
	Pharmaceutical and/or medical device research and development	Agreement on Trade-Related Aspects of Intellectual Property Protection (TRIPS), 1994 (WTO)
	Product development partnerships for ‘neglected’ diseases <sup>79</sup>	<ul style="list-style-type: none"> <li>• Drugs for Neglected Diseases initiative (DNDi)</li> <li>• Global Alliance for Vaccines and Immunization (GAVI), Medicines for Malaria Venture, and TB Alliance</li> </ul>
	Product quality assessment	Prequalification of Medicines Program, 2001 (WHO)
	Sharing of knowledge on practices or policies	International regulatory coordinating and information-sharing bodies (e.g., ACSS, IGDRP)

<sup>78</sup> This table has been informed by the works of Moon et al. (2017) and Labonté and Torgerson (2003). See Moon, Røttingen, and Frenk, “Global Public Goods for Health: Weaknesses and Opportunities in the Global Health System,” Table 2. See also ; Labonté and Torgerson, “Frameworks for Analyzing the Links Between Globalization and Health,” 31.

<sup>79</sup> Hoogstraaten, Boon, and Frenken, “How Product Development Partnerships Support Hybrid Collaborations Dealing with Global Health Challenges,” 191.

**Table 3.3-B, Continued**

Category	Examples of GPGs for Health	Related National and Global Policies, Institutions, Rules, Legal Instruments, Standards, or Other Regime
Normative Functions	‘Mobilizing solidarity’ to address acute health care crises	International Health Regulations (IHR), 2005 (WHO)
	Food safety in international trade	Agreement on the Application of Sanitary and Phytosanitary Measures (SPM), 1994 (WTO)
	Standards development	International Statistical Classification of Diseases and Related Health Problems (ICD), 2019 [1893] (WHO [International Statistical Institute]) <sup>80</sup>
	Workplace safety and health	International Labor Organization Convention, C155 on Occupational Safety and Health (1979)
	Access to public health and health care services	International Covenant on Economic, Social, and Cultural Rights (1966)
Managing Externalities	Early warning systems for natural disasters	<ul style="list-style-type: none"> <li>• International Consortium on Landslides (ICL)</li> <li>• Tsunami Warning Systems</li> <li>• International Platform on Earthquake Early Warning Systems (IP-EEWS)</li> <li>• Improving Resilience to Emergencies through Advanced Cyber Technologies(I-REACT)</li> </ul> <p>Note: Each is a United Nations Educational, Scientific, and Cultural Organization (UNESCO) project.<sup>81</sup></p>
	Collective purchasing of public health supplies	Covid-19 Vaccines Global Access (COVAX) Facility
	Infectious disease surveillance	Electronic state Parties Self-Assessment Annual Reporting Tool (e-SPAR) (WHO)
	Management of infectious disease pandemic risk	<ul style="list-style-type: none"> <li>• IHR, 2005 (WHO)</li> <li>• Index for Risk Management (WHO)</li> </ul>

<sup>80</sup> World Health Organization, “International Statistical Classification of Diseases and Related Health Problems (ICD-11).”

<sup>81</sup> United Nations, “Disaster Risk Reduction: Early Warning Systems for Geohazard Risk Reduction.”



**Table 3.3-B, Continued**

Category	Examples of GPGs for Health	Related National and Global Policies, Institutions, Rules, Legal Instruments, Standards, or Other Regime
Managing Externalities, Continued	‘Mobilizing solidarity’ to address acute health care crises	International Health Regulations (IHR), 2005 (WHO)
	Antimicrobial resistance	Political Declaration of the High-Level Meeting on Antimicrobial Resistance, 2015 (UN) <sup>82</sup>
	International flow of narcotic drugs and other illicit substances	Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988) (UN)

Author compiled and generated examples based on research, including sources referenced within the table.

theory beyond the bounds of Economics; first to Political Science and, later, IPE.<sup>83</sup>

Through an individual level-of-analysis, Olson’s application holds that whatever happens in the social world, including in the global political economy, can be explained by individual choices. For example, the actions of a state can be explained by the choices of individuals (e.g., the state’s representative bureaucrats and politicians), who are rational and self-interested; they want to make themselves better off. When applied to the global political economy, the theory suggests that – when individuals act in a rational and self-interested way – the overall result or outcome for states and/or economic systems will be the best possible.

Olson argues that collective action on public goods, for example, may be impaired by the impact of free-riding effects and diffuse incentives for participation. Rational individuals may not have an incentive to join or participate in large, voluntary associations if they can benefit from the

<sup>82</sup> United Nations, “Press Release: High-Level Meeting on Antimicrobial Resistance.”

<sup>83</sup> Op. cit., Olson, *The Logic of Collective Action*.

public goods (or GPGs for health) without having to incur the costs of membership.<sup>84</sup> A central tenet of Olson's approach to rationality concerns the objectives pursued by individuals:

The only requirement is that the behavior of individuals in large groups or organizations of the kind considered should generally be rational, in the sense that their objectives, whether selfish or unselfish, should be pursued by means that are efficient and effective for achieving these objectives.<sup>85</sup>

If compelling incentives are not established or the free-rider problem otherwise curbed, the result is diminished collective action or inaction even when common interests exist within a collective.

Smaller collectives – or 'minority interests' – face comparatively lower costs for collective action and potentially higher gains, driving a concentration and overrepresentation of minority interests.

### **3.4 Looking Beyond Positivist Models and Market-based Assumptions**

Akin to the ethical, social justice, and political rationale articulating the merit of investing in mechanisms for the collective governance, investment, provision, and/or protection of public goods and other GPGs, there are deeply compelling rationale for global cooperation on GPGs for health. While mechanisms for the provision of public goods and select other GPGs (e.g., maritime security, trade imbalances) have more mature mechanisms at the national and global levels through which to structure policymaking around their provision, GPGs for health may be nonexistent, scarce, or remain private or club goods due to the far more limited maturity and powerfulness of global health governance structures.

Considering Olson's argument that larger collectives face a host of challenges and reiterating Judt's argument there has been a practical sea-change in global perception of public goods (i.e., market goods are better), it is possible to theorize that global cooperation on health and on GPGs for health has been elusive because of the strength of minority interests – whether motivated by

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<sup>84</sup> Pages 58-59 in Olson.

<sup>85</sup> Ibid., Page 65.

economic priorities or non-health interests – and the weaknesses of global social interests. Returning to Judt (2010), if we consider this tension within the context of the overlaying politico-economic structure of globalization and neoliberalism, the absence of globally governed goods (for health) is “purely pragmatic.”<sup>86</sup> In a global age of economic contraction and budgetary constraints, privatization not only “appears to save money” but also grows the international political economy.<sup>87</sup>

The absence of meaningful global health governance frameworks to facilitate GPGs for health also is a product of the continued depoliticization, individualization, and commodification of health around the globe. This depoliticization and commodification of health runs counter to ‘majority interests’ in the advancement of a substantive global governance framework for health, health equity, and other global health priorities. As examined in Chapter 6, particularly, Chapters 6.1 and 6.4.3, the examples of hepatitis C (hepC) and Covid-19 may demonstrate that global collective inaction on health is illogical in terms of global health goals and values, but expressly rational in terms of the privileging of certain actors and these actors’ interests (i.e., the advancement of global capitalism).

To understand the challenges and opportunities for collective action on health, and a strengthened GPG-H or global governance for health framework, examine the motivations, interests, and incentives driving the actors that establish hegemonic ideas, global health norms, policies, and outcomes. GPGs-H suffer from the same collective action problem as public goods and all other GPGs—a problem that has far more to do with traditional political questions (of power and interest) than of economics.<sup>88</sup> Even at their most optimal, markets are ill suited to address political questions, just as they are constrained in their ability to sort through the thorny

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<sup>86</sup> Page 107 in Judt, *Ill Fares the Land*.

<sup>87</sup> *Ibid.*

<sup>88</sup> Jamison, Frenk, and Knaul, “International Collective Action in Health: Objectives, Functions, and Rationale.”

ethics of providing public goods. The differential concentrations of, or disparities in, access to pharmaceuticals, whether a curative treatment or preventative vaccine, show the negative and positive externalities associated with the absence of meaningful institutions for collective action on GPGs-H. So, too, do they illustrate well the same inherent challenge first observed by Musgrave and Samuelson: economics, on its own, cannot account for political processes (e.g., distribution of limited or scarce health resources) or their ethical and equitable, and efficient, optimization. Musgrave and Samuelson understood the reality within which their models would apply was fraught with political and social dynamics that could not be quantified.<sup>89</sup>

Within Samuelson's original model he included a social welfare function, which assumed questions pertaining to economic fairness and ethical allocation of public resources were to be resolved *a priori* to economic considerations. As Economist Nina Banks (2021) notes in her description of the normative economists of Sadie T. M. Alexander:

I think one of the wrong turns is there is too much reliance on mathematics and economics has become concerned with solving mathematical problems rather than solving economic problems. Sadie Alexander focused on the big questions, the big economic problems and issues that were facing African Americans and, I think, facing the nation in general.<sup>90</sup>

Akin to Samuelson, Musgrave, and Kallhoff, Alexander saw the normative potential of economics, including and especially related to questions of social conditions and public goods. The practical implications are two-fold. *First*, it implies that economics is dependent on ethics, which themselves are dependent on politically determined, socially constructed, often diverse, and potentially

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<sup>89</sup> To Samuelson's credit, he acknowledges this inherent limitation: "economics cannot deduce a social welfare function; what it can do is neutrally interpret any arbitrarily specified welfare function." See Samuelson, "Diagrammatic Exposition of a Theory of Public Expenditure."

<sup>90</sup> As interviewed by White, "How Sadie Alexander Became America's First Black Economist." Banks is the author of *Democracy, Race, and Justice: The Speeches and Writings of Sadie T. M. Alexander* (2021) about the economics theory, research, and thought-leadership of the first Black economist in the U.S., Sadie Tanner Mossell Alexander.

contradictory “ethical views.”<sup>91</sup> *Second*, it admits that “laissez-faire reliance on markets and voluntary exchange public finance both lead to sub-optimal outcomes by not getting the community to the ethically best point on the utility frontier.”<sup>92</sup> Though Samuelson sought to achieve public expenditures that were “efficiency inclusive of equity,” he himself acknowledged it was impossible within purely economic frameworks. And that brings the discussion of GPGs-H squarely from one of economic preference to power.

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<sup>91</sup> Samuelson, “The Pure Theory of Public Expenditures.” Page 387.

<sup>92</sup> Hammond, “The Economist as Social Physician: Stigler’s Thesis Revisited.” Page 4.

## CHAPTER 4

### THE LAW OF SUPPLY AND DEMAND AND THE BEHAVIOR OF MARKETS: REVIEW OF THE MACROECONOMICS LITERATURE

“Health care is different from other goods and services: the health care product is ill-defined, the outcome of care is uncertain, large segments of the industry are dominated by nonprofit providers, and payments are made by third parties such as the government and private insurers. Many of these factors are present in other industries as well, but in no other industry are they all present. It is the interaction of these factors that tends to make health care unique.”

—Michael A. Morrissey (1993)<sup>1</sup>

“We are in a science and technology race for the future. It is with science and technology that we address things like Covid [-19] and the biggest challenges the world has. The health of our economy, our security, which is key to all of the above.”

— Massachusetts Institute of Technology President Rafael Reif (2021)<sup>23</sup>

Rolling like waves, political attention to health care ebbs and flows. Published during consideration of the Health Security Act — former President Bill Clinton’s (U.S.) health reform proposal<sup>4</sup> — a 1994 *Health Care Finance Review* article by Kathleen Gondek describes pharmaceutical policy as “an area that has become increasingly important.”<sup>5</sup> Gondek then articulates concerns for pricing, access, and spending from the 1960s, 1970s, and 1980s within the U.S., Canada, and Germany. A decade after the unsuccessful Health Security Act, U.S. public concern for the affordability of medicines was renewed and resulted in the 2003 enactment of a new public health

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<sup>1</sup> Morrissey, “Health Care Industry,” in Henderson, Ed., *The Fortune Encyclopedia of Economics*.

<sup>2</sup> Ryssdal, “Major Scientific and Technological Investments Sought to Better Compete against China.”

<sup>3</sup> Ryssdal.

<sup>4</sup> The Health Security Act would have established a prescription drug benefit for older Americans a decade before President Clinton’s successor, President George W. Bush, would propose the Medicare Prescription Drug Program (‘Part D’), which ultimately was enacted. See Congress (U.S.), Medicare Prescription Drug, Improvement, and Modernization Act.

<sup>5</sup> Gondek, “Prescription Drug Payment Policy: Past, Present, and Future.”

insurance program specific to pharmaceuticals, the Medicare Prescription Drug, Improvement, and Modernization Act, which established the Medicare Prescription Drug Program (Medicare Part D).<sup>6</sup> Fast forward 15 years and testing various cost-control mechanisms in multiple countries,<sup>7</sup> and a “chorus of concern over the cost of prescription drugs... has been growing louder” again.<sup>8</sup>

This chapter explores the politico-economic context of global and national pharmaceutical spending, including trends in spending, use, and pipeline composition for developed (“advanced”) and emerging (“pharmerging”) economies alike (Chapter 4.1). Current trends help to articulate the scale, scope, and breadth of this important tri-part global-local phenomenon of reliance on pharmaceuticals to achieve global health goals; high prices and higher barriers to access medicines; and politico-economic challenge of reducing unaffordable spending while expanding individual access to health care.

Because pharmaceutical use and spending trend lines are complex and shifting meaningfully, we also discuss the composition of the pharmaceutical pipeline and, for advanced economies, the near-term projection that pharmaceutical spending will surpass spending on hospital services, which is the leading and largest segment of global health expenditures (Chapter 4.2). The chapter concludes with a discussion of the special economics of health, including how health, when constructed as a market, often deviates from standard theories of how markets work (or should work), which is important as actors and political systems wrestle with questions of funding, distribution, and provision, including market-based mechanisms. Pharmaceuticals, which are further ‘deviant’ from the standard expectations of how markets should work, are specifically discussed (Chapter 4.3).

These trend lines, however, do not exist in isolation. They also represent expressly difficult

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<sup>6</sup> Congress (U.S.), Medicare Prescription Drug, Improvement, and Modernization Act.

<sup>7</sup> Busse and Schlette, “Chapter 8: Drug Policies and Pricing”

<sup>8</sup> Wilensky, “A New Focus on Prescription Drug Spending”

political questions, particularly, as state actors dominate the global payor landscape for pharmaceuticals and, themselves, face competing political priorities. In “The Complicated Domestic Politics of Biomedicine” (Chapter 4.4), we explore the intersectionality of health, politics, and economics, with decision-making in one policy space that then generates externalities in other spaces—a tension true for advanced and emerging economies as they balance access and spending. Each dollar spent (on pharmaceuticals) represents an investment in the global-local health system through opportunities for improved health at the individual, meso and macro levels, investment in positive externalities. That same dollar, however, represents an absence of investment elsewhere: in public or private spending in another area of human need, such as education, food, or housing, or non-essential goods (e.g., travel and recreation) with global economic benefit. Similarly, the absence of such a dollar spent on health care and pharmaceuticals – whether because a medicine is overpriced (i.e., excess cost) or otherwise unaffordable, or a health care system cannot facilitate access because of other public expenditure priorities – can generate negative externalities, including absence of preventative, primary, or chronic care, which itself generates global-local losses through poorer health and increased disease prevalence.

The trend lines and complexity of a market not behaving like a market, layered with domestic regulation, made essential to the global market, are compounding, but this layered complexity is not an academic exercise, but one of practical consequences. As explored in Chapter 3, they also represent expressly difficult political questions, particularly, as state actors are simultaneously encouraged and discouraged from political action that incentivizes the growth of a market that, in some ways, state and Society can ill afford.

#### **4.1 High and Rising Spending on Health Care and Medicines**

In most Organization for Economic Cooperation and Development (OECD) Member Countries, more than 70% of health care spending, including spending on pharmaceuticals, is



funded by public sources, whether governmental transfers to national health service-type financing schemes (e.g., Denmark, Norway, the United Kingdom (U.K.); a mix of social insurance contributions from employers and government transfers (Japan); or employer and individual premium payments funded — and tax exempted — through private sources of insurance (e.g., Germany, Switzerland, the United States of America (U.S.)).<sup>9</sup> Though the schema of government financing of health care range across this funding-model spectrum, what is consistent is the significance as a share of total government expenditure and growth of private and public funding of health care, including pharmaceuticals.

Pharmaceutical significance and market share do not discriminate based on health system funding model, or whether health care is deemed by the state to be a human right through universal health coverage (UHC). The decision to structure a national health system in terms of public versus private financing reflects interaction of the same norms and beliefs that frame medical practice and health as a public good that has been marketized. This subchapter discusses the fiscal and budgetary trends associated with pharmaceutical spending, noting that such financing model decisions are not associated with higher or lower net use of pharmaceuticals, more or less efficient use, higher or lower levels of spending, maximized or minimized politico-economic prominence of the pharmaceutical industry, or other trends identified in this research.

#### 4.1.1 National Health Care Spending Outpaces Economic Growth

For 2017, public funding of health and medicines accounted for 15% of total government expenditures across OECD countries, with higher shares of 20% or greater in Germany, Ireland, and New Zealand and shares of 23% in Japan and the U.S.<sup>10</sup> This share as a percentage of government expenditures has increased by 14% since 2005, “reflecting the fact that health plays an

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<sup>9</sup> Organization for Economic Co-operation and Development, “Public Funding of Health Care.”

<sup>10</sup> Ibid., Organization for Economic Co-operation and Development.

increasingly important role in government budgets” (Figure 4.1-A).<sup>11</sup> Updated projections of public health spending by the International Monetary Fund (IMF) present an increasingly difficult outlook for advanced and emerging economies.<sup>12</sup> The 2012 model projects public health spending in developed economies will grow by an average of 3 percentage points of gross domestic product (GDP) by 2030, with scenarios ranging from 2.1 to 4.1 percentage points.<sup>13</sup> For emerging economies, the IMF projected average increases of 1 percentage point of GDP.<sup>14</sup>

In Europe, spending is also expected to rise by 2 percentage points of GDP, with spending rising by more than 3 percentage points in seven European countries. The baseline projections of the European Commission, however, anticipated public spending on health to rise by only three-quarters of 1 percentage point of GDP—based largely on assumptions of low excess cost growth, which heretofore have not panned out. The IMF’s own findings agreed with those of the CBO: future public health spending increases will be driven by excess cost growth associated with pharmaceuticals.<sup>15</sup>

These projections are in line with the U.S. government’s long-term outlook. Per the Congressional Budget Office’s (CBO, 2020), which conducts budget and economic analysis on behalf of the U.S. Congress, seminal annual report on U.S. federal government deficits, debt, spending, and revenues, U.S. public spending on health is projected to nearly double between 2019 and 2050: from 5.9% to 10.7% of GDP (Figure 4.1-B).<sup>16</sup> Of this, 3.1 percentage points were contributable to population aging and 3.4 percentage points to excess cost growth.

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<sup>11</sup> Op. cit., Kay and Williams, *Global Health Governance: Crisis, Institutions and Political Economy*. Page 3.

<sup>12</sup> Mauricio Soto, Baoping Shang, and David Coady, “New Projections of Public Health Spending, 2010-50.” Chapter 3 of Clements, Coady, and Gupta, *The Economics of Public Health Care Reform in Advanced and Emerging Economies*.

<sup>13</sup> Op. cit., Clements, Coady, and Gupta. Appendix Table 3.3, Page 50.

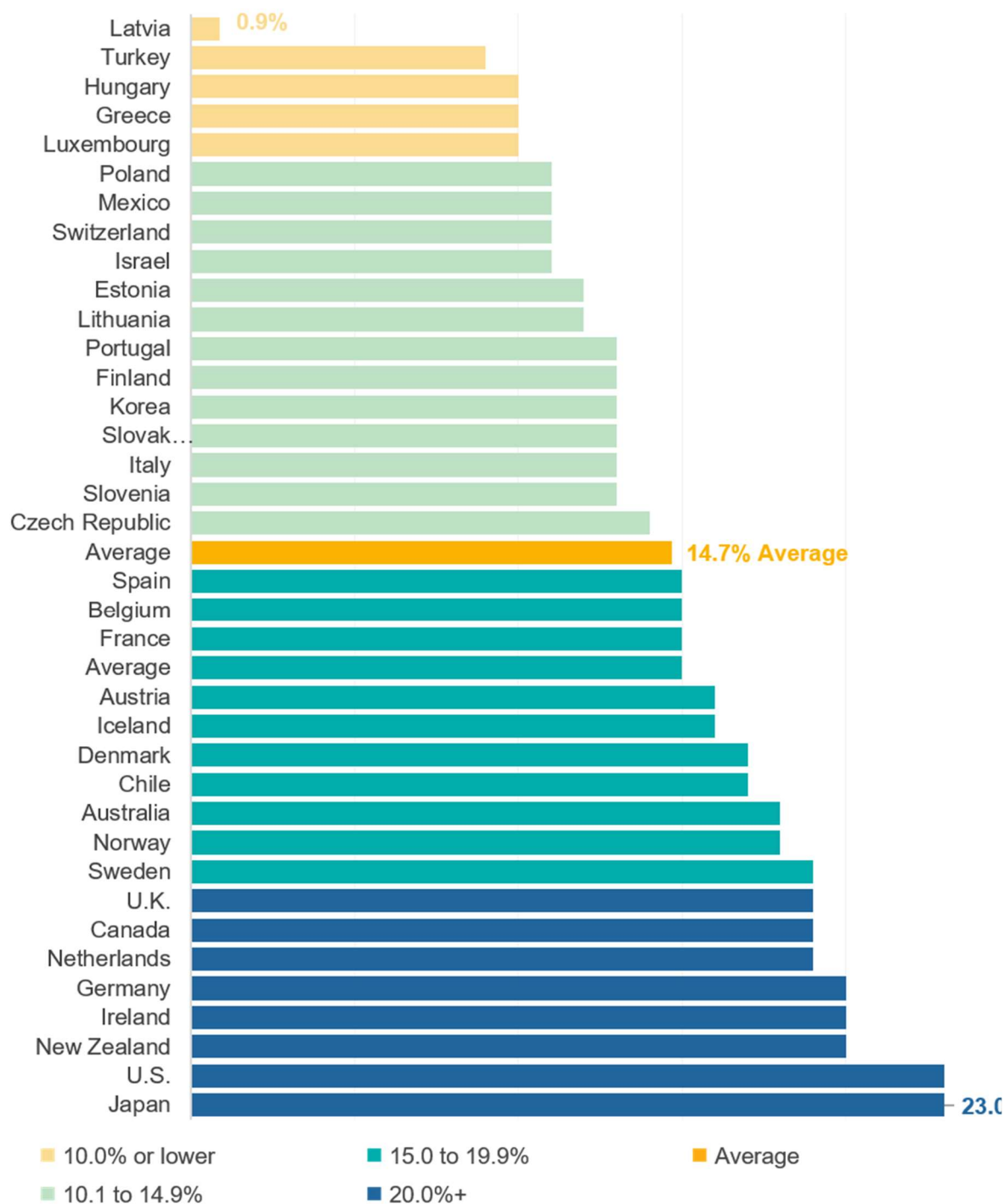
<sup>14</sup> Ibid., Clements, Coady, and Gupta. Page 51.

<sup>15</sup> Op. cit., Clements, Coady, and Gupta. Pages 37-38 and 51.

<sup>16</sup> We do not focus on the projected increases in Social Security spending, though the CBO chart includes these figures. For more information, see Congressional Budget Office (U.S.), “The 2020 Long-Term Budget Outlook.”

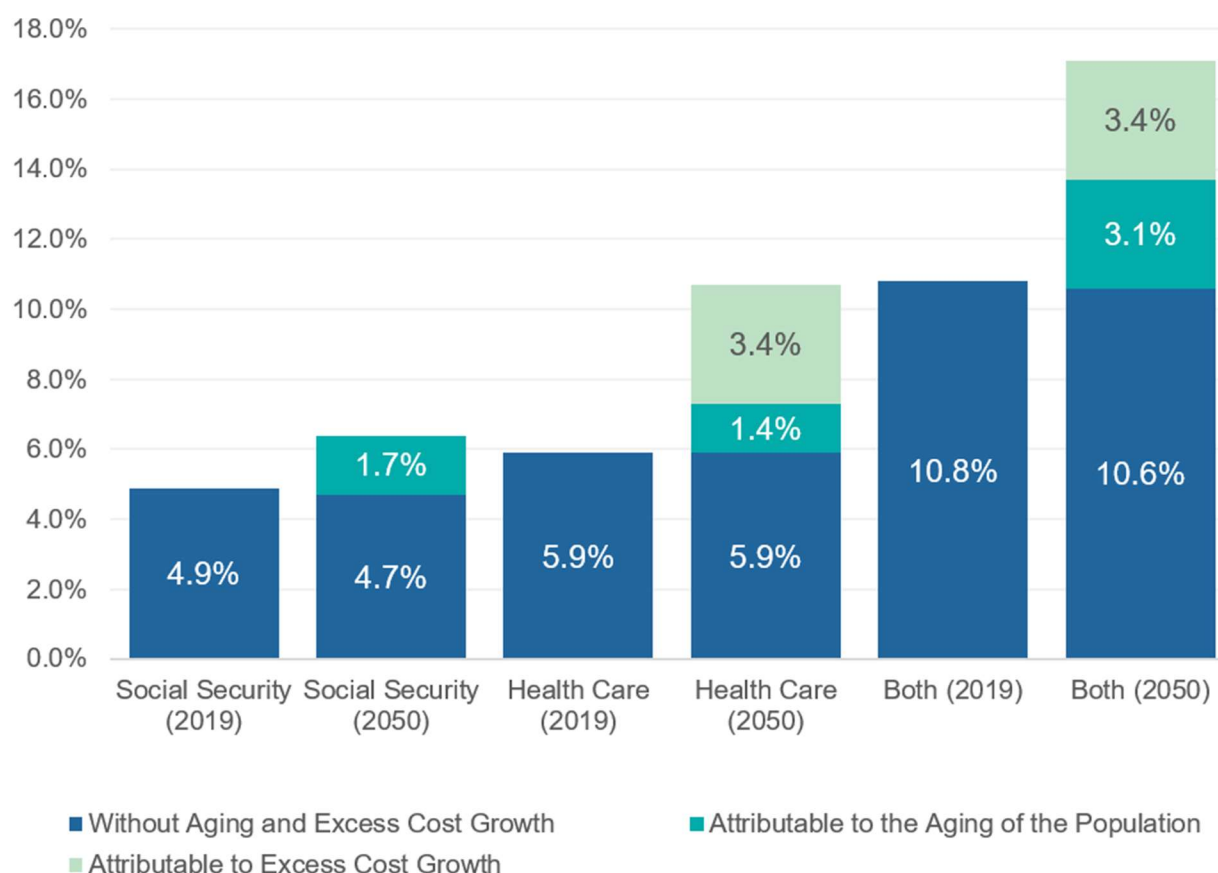
Figure 4.1-A. Health expenditures from public sources, share of total government

expenditures, 2017 or latest available



States with health care systems that rely on the private firms and individual payment, notably Japan and the U.S., have the highest levels of public expenditure on health. These figures do not include the value of tax-exempted benefits. Author-estimated average. Author-generated image based on data courtesy of OECD, "Public Funding of Health Care."

**Figure 4.1-B. U.S. spending on social insurance and public health care programs, Share of GDP (2019 actual and ≈2050)**



The role of excess cost growth versus other causes of growth in spending, such as population aging, is pronounced in the U.S., where public health spending is expected to increase by 5.1 percentage points of GDP (range of 3.9 to 6.4 percentage points) — the highest of the developed economies. Author-generated image based on data courtesy of Congressional Budget Office (U.S.), “The 2020 Long-Term Budget Outlook.” Pages 3 and 32.

#### 4.1.2 “It is hard to find a government that is not struggling with the high prices of medicines”<sup>17</sup>

Between 2014 and 2019, pharmaceutical spending grew from 777 to 955 billion USD—a 23% jump in five years.<sup>18</sup> The IQVIA Institute, formerly Quintiles and IMS Health, Inc., estimates this figure will exceed 1.6 trillion USD in 2025<sup>19</sup>—an increase of 67% and 500 billion USD from the prior year’s projection of 1.1 trillion USD by 2024. The global pharmaceutical market will grow by 3% to 6% compound annual growth rate (CAGR) over the next five years (Figure 4.1-C).<sup>20</sup>

Advanced economies have experienced slightly steadier CAGRs, of 4.8% and 3.8%, in net market size for the 2010-15 and 2016-20 periods, respectively, with five-year forward outlooks of between 2% and 5% (2021-25).<sup>21</sup> Emerging economies have seen the greatest historical growth driven by access expansion, including 11.7% and 7.4% for the same periods, and are forecast to experience still high CAGRs of 7% to 10% to 10% through 2025.<sup>22</sup> Lower income economies have dramatically lower access to pharmaceuticals than either advanced or emerging economies, and access has been declining for the past five years, potentially putting prior health improvements at risk. Reflecting more of the same, pharmaceutical spending trends in lower income economies are forecasted at 3% to 6% CAGRs for the five-year outlook, which roughly reflects the range of the prior decade: 6% and 3.9% for the 2010-15 and 2016-20 periods, respectively.<sup>23</sup>

In emerging economies, pharmaceutical use and spending growth are being led by China, the second largest global pharmaceutical market behind the U.S. In China, the IQVIA Institute (2021) estimates that use of new and original pharmaceuticals, also called brand drugs and biologics, will accelerate following the Covid-19 pandemic which, overall, has driven foregone and deferred care

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<sup>17</sup> (Staff), “The Global Battle over High Drug Prices.”

<sup>18</sup> Kleinrock and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2024.”

<sup>19</sup> Aitken, Kleinrock, and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2025.”

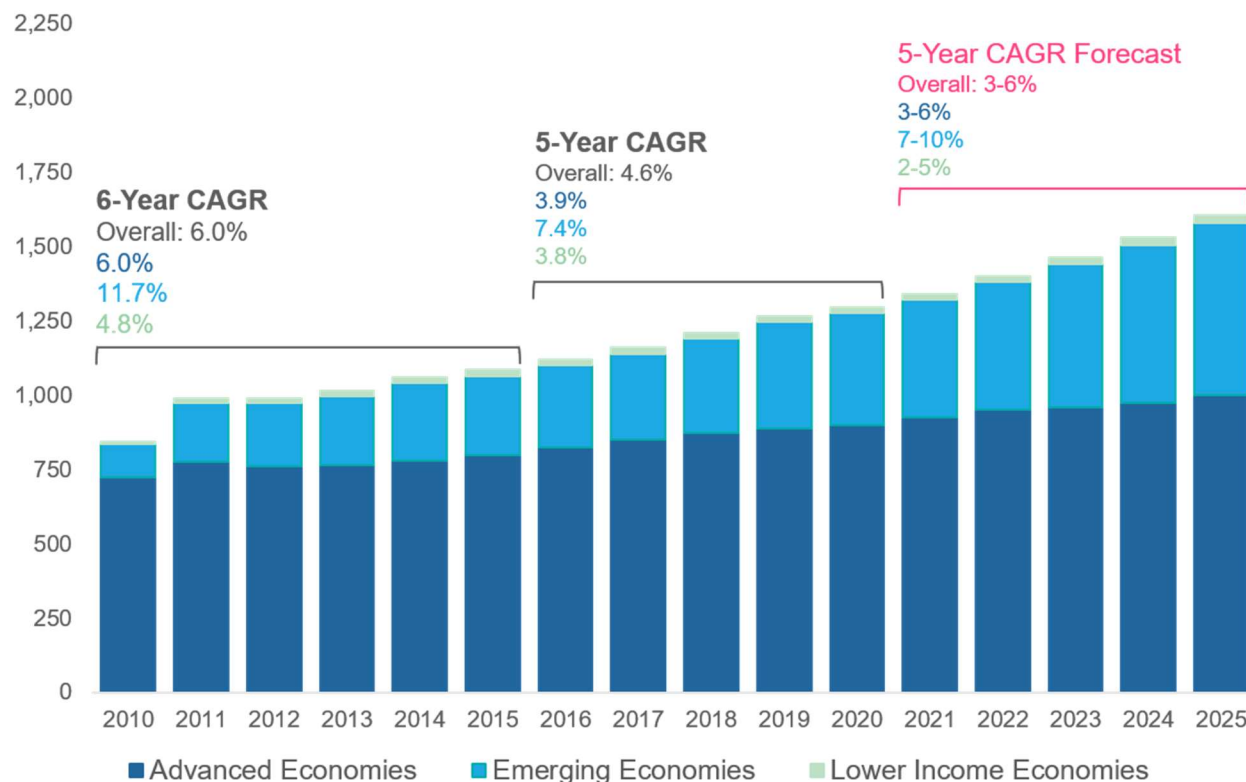
<sup>20</sup> Op. cit., Aitken, Kleinrock, and Munoz.

<sup>21</sup> Ibid., Aitken, Kleinrock, and Munoz. Exhibit 17.

<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

**Figure 4.1-C. Global pharmaceutical market growth, CAGR ( $\approx$ 2010-2025)**



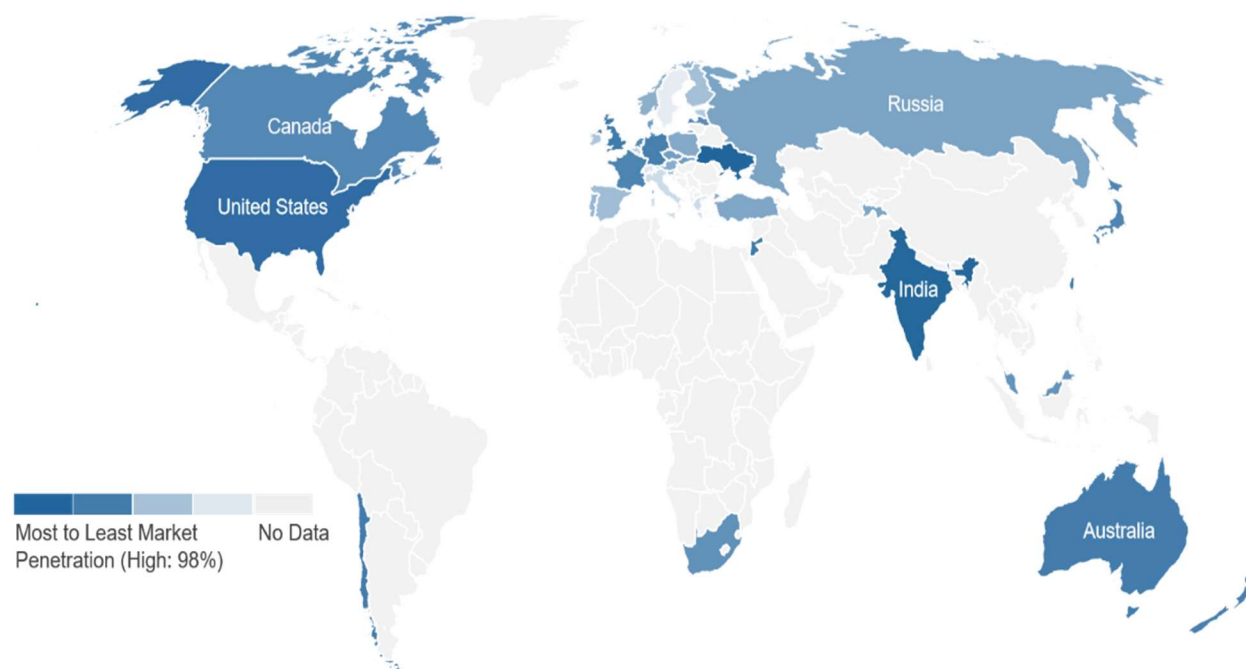
Does not include estimates for Covid-19 vaccines. Spending in billions USD with variable exchange rates. CAGR reflects USD for second quarter 2020 exchange rates. Lower income is low or lower middle income based on the World Bank income bands but excluding emerging economies with higher national incomes and are shown separately. Aitken, Kleinrock, and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2025,” Exhibit 17.

trends due to fears of contracting the virus in medical settings.<sup>24</sup> Among advanced economies, the trends also vary. In the U.S., the market is forecast to grow up to 3% CAGR over the next five years, whereas in Japan, the third largest global pharmaceutical market, flat-to-declining spending is expected “as a result of the continued biennial price cut policy” mandated by the Japanese government.<sup>25</sup> Conversely, in Europe pharmaceutical spending is expected to increase between 2%

<sup>24</sup> WillisTowersWatson, “The up and down Impact of the Pandemic on Health Care Costs.”

<sup>25</sup> Op. cit., Aitken, Kleinrock, and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2025.”

**Figure 4.1-D. Market penetration of generic and biosimilar medicines, 2020 or latest available**



Author compiled from various data sources for market penetration by volume. All data from 2019 except Japan (2020); Australia, Belgium, Czech Republic, Finland, Russia, Slovak Republic, Taiwan, Tajikistan, Turkey, and Ukraine (2018); Austria, Chile, Denmark, Germany, Greece, Ireland, Luxembourg, Netherlands, New Zealand, Slovenia, Spain, and the U.K. (2017); France (2016); and Poland and Sweden (2013). See OECD, “Health at a Glance 2019;” Statista, “Volume Share of Generics in Select Prescription Drug Markets;” Smart Pharma, “The French Generics Market;” IGBA, “The Positive Impact That Generic and Biosimilar Medicines Have on Patients and Health Systems;” and Wouters, Kanavos, and McKee, “Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending.”

and 5% CAGR, or more than \$35 billion, through 2025.<sup>26</sup> Overall growth in global pharmaceutical spending is expected to be driven by emerging economies and offset by slower spending growth in advanced and lower income economies. Though slower growing, metrics associated with the dispensing of medicines at retail pharmacies suggest that pharmaceutical use is disproportionately

<sup>26</sup> Op. cit., Aitken, Kleinrock, and Munoz.

high in advanced economies.<sup>27</sup>

Intended to offset this high use, political and fiscal decision-makers project slowing rates of spending growth in developed economies based on future lower unit prices (versus declines in volume) derived from therapeutic competition, like generics and biosimilars (Figure 4.1-D).<sup>28</sup> IQVIA cites “competition from generics” as one of three “main factors influencing medicine spending and growth,” with specific emphasis for “contributing to historically slow market growth” in China, Japan, Europe, and the U.S.<sup>29</sup> Though global estimates of generic medicines’ market share in volume are not reported consistently by the OECD or WHO, the International Generic and Biosimilar Medicines Association estimates 2020 year-end rates as high as 97% (India) and as low as 60% (Malaysia).<sup>30</sup> While these are reasonable expectations, actual versus estimated reductions in total spending rely on the assumption that future pharmaceutical use will reflect the present, or that generic volume (use) will continue to grow in absolute terms offset by price deflation.

Should the pharmaceutical market composition shift toward slightly higher use of branded products and biologics, which are exceedingly more expensive, or generic pricing increase (because of drug shortages or generic manufacturer exists), the positive effect of generic spending and use growth will be muted. This also is possible if generic volume increases, all other trends equal, as IQVIA has noted for emerging and lower income economies.<sup>31</sup> National pharmaceutical policies

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<sup>27</sup> Defined daily doses (DDD) are used as a standard for the measurement of pharmaceutical use and exposure in a population. The WHO defines the DDD as the assumed average maintenance dose per day for a drug used for its main indication in adults. See World Health Organization, “2021 Guidelines for ATC Classification and DDD Assignment, 24th Ed.” For a discussion of other measures of pharmaceutical use, including prescribed daily dose (PDD) and whether the standard should differ dependent on the class of drug, see Grimmsmann and Himmel, “Discrepancies between Prescribed and Defined Daily Doses: A Matter of Patients or Drug Classes?”

<sup>28</sup> Therapeutic competition refers to the following: as IP patent and/or market exclusivity protections expire for currently used and very high-cost pharmaceuticals (called loss of exclusivity, or LOE), lower-cost competitive therapeutics come to market, driving overall drug costs down.

<sup>29</sup> Pages 2, 21, 24-26, and 28 in Aitken, Kleinrock, and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2025.”

<sup>30</sup> Generics includes non-original branded products, so-called ‘authorized’ or ‘branded’ generics (i.e., generics manufactured and marketed by their originator or a licensed partner), as well as biosimilars, which are, in essence, the ‘generic’ to a reference biological product. See International Generic and Biosimilar Medicines Association, “The Positive Impact That Generic and Biosimilar Medicines Have on Patients and Health Systems.”

<sup>31</sup> Page 32 in Aitken, Kleinrock, and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2025.”



that encourage generics and biosimilars for off-patent medicines will, therefore, be more or less effective depending on the actual composition of the pharmaceutical development pipeline and the within-market pharmaceutical use and spending composition. Take, for example, the potential impact of newly launched innovative products, including cell and gene therapies, like 2.1 million USD Zolgensma. It is possible to imagine scenarios where such products' even marginal use would outweigh the deflationary impact of competition-driven policies.

To place these large figures into perspective, retail pharmaceutical spending, meaning the pharmaceuticals bought by a patient at a pharmacy, represents between 6 cents (Denmark) and 35 cents (Bulgaria) of every dollar spent on health care; all other OECD countries fall within this range. In Austria, Belgium, Canada, France, Germany, the Netherlands, Sweden, Switzerland, and the U.K., a recent OECD analysis found 16 cents of every public health care dollar was spent on pharmaceuticals.<sup>32</sup> Projections of the pharmaceutical share of U.S. national health expenditures corroborate these global ranges, suggesting the U.S. spends approximately 14% of its total health care dollar on medicines.<sup>33</sup> Within the context of overall economic activity, retail pharmaceutical spending is as much as 2.6% of GDP (Bulgaria) for OECD member and membership-seeking countries (Figure 4.1-E).

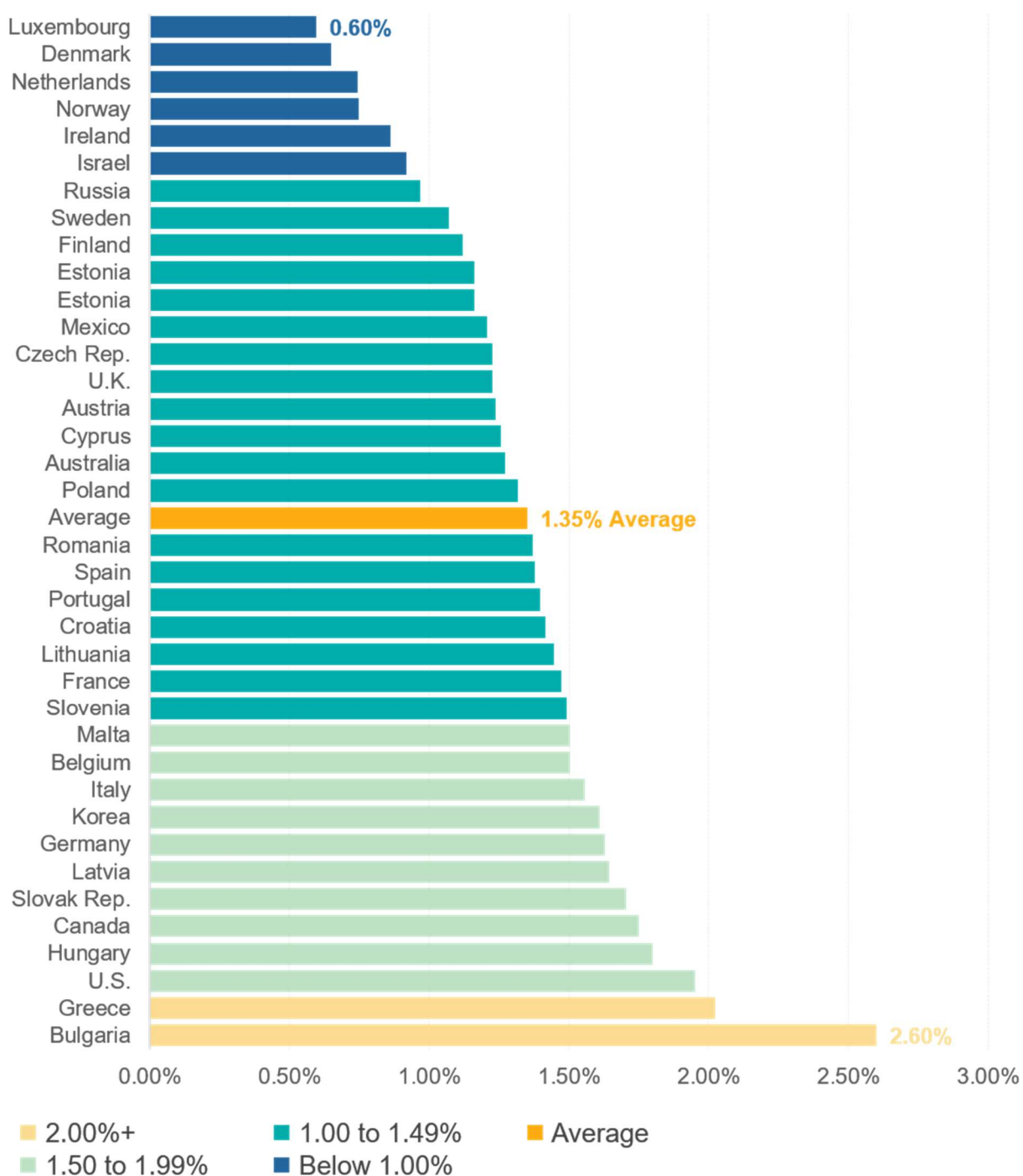
Recall the cost of NCDs like diabetes. Health care costs related to diabetes in China are estimated to be 2.6% of Chinese GDP. Considering that the standard first-line treatment for most NCDs, diabetes and high blood pressure included, rely on pharmaceuticals, the growing global and within-country prevalence of NCDs will only further the significant and rising share of overall economic activity that pharmaceuticals comprise ('drug-makers'). From the patient perspective, estimates (Figure 4.1-F) suggest per capita retail pharmaceutical spending is climbing.

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<sup>32</sup> Kurani and Cox, "What Drives Health Spending in the U.S. Compared to Other Countries?"

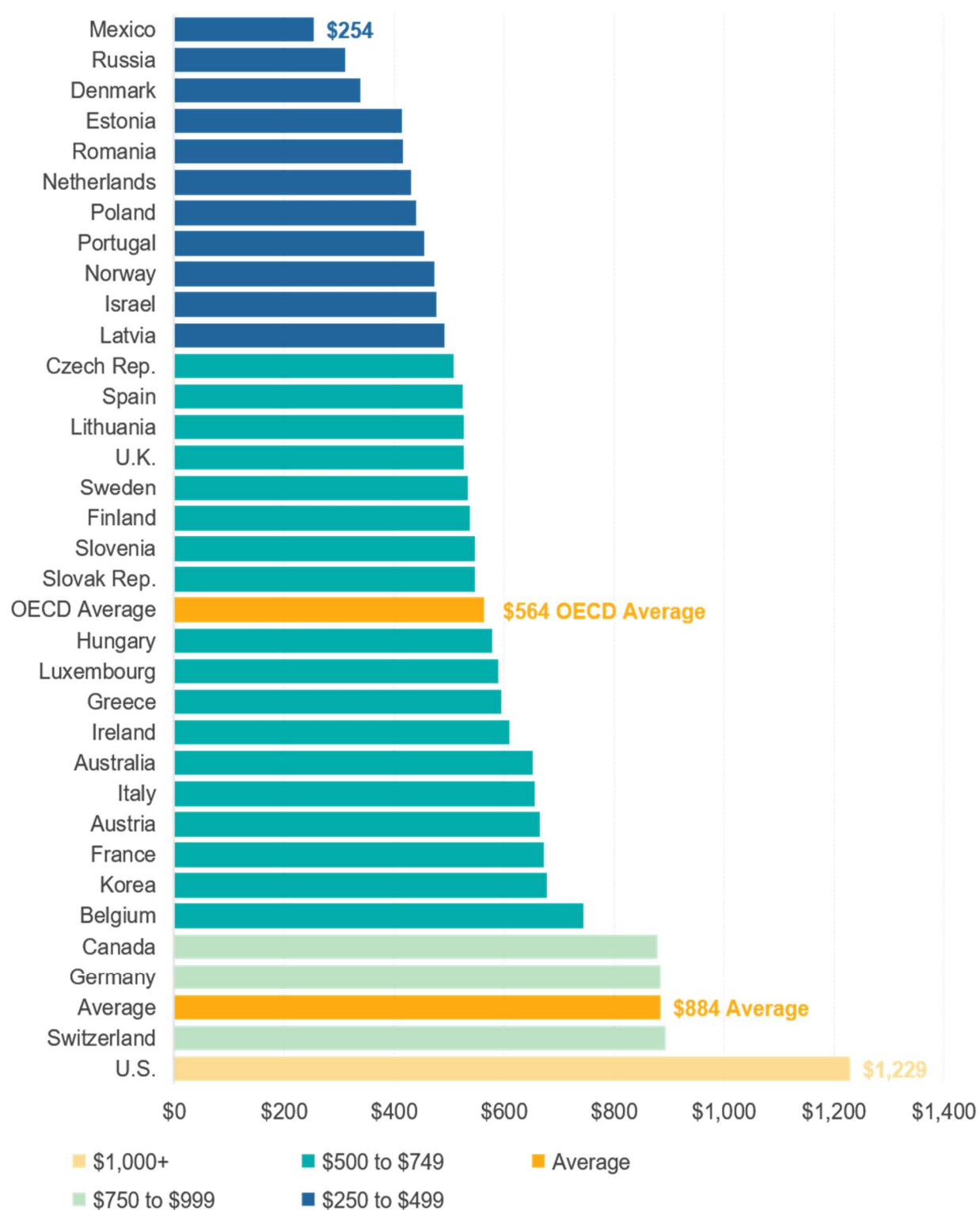
<sup>33</sup> Roehrig and Turner, "Projections of the Non-Retail Prescription Drug Share of National Health Expenditures."

**Figure 4.1-E. Total retail pharmaceutical spending, Share of GDP (2019 or latest available)**



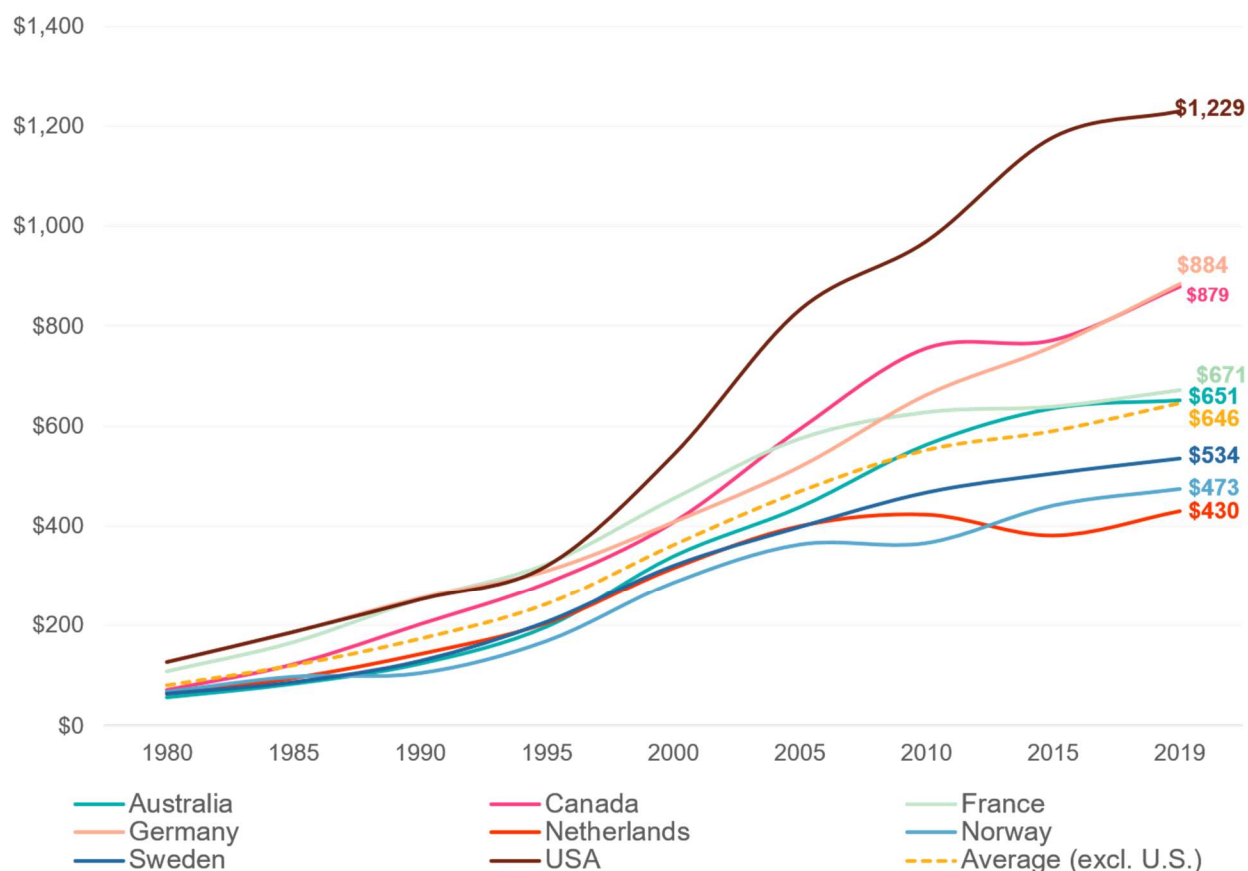
Total pharmaceutical spending estimates often exclude physician-administered medicines, which are included in hospital spending figures. For more accurate future spending trends, such accountings should either clarify this exclusion or else incorporate this growing segment of pharmaceuticals in official totals. Author-generated image based on data from OECD, "Pharmaceutical Spending (Indicator), Total, % of GDP, 2019 or Latest Available."

Figure 4.1-F. Retail pharmaceutical spending, USD per capita (2019 or latest available)



Author-generated image based on data from Rae, Kamal, and Cox, "Who Is Most Likely to Have High Prescription Drug Costs?"

**Figure 4.1-G. National trends in per capita pharmaceutical spending, Percent change (1980-2019, latest available)**



Author-generated image based on data from Rae, Kamal, and Cox.

For some, per capita spending is far greater (Figure 4.1-G). Approximately 10% of Americans accessing health insurance through their employer have average annual out-of-pocket (OOP) costs exceeding 2,000 USD; for 4% of Americans, costs exceeded 5,000 USD; and, for a select 2%, costs exceeded 10,000 USD.<sup>34</sup> Though the U.S. is a clear outlier in this respect, with per capita retail pharmaceutical spending approximately 37% higher than that of the second highest

<sup>34</sup> Rae, Kamal, and Cox, "Who Is Most Likely to Have High Prescription Drug Costs?"

spending country (Switzerland, 894 USD), per capita spending trends over time are dramatic: excluding the U.S., per capita retail pharmaceutical spending has increased 79% since 2000 and 718% since 1980.

## 4.2 The Future of Medicine: Fewer Hospital Stays, but Higher Costs Elsewhere

While hospitals continue to account for the largest share of total health spending, particularly, in advanced economies, that sector is dwarfed by the pace of pharmaceutical innovation in advanced economies. An estimated 4.6 billion prescriptions were filled in the U.S.<sup>35</sup> and projected to grow at a 3% to 6% CAGR through 2025, which is faster than that projected for the global economy over the same period.<sup>36</sup> Emerging economies' higher CAGRs are driven by expanded access to pharmaceuticals, as compared to expanded access and excess cost growth in economies with already high per capita pharmaceutical use and spending (Figures 4.2-A and 4.2-B).

Compared to the global pharmaceutical market, the global hospital services market, which is heavily concentrated in North America, is projected to grow at an 8.2% CAGR between 2020 and 2027.<sup>37</sup> Hospital services may reflect an overcount as this category often includes inpatient pharmaceutical spending. Conversely, pharmaceutical services may reflect an undercount of actual and total pharmaceutical spending, and potentially meaningfully so, as common calculations exclude pharmaceuticals administered in the hospital or a doctor's office—often referred to as 'inpatient' drug. Take, for example, remarks by *NBER Today* Contributor Marie Bussing-Burks (2001) on the opportunity to shift away from hospital services spending to prescription drug spending, which yields “reduc[tions in] the total cost of treatment”:

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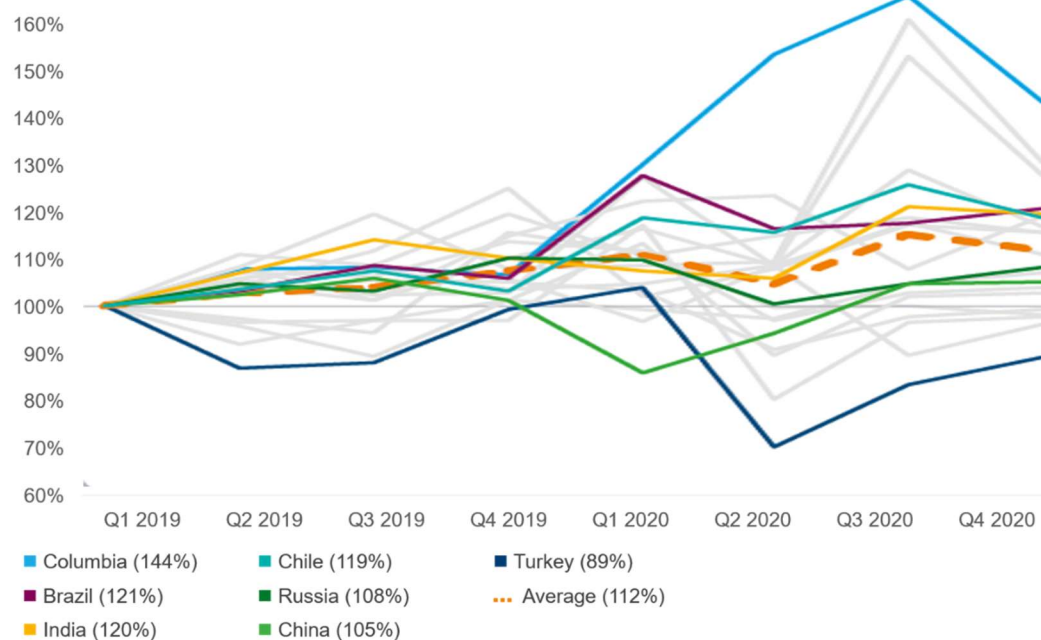
<sup>35</sup> Op. cit., Aitken et al., “The Global Use of Medicine in 2019 and Outlook to 2023.” Page 5 and Exhibit 1.

<sup>36</sup> The IMF projects the global economy will grow 5.5% in 2021 and 4.2% in 2021. See International Monetary Fund, “World Economic Outlook Update, January 2021: Policy Support and Vaccines Expected to Lift Activity.”

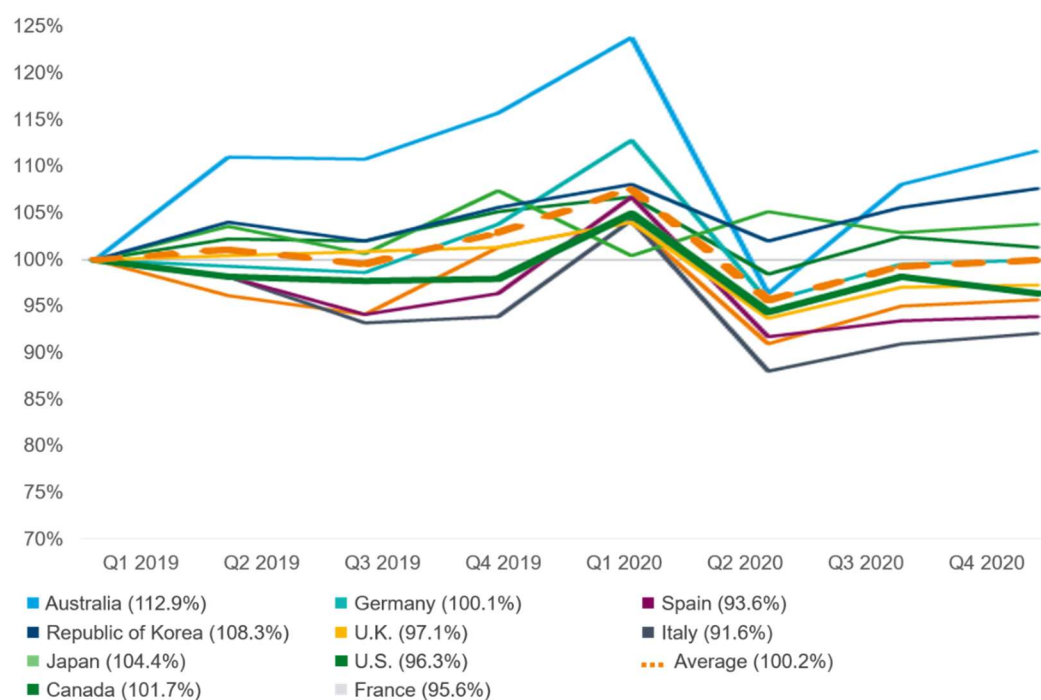
<sup>37</sup> Precedence Research, “Hospital Services Market Size, Share, Growth, Trends, Scope 2027.”

**Figure 4.2-A. Pharmaceutical use in pharmerging and advanced economies, Percent change in defined daily dose (DDD, 2019 to ≈2029)**

### Pharmerging Economies

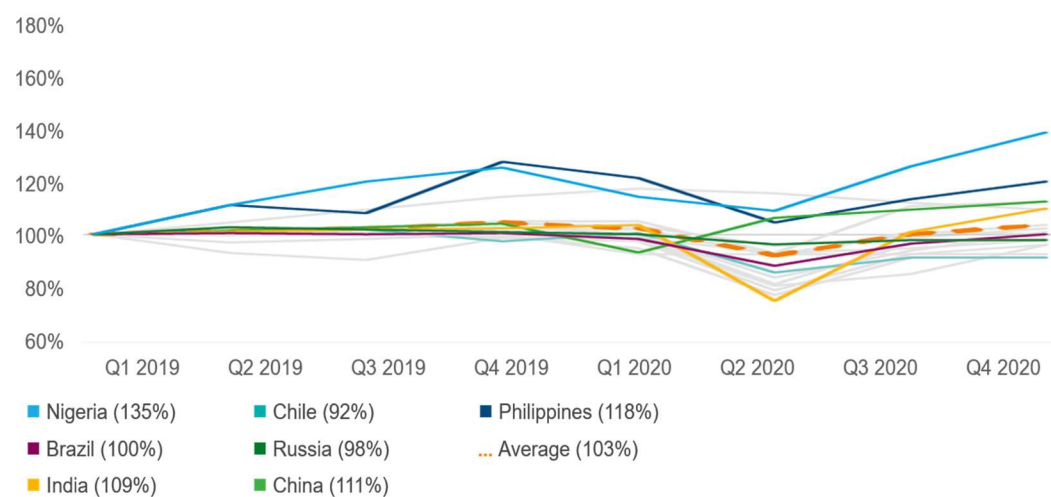


### Advanced Economies

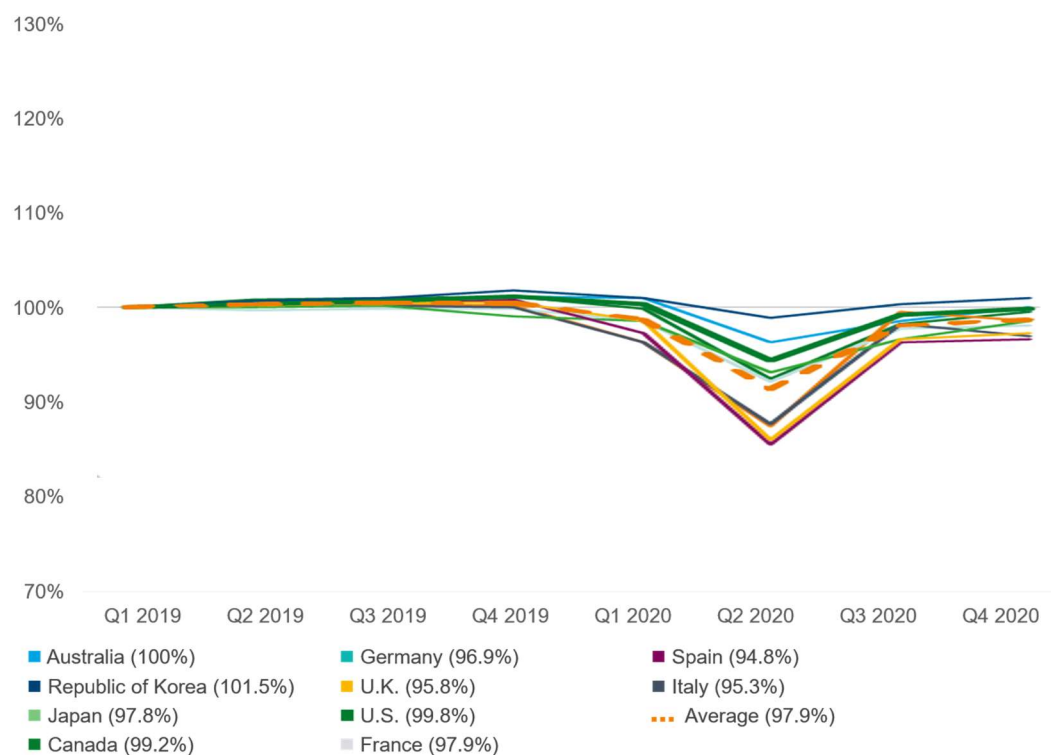


**Figure 4.2-B. Pharmaceutical spending in ‘pharmerging’ and advanced economies, Percent change in gross domestic product (GDP, 2019 to ≈2029)**

### Pharmerging Economies



### Advanced Economies



Charted values are indexed to Q1 2019 values such that the Q1 2019 value is set to equal 100%. Op. cit., Aitken, Kleinrock, and Munoz. Exhibits 4 and 5.

Replacing 1,000 old prescriptions with 1,000 new prescriptions will increase drug costs by \$18,000 but will reduce the number of hospital stays by nearly six. Since the average cost of a hospital stay is \$7,588, a total reduction of \$44,469 in hospital costs could be expected. Even larger hospital cost savings result because use of new drugs reduces average length of stay as well as the number of stays. The total reduction in non-drug medical expenses is about four times the increase in the costs of the drugs—so reducing the age of drugs [by using new brand drugs] substantially reduces the total cost of treatment.<sup>38</sup>

A 2018 OECD report estimated actual total pharmaceutical spending at 9% to 30% higher than estimates of retail pharmaceutical spending alone, meaning that much of the total pharmaceutical spending takes place in a hospital or outpatient care setting versus at the kitchen table.<sup>39</sup> This discrepancy is rooted in common calculations and definitions for reporting of total pharmaceutical spending (e.g., “budget for pharmaceuticals”<sup>40</sup>), including those employed by the U.S. and many other states, and the OECD, that do not account for and exclude pharmaceuticals used in hospitals (called ‘inpatient’) or administered by physicians in outpatient health care settings. For example, the OECD itself has noted that “[m]ost countries tracking expenditures and/or utilization at [the pharmaceutical] product level do so only for medicines dispensed by retail/community pharmacies.”<sup>41</sup>

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<sup>38</sup> Bussing-Burks, “Benefits of Newer Prescription Drugs Exceed Their Costs.” The referenced research can be found at Lichtenberg, “Benefits and Costs of New Drugs: An Update” (2007), which is an update to Lichtenberg, “The Benefits and Costs of Newer Drugs: Evidence from the 1996 Medical Expenditure Panel Survey,” Working Paper 8147, National Bureau of Economic Research (March 2001).

<sup>39</sup> OECD, “Pharmaceutical Innovation and Access to Medicines.”

<sup>40</sup> This report defines pharmaceuticals, for the purposes of survey reporting for analysis of total expenditures, as “A ‘budget for pharmaceuticals’ refers to a budget allocation for the purpose of public expenditure on pharmaceuticals by a national or a sub-national government, as part of the budgetary process. This budget may include all public spending related to pharmaceuticals, or only some categories of medicines (e.g., only medicines purchased in community pharmacies, or only high-cost medicines). In fact, some countries may budget separately different categories of medicines. This budget may or may not be directly managed by the level of government setting it.” This definition shows the inherent flexibility in the reporting level, which allows for pharmaceuticals to be ‘lumped’ into the *delivery mechanism* versus the nature of the service or reporting on pharmaceutical expenditures commonly reflecting reporting on pharmaceutical expenditures through community or retail pharmacy settings (meaning, not pharmacies located on site of a hospital), and thereby excluding pharmaceuticals administered or dispensed through a hospital or a physician’s office. See OECD, “Improving Forecasting of Pharmaceutical Spending—Insights from 23 OECD and EU Countries: Analytical Report,” (April 2019) 13, Box 1.1..

<sup>41</sup> For example, “Whereas trends in retail drug spending are available through national data collection and reporting efforts, such as the National Health Expenditure data, those sources do not reflect the experience of major drug purchasers: hospitals and health systems.”



In a study of U.S. hospital pharmaceutical spending, researchers at the University of Chicago found total hospital spending for inpatient and outpatient pharmaceuticals increased 18.5% between 2015 and 2017; spending on inpatient pharmaceuticals increased 28.7% between 2015 and 2016 alone.<sup>42</sup> Examining these trends longitudinally, a 2020 study by the Office of the Actuary at the U.S. Centers for Medicare & Medicaid Services (CMS), the agency responsible for administering U.S. public health care insurance, found the balance of total health expenditures is shifting from inpatient hospital services to pharmaceuticals. The report projected retail drug spending itself will grow faster than other areas of health care over the next decade, and spending on physician-administered drugs will grow “even faster.”<sup>43</sup> A complement to the CMS Office of the Actuary report prepared by the Altarum Institute estimates the non-retail component of U.S. prescription drug spending.<sup>44</sup> Altarum’s 2020 report found that U.S. retail spending in 2018 accounted for 9.2% of total health expenditures (THE), while non-retail (or hospital) spending accounted for an additional 4.5%. They estimate that retail and non-retail drug spending will comprise 13.9% of THE in 2028 driven by growth in the non-retail segment. Retail drug spending is estimated to grow from 335.0 billion USD to 560.3 billion USD (67%) and non-retail spending from 164.7 billion USD to 302.4 billion USD (83%).

Analysis of the three most recent years of data from IBM Truven MarketScan®, the Medicare Limited Data Set (LDS), and Medicare Part D and Part B finds that prescription drug spending (retail and physician-administered drugs) appears to have surpassed inpatient spending in

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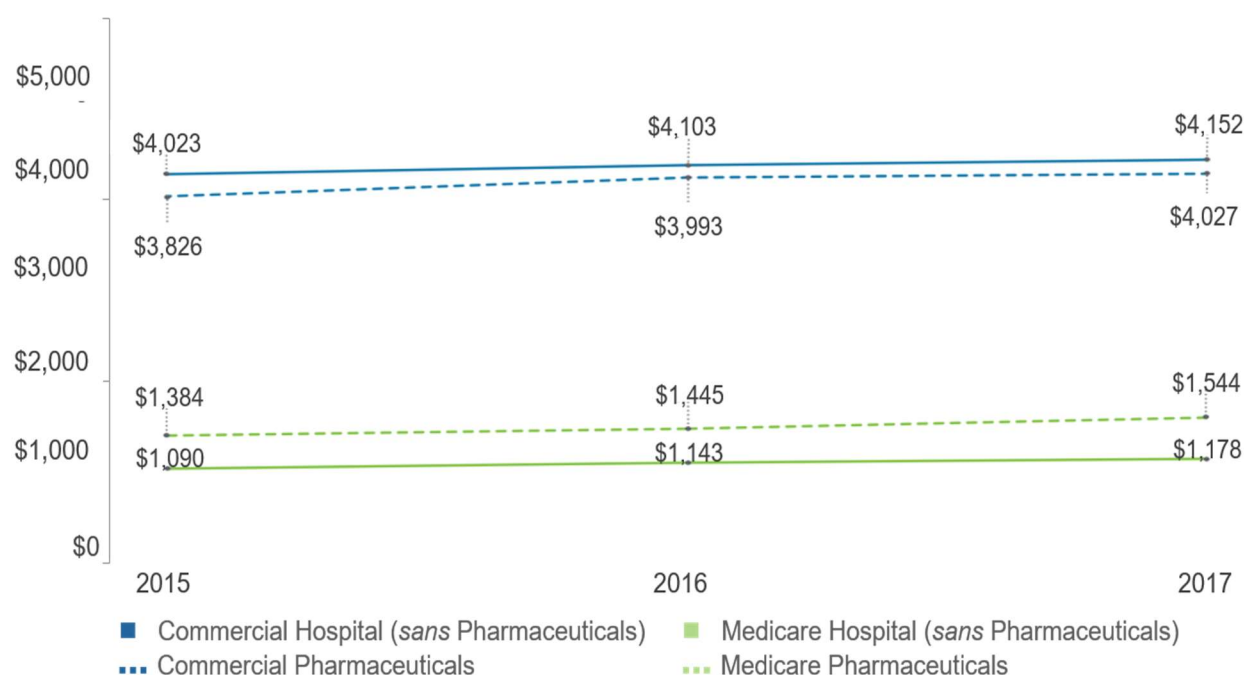
And also, “As part of the System of Health Accounts (SHA) annual data collection, most OECD and EU countries provide information on ‘retail pharmaceutical expenditures,’ and a few countries also report information on pharmaceutical expenditures in hospital settings,” per, op. cit., OECD (April 2019), which refers to the definitions of terms and guidelines for reporting pharmaceutical and other health care expenditures (e.g., OECD, Eurostat and WHO).

<sup>42</sup> Op. cit., NORC at the University of Chicago, “Recent Trends in Hospital Drug Spending and Manufacturer Shortages,” Figures 1 and 2.

<sup>43</sup> Van Antwerp, Boozer Cruse, and Arora, “Drug and Inpatient Spending Lines Are Crossing.”

<sup>44</sup> Roehrig and Turner, “Projections of the Non-Retail Prescription Drug Share of National Health Expenditures.”

**Figure 4.2-C. Annual per capita retail and hospital pharmaceutical expenditures for private and public health insurance programs, U.S. (2015-17)**



Retail and hospital pharmaceutical expenditures for private ('Commercial') and public health (Medicare) insurance programs, U.S. Figure courtesy of Van Antwerp, Boozer Cruse, and Arora, "Drug and Inpatient Spending Lines Are Crossing," 5, Figure 2.

the commercial population (Figure 4.2-C). Meanwhile in Medicare, the gap between inpatient spending and prescription drug spending is narrowing. Population growth and aging, prescriptions per capita, general inflation, drug prices, and introducing high-cost novel drugs are all contributing to this trend.<sup>45</sup> Deloitte Insights® (2020) captures these trends and the implications well, noting:

Today, the balance of spending is shifting from inpatient hospital (historically the costliest sector) to prescription drugs, according to an analysis of Medicare and commercial spending [(U.S.)] on inpatient medical services and prescription drugs. In the future, wider availability and greater adoption of targeted therapies (precision medicine), such as cell and gene therapies, will likely accelerate this trend... One key

<sup>45</sup> Op. cit., Van Antwerp, Boozer Cruse, and Arora, "Drug and Inpatient Spending Lines Are Crossing"

takeaway from the interviews is that higher drug spending isn't necessarily bad if it helps keep people out of the hospital and provides value to the system.<sup>46</sup>

National policy, however, suggests the overall shift demonstrates that pharmaceuticals are serving as an essential and preferred point of medical care, reflecting goals to direct patients to less costly settings of care and to use prescriptions as a mean to prevent acute events necessitating hospital care.<sup>47</sup>

The balance of health care spending in advanced economies is shifting from hospital services, which historically have been the costliest sector, to pharmaceuticals. If total pharmaceutical spending (retail and physician-administered) already surpasses hospital spending in select markets, including the U.S. commercial market (i.e., private health insurance coverage most often offered by employers), it is easy to imagine the lines may be close to intersecting for other markets. This is far more intuitive when one considers the emergence of new curative and preventive, but expensive, treatments like Novartis' Zolgensma, a one-time gene therapy for spinal muscular atrophy that costs 2.1 million USD, and the increasing role of daily pharmaceuticals to treat the leading global causes of mortality—the priority NCDs of heart disease, diabetes, and trachea, bronchus, and lung and other cancers, and lower respiratory infections (Figures 4.2-D, 4.2-E, and 4.2-F). These disease class concentrations are complemented by the growth in hospital pharmaceuticals over retail pharmaceuticals. The global use of medicines has been growing for the past decade, driven by access expansions in emerging economies and the market introduction of ever-higher cost pharmaceutical innovation.

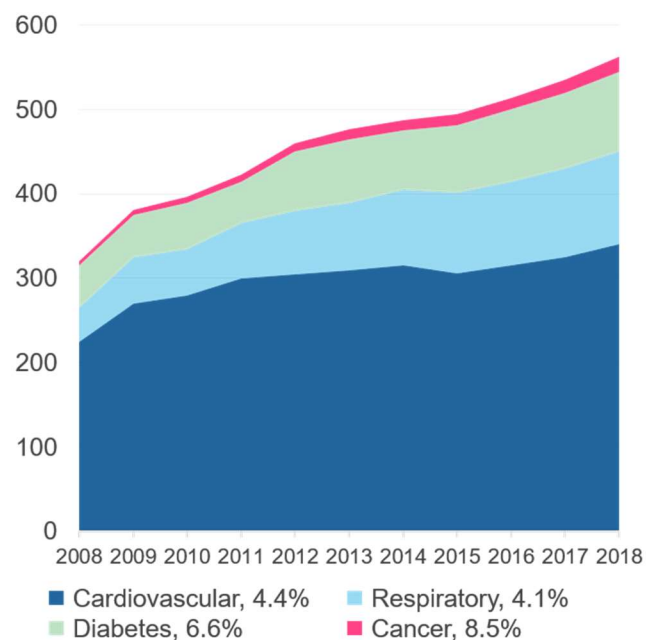
The high and growing global use of pharmaceuticals, and their associated spending, is on the

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<sup>46</sup> Van Antwerp, Boozer Cruse, and Arora, "Drug and Inpatient Spending Lines Are Crossing"

<sup>47</sup> Bussing-Burks, "Benefits of Newer Prescription Drugs Exceed Their Costs." The referenced research can be found at Lichtenberg, "Benefits and Costs of New Drugs: An Update" (2007), which is an update to Lichtenberg, "The Benefits and Costs of Newer Drugs: Evidence from the 1996 Medical Expenditure Panel Survey," Working Paper 8147, National Bureau of Economic Research (March 2001).

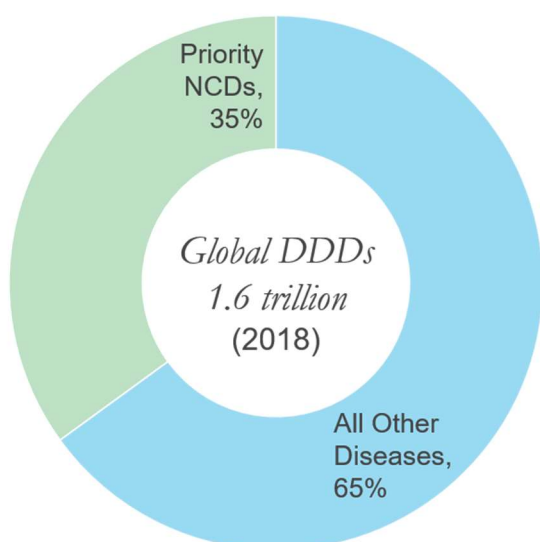
**Figure 4.2-D. Pharmaceutical use is concentrated in leading causes of death and growing, with 10-year CAGR (2008-18)**



Figures reflect prognosis based on September 2019 and January 2020 analyses. Author-generated figure based on data from Kleinrock and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2024;” and Belloni, Morgan, and Paris, “Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges.”

rise in advanced, emerging, and low-income economies, while other health care services stabilize or decline in terms of volume (e.g., hospital services). While partly driven by declines in elective procedures and deferrals of care brought on by the global Covid-19 pandemic, these trends also reflect a shift in preference from traditional and higher-cost settings of care to home- and community-based settings of care, primary care, and less invasive forms of therapy, such as pharmaceuticals. Whether at the market (share of GDP or volume of health care services), industry (share of total health expenditures), or individual (per capita spending) level, pharmaceutical spending is a primary component of health care and economic activity only projected to grow in size and relevance. In terms of projected volume, use, price growth, and relevance, there does not appear

**Figure 4.2-E. Heart disease, diabetes, respiratory infections, and cancers comprise 35% of global pharmaceutical use, in Defined daily doses**



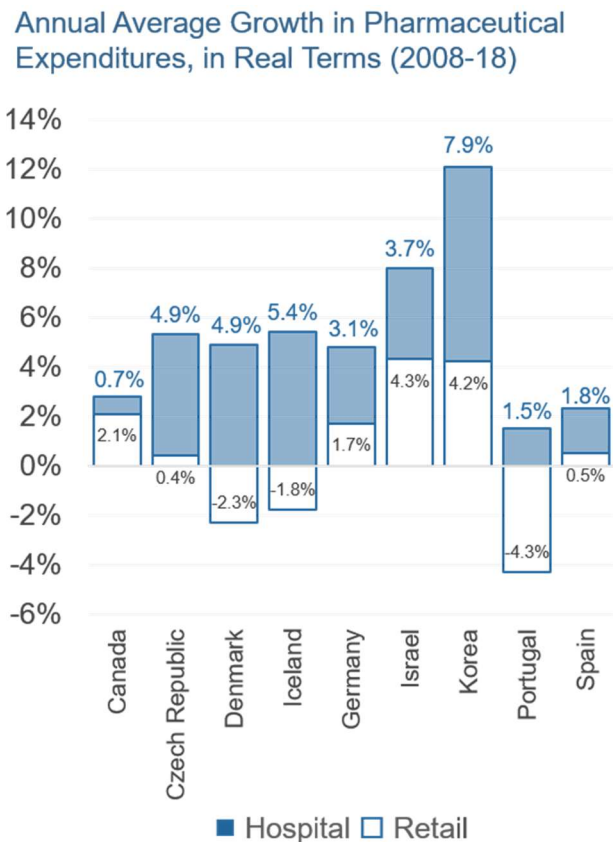
Figures reflect prognosis based on September 2019 and January 2020 analyses. Author-generated image based on data from Kleinrock and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2024;” and Belloni, Morgan, and Paris, “Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges.”

to be any other component of global health that even comes close to pharmaceuticals.

### 4.3 The Special Economics of Health Care

The standard economic theory of how markets work relies on the law of supply and demand: the price of a good will tend toward a point, called the market-clearing price, where the quantity demanded is equal to the quantity supplied. This price is set by the ‘invisible hand,’ or the ‘impersonal’ forces of supply and demand. Increasing prices reduce consumer demand and more supply enters the market; if the price is too high, supply will exceed demand and producers will be stuck with the excess. Conversely, as the price of a good goes down, consumers demand more of it and less supply enters the market, making goods unattainable for consumers. Neither condition, over time, is optimal. As its name suggests, the market-clearing price clears the market of excess supply or excess demand, optimally allocating resources and distribution of income—a perfectly or

**Figure 4.2-F. Hospital pharmaceuticals drive spending increases**



Figures reflect prognosis based on September 2019 and January 2020 analyses. Author-generated image based on data from Kleinrock and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2024,” and Belloni, Morgan, and Paris, “Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges.”

purely competitive market.

Economic theories of perfect competition often assume a set of particular conditions, including that many firms produce identical goods consumed by many buyers (i.e., the assumption of many buyers and sellers); it is easy for new firms or producers to enter the market and for existing ones to exit (ease of entry and exit); the main interested parties are the sellers and the buyers, and no buyer or seller has influence over the market price (price takers); and consumers and producers have complete information about market conditions. Under these conditions, the “impersonal forces of supply and demand” drive efficient allocation of a market’s goods.

Theoretical models, including that of supply-and-demand, are informed assumptions about behavior, the behavior of markets. The assumptions of this model are not universally applicable or relevant, nor is it practical to achieve perfection competition in real-world conditions. Modern economics, however, assumes this model is a good description for many goods and services in the economy. Health care is a significant exception, as explained by Public Health researchers Ari Mwachofi and Assaf F. Al-Assaf (2011):

A common argument in the health policy debate is that market forces allocate resources efficiently in health care, and that government intervention distorts such allocation. Rarely do those making such claims state explicitly that the market they refer to is an ideal in economic theory, which can only exist under strict conditions.<sup>48</sup>

Indeed, none of these five assumptions – identical products, many buyers and sellers, easy entry and exit, complete information, and buyers and sellers as price-takers – reflects what goes on in the market for health care, including pharmaceuticals.

#### 4.3.1 Assumptions of Market Behavior: Health Care as a Deviant Case

While health care is not the only good or service that departs from the standard model of supply-and-demand (e.g., natural and artificial monopolies, club goods, pure public goods), health care may be the most important good or service that departs so radically from this benchmark for three reasons: health care is a “good” that all consumers will have need for; the externalities of health mean market activity for one buyer (or seller) has consequences for all other buyers (or sellers); and, most important, health dominates public expenditures. Examining the economics of health care is a good starting point for understanding not only why health care as a market is special, but also why economics alone are imperfect for explaining and influencing global health.

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<sup>48</sup> Mwachofi and Al-Assaf, “Health Care Market Deviations from the Ideal Market.”

### Assumption 1: The Market Offers Identical Products

*First*, like other markets, the health care market has buyers (e.g., patients, governments, insurers) and sellers (e.g., doctors, nurses, pharmaceutical manufacturers). Other features of this market, however, complicate the analysis of their interactions and depart from the core assumptions, beginning with the assumption of identical goods or services. Though standards, treatment protocols, and best or promising practices permeate the practice of health care, they are not universal in their application, availability, or quality, and there may be competing versions of some health care goods (e.g., generic medicines, x-ray machines).

Besides differences in the technical experience of health care, each patient may experience health care in a unique and individual way: a patient may have a different rapport with one physician versus another; or a particular medication may be the first-line therapy for most patients, but pharmacogenomics indicate it would not be effective for a particular patient. Though these are simple examples, common shopping and market competition techniques may not always be possible or helpful for patients. Using the example where a known first-line anti-depressant produces seizures in a patient with a genetic predisposition, comparing two anti-depressants solely based on price – and without consideration of pharmacogenomics or other patient-specific clinical side effects – would be impractical and potentially harmful.

### Assumption 2: The Market Has a Large Number of Buyers and Sellers

*Second*, contemporary models also assume many buyers and sellers. A substantial number of empirical studies have explored the relationship between market size (population of buyers) and the number of firms (sellers) in different health care markets, finding that population size has a large and



significant impact on the number of specific health care providers.<sup>49</sup> What these studies do not account for, however, is that health care buyers and sellers often are pooled, whether through provider networks or health care systems (sellers) or private or public insurance schemes (buyers), which bifurcates the number of buyers and sellers. In addition, particular goods and services within health care can be specialized to meet unique health care needs (e.g., rare diseases, specialty providers, infused drugs), which can winnow both sellers and interested buyers.

#### Assumption 3: The Ease of Market Entry and Exit

*Third*, most contemporary markets are governed (“regulated”), whether through industry standards of practice or formal regulatory requirements imposed on firms. Such regulation may naturally, and purposefully, impair easy entry and exit. Specific to health care, preventable patient harm is a leading cause of morbidity and mortality internationally: Maria Panagioti et al. (2019) estimate that approximately one in 20 patients (6%) are exposed to preventable harm in medical care, of which between 9% and 15% of cases were severe or led to death.<sup>50</sup> Such systemic prevalence and severity naturally invite higher degrees of scrutiny and regulation to ensure the market is operating safely. When this necessary regulation is combined with the inherent specialization of many health care sectors, together they can pose stark barriers to entry and to exit.

#### Assumption 4: The Market Is Comprised of Buyers and Sellers that Are Price-Takers, not Negotiators

Fourth, supply-and-demand not only assumes but requires buyers and sellers to be price-takers, not negotiators or setters. Health care “sellers,” whether providers or device and drug

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<sup>49</sup> For a summary of the contemporary literature on health care market size and physician participation, see Lábaj et al., “Market Structure and Competition in the Healthcare Industry.”

<sup>50</sup> Panagioti et al., “Prevalence, Severity, and Nature of Preventable Patient Harm across Medical Care Settings: Systematic Review and Meta-Analysis.”

makers, are rarely paid directly by the consumer (the patient); rather, they are indirectly paid by the consumer through a buyer, whether a state payer of health care or a private insurer. These intermediary payers and purchasers may negotiate prices with sellers or set prices. The notion that health care firms sit back and let the market determine price also defies scholarship and practical evidence asserting the behavior of firms and their interaction with other market actors, including specific to the health care market. Evidence and practical experience, including the outcomes of the external reference pricing framework explored in Chapter 6.4, affirm that firms (e.g., multinational pharmaceutical corporations), customarily do set prices and negotiate with buyers (states).

#### Assumption 5: The Market Is Transparent and Reflects Buyer and Seller Access to Complete Information on Market Conditions

*Fifth*, the concept of complete and transparent information on market conditions between buyers and sellers. While patients rarely know what health care services they may need, may not have access to complete pricing and value information, and may not comparatively evaluate potential treatment options, the concept of “complete information” also assumes choice, including the choice not to purchase a health care good or service. The need for health care or the health care purchased may not be elective or discretionary. Even in conditions of complete information, a buyer experiencing an emergency is unlikely to make an informed market choice.

Performing a similar though more descriptive walk-through of health against the assumptions of market behavior á la Pareto optimality, Ari Mwachofi and Assaf F. Al-Assaf find that “obviously, health care markets do not function like the ideal economic market” (page [149](#)). Mwachofi and Al-Assaf discuss the efficiency inherent in health, including whether health is paid for and delivered through a market or by a state. Concluding that health care is a “merit good” (public good) of “human capital,” they align with Michael Grossman’s (1972) concept of Health Capital, which considers health care and human health through the concept of a “durable capital stock that

products an output of healthy time”:

These [health care] markets do not meet all necessary or sufficient conditions for the ideal economic market. Therefore, there are numerous market failures and inefficiencies due to such failures. Moreover, the distribution of health and health care is not at a desired level. As a consequence, there have to be interventions in these markets to close gaps and improve efficiency. However, issues of economic efficiency, market structure, and whether the government has any role in the health care of its citizens can be a cause of bitter and divisive political debates. Such debates tend to use economic theory without full disclosure of the assumptions made about the market. This is particularly true of arguments that support the market economy blindly without consideration for market failures and their impact on economic efficiency and social welfare. The result is statements that sound true to a non-economist but are totally false given that the wrong assumption has been made.<sup>51</sup>

A helpful, practical example of such negative externalities and the market failures health as a public good may generate is access to preventative vaccines. If a market actor (patient) decides that their own, individually determined and pursued, optimal level of health excludes being vaccinated against infectious diseases (e.g., Covid-19), this *individual choice* generates conditions that make optimum market conditions *ex ante* impossible to achieve (i.e., the market optimum would seek the discouragement of inefficiency in larger societal benefit via mass vaccination). Rather than a prime condition for health, when public goods are reserved to the market, they generate a cycle of under-consumption, inequitable distribution (given differential market negotiation capabilities), and inefficiency, leading to market waste expressed in both quantitative and qualitative forms, like the *personal choice* to forego health care services because of price and income.

#### 4.3.2 The Price and Income Inelasticity of Health Care

The standard theory of how markets work also assumes that the prices of goods and services are elastic, meaning demand responds to changes to one of its determinants, namely price.<sup>52</sup> price

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<sup>51</sup> Mwachofi and Al-Assaf, “Health Care Market Deviations from the Ideal Market.”

<sup>52</sup> The demand determinants for which elasticity measures apply typically are the price of the good or service, the income of the buyer (consumer), and the prices of related goods or services. Elasticity measures are typically computed based on over or under 1, but otherwise are free of units of measurement, making them particularly apt for market-to-market comparisons.

and income elasticity and whether health care can be characterized as a luxury, consumption, or necessary good has garnered significant attention in the literature.<sup>53</sup> In terms of price elasticity, a comprehensive 2002 literature review found demand is consistently price inelastic.<sup>54</sup> Although the range of price elasticity estimates is wide, estimates approximate a median inelasticity of -0.17, meaning that a 1% increase in prices (of a health care good or service) will reduce health care spending by 0.17%. The same review concluded that price-induced changes in demand for health care are “attributed to changes in the probability of accessing any care rather than to changes in the number of visits once care has been accessed,” meaning demand is artificially constrained. For outpatient services, for example, the probability of outpatient visits decreases by 41.4% if outpatient care prices increase 100%.<sup>55</sup>

M. Christopher Roebuck et al. (2011) found that the converse also is true: “although improved medication adherence ... increased pharmacy costs, it also produced substantial medical savings as a result of reductions in hospitalization.”<sup>56</sup> Increased costs can reduce medication adherence and raise overall health care costs elsewhere, whereas increased medication adherence may raise pharmaceutical costs and prevent or lower other health care costs.

Conversely, health care has a significant and positive income elasticity, meaning that the volume of health care services used increases as personal income increases. Returning to the example of outpatient care, Zhongliang Zhou et al. (2011) found the “probability of outpatient visits increase by 9.8% if [personal] income is doubled; outpatient visits among users increase by 13.6% in

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<sup>53</sup> See Newhouse, “Medical-Care Expenditure: A Cross-National Survey”; Parkin, McGuire, and Yule, “Aggregate Health Care Expenditures and National Income. Is Health Care a Luxury Good?”; Hitiis and Posnett, “The Determinants and Effects of Health Expenditure in Developed Countries”; Barros, “The Black Box of Health Care Expenditure Growth Determinants”; Farag et al., “The Income Elasticity of Health Care Spending in Developing and Developed Countries.”

<sup>54</sup> Ringel et al., “The Elasticity of Demand for Health Care: A Review of the Literature and Its Application to the Military Health System.”

<sup>55</sup> Zhou et al., “New Estimates of Elasticity of Demand for Healthcare in Rural China.” Page 260.

<sup>56</sup> Roebuck et al., “Medication Adherence Leads To Lower Health Care Use and Costs Despite Increased Drug Spending” Page 99.

this case.”<sup>57</sup> When considered at the national level, health care spending and use demonstrates similar income elasticity, as noted by Sarah Goodman (2017). Specifically, Goodman finds that the share of GDP spent on health care, including pharmaceuticals, is non-zero with an income elasticity estimate of 0.4, which means “that the share of income going to health will continue rising with increasing global income.”<sup>58</sup> For example, an income elasticity of 0.4 suggests a 1% increase in gross national income (GNI) would be associated with a 0.4% increase in national health expenditures as a share of GDP.<sup>59</sup> Goodman’s findings suggest that relative increases in national health expenditures will continue to outpace the rate of income growth, and non-income, country-specific factors are more important indicators of the health share of GDP (e.g., personal income, pricing and market access policies, mandatory discounts or negotiated).<sup>60</sup> The economics of health care are more aligned with the assumptions of imperfect competition, or situations where the equilibrium price (“market-clearing price”) is not the result of the impersonal forces of supply and demand.

Rather, price can result from limited competition (between large rivals), a small population of buyers, inherent market structures that require high barriers to entry, and differentiated products. Rather than achieving an optimal price, reserving health care to the “impersonal forces of supply and demand” restricts the supply of health care to consumers insensitive to price. As Inge Kaul, Isabelle Grunberg, and Marc A. Stern (1999) note, “the poor have different health priorities from the rich—and the rich have greater preventive and protective capabilities than the poor.”<sup>61</sup> The special economics of health care distinguish its goods and services from those of markets here but, most important, because optimal economic efficiency does not imply optimal equity. Decisions on

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<sup>57</sup> Op. cit., Zhou et al. (December 2011), Page 262.

<sup>58</sup> Goodman, “The Income Elasticity of Demand for Health Insurance.” Page 21.

<sup>59</sup> Goodman. Page 21.

<sup>60</sup> Ibid.

<sup>61</sup> Kaul, Grunberg, and Stern, *Global Public Goods: International Cooperation in the 21st Century*. Page 92.

the allocation of health care resources, whether by the market itself or through public policy, may struggle to balance the “weighty distributional issues of unequal access and biased priorities.”<sup>62</sup>

#### 4.3.3 Medicines as a Supra-deviant Case

Besides the particularities of health as a market good, pharmaceuticals also deviate from the assumptions of market behavior in five ways, which raise market complexities that are not evident in other areas of marketized health. How pharmaceuticals deviate further from market assumptions are essential for understanding the complexity inherent in global governance of pharmacies, designing policy to avoid regulatory capture, and curbing the impact of such deviance – via rules and governance – for individual patients, states, and the broader global health community.

##### Deviance No. 1: Medicines Are Regulated By National Governments, Global Intergovernmental Bodies, and Industry Associations for Safety, Efficacy, and Quality

*First*, akin to medical devices and imported food goods, medicines are nationally and globally regulated – by state actors, states in coordination through intergovernmental organizations, and also nonstate actors, including sub-global and global institutions (e.g., U.S. Pharmacopeia) – for safety, efficacy, and quality.

##### Deviance No. 2: Medicines Are Extremely Expensive, Reflect a Disproportionate Share of Most Countries’ Total Health Expenditures, and Sometimes Derive Limited-to-Clinical Benefit

*Second*, as detailed extensively in Chapter 2, medicines have become increasingly expensive when their actual derived individual value (to patients) is not only open to scrutiny (e.g., rescission of marketing approval following longitudinal evidence), but increasingly a question of valid global expenditure and prioritization (i.e., as compared to similar investment in preventative and other public health strategies).

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<sup>62</sup> Op. cit, Kaul, Grunberg, and Stern.

### Deviance No. 3: Medicines Have an Outsized Role in National Economies and the Global Economy

*Third*, also discussed in Chapter 2 and again in Chapter 3.4, medicines represent a growing portion of national and global economic activity, particularly, supporting positive trade balances in leading European countries through high levels of exports. The pharmaceutical sector also is a major employer in many countries and comprise a growing share of these same countries' total health expenditures.

### Deviance No. 4: Medicines Are Uniquely Protected from Market Forces

*Fourth*, medicines are not only regulated for safety, quality, and efficacy but they also represent a market good politically constructed to be protected from market forces, often for extensive periods of time uncommon to other markets for goods and services. State actors on their own, through national pharmaceutical policies, and in coordination with other states, through international agreements, establish intellectual property (IP) protections, called patents, and also so-called 'exclusivities,' which afford additional information and/or market competition protections. One form relates to the exclusive rights to market a drug product ('market exclusivity'), and another protects product-related data, including clinical trial data ('data exclusivities'). The terms of market exclusivity, data exclusivity, and IP patents are rarely concurrent and often separate; for example, the period of data exclusivity may extend beyond the term of any patent protecting the same product.

### Deviance No. 5: Medicines Reflect a Series of Constructed Narratives that Sustain And Reinforce the High Consumption, Economic Reliance, and Political Protection of this Sector

*Fifth*, and last, medicines are promoted actively by not only their powerful industrial backers (i.e., transnational and multinational pharmaceutical manufacturers), but also by state actors and intergovernmental organizations—whether as a signal for a political entity's prioritization of its constituency's normative concerns, of technological innovation, and/or access to health care itself,

particularly, as medicines dominate the actual standard medical practice and global treatment guidelines. In this way, medicines and health policies and rules affecting or relating to them generate significant complexities that markets are ill-equipped to manage, despite the invisible hand's dominant role in research and development, pricing, distribution, allocation, and access.

#### 4.3.4 The Extra-long Protected Life of an Arthritis Drug: AbbVie's Humira®

A notable example from the global pharmaceutical market is Humira® (adalimumab), a biological disease-modifying antirheumatic drug (bDMARD) to treat moderate to severe rheumatoid arthritis (RA), psoriasis, inflammatory bowel diseases (IBDs) like ulcerative colitis and Crohn's disease, and other autoimmune diseases<sup>63</sup> in adults.<sup>64</sup> Though Humira is among a class of second-line treatments for many of these autoimmune diseases, it is “the highest grossing drug in the world,” netting 16 billion USD in revenue based on 2020 U.S. sales alone.<sup>65</sup> The first U.S. patent for Humira® was granted in 1994 and, within the U.S. market, it continues to lack direct competition.<sup>66</sup> A 2021 report by the Majority Staff of House of Representatives Committee on Oversight and Reform, a legislative body of the U.S. Congress, found that the U.S. price for Humira® is 77,000 USD per patient, per year, which is approximately 470% higher than in 2003.<sup>67</sup>

The biological product's manufacturer, AbbVie (and partner Janssen Biotech, a subsidiary of Johnson & Johnson), filed 257 patent applications following Humira's primary patent, 130 of which

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<sup>63</sup> Emerging evidence suggests a relationship between the immune system and the “gut microbiome,” including that “nutrition can be a key factor for the development and progress of psoriasis” and “complex interactions between genetics, environmental factors, and the host immune system lead to aberrant immune responses and chronic intestinal inflammation,” see Karina Polak et al., “Psoriasis and Gut Microbiome—Current State of Art,” Atsushi Nishida et al., “Gut microbiota in the pathogenesis of inflammatory bowel disease,” and Naoko Kanda, Toshihiko Hoashi; Lihui Chen et al., “Skin and Gut Microbiome in Psoriasis: Gaining Insight Into the Pathophysiology of It and Finding Novel Therapeutic Strategies,” and Hidehisa Saeki, “Nutrition and Psoriasis.” Other evidence suggests treatment for psoriasis via diet may result in “complete resolution,” see Ang Peng Wong et al., “Efficacy of nutritional treatment in patients with psoriasis: A case report.”

<sup>64</sup> Type 1 diabetes is an autoimmune disease commonly diagnosed in children, though not discussed herein, which is why the clarification afforded by “in adults” is necessary.

<sup>65</sup> House of Representatives (U.S.), “AbbVie—Humira and Imbruvica.”

<sup>66</sup> Shah, *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020).

<sup>67</sup> *Op. cit.*, House of Representatives (U.S.), “AbbVie—Humira and Imbruvica,” i.



Figure 4.3. AbbVie explanation of Humira™ intellectual property “estate”

Broad U.S. Humira Patent Estate							
Approved Indication	Rheumatoid Arthritis	Gastro Indications	Psoriasis	Psoriatic Arthritis	Ankylosing Spondylitis	Juvenile Idiopathic Arthritis	Hidradenitis Suppurativa
Composition of Matter	Expires Dec. 31, 2016						
Indication / Method of Treatment	4 patents Earliest Expiry: 2022	6 patents Earliest Expiry: 2022	3 patents Earliest Expiry: 2023	4 patents Earliest Expiry: 2023	3 patents Earliest Expiry: 2022	1 patent Expiry: 2030	1 Patent Expiry: 2031
Formulation	14 Patents Expire 2022 – 2028						
Manufacturing	24 patents Expire 2027 – 2034						
Other (Device, Diagnostics, etc.)	15 patents Expire 2024 – 2032						

Public document. AbbVie, “AbbVie Long-term Strategy,” presented by Richard Gonzalez, chair and chief executive officer, at AbbVie’s 2015 Investor Relations Conference (October 30, 2015), Slide 14, <https://investors.abbvie.com/static-files/af79eef2-5901-4b62-9354-982d2d95404e>.

were granted and at least 76 were active through 2022 (Figure 4.3). Though Humira’s primary patent expired in 1994, these additional filings preserve patent protection through 2037 when the last of these supplemental patents is set to expire—marking 43 years of state-granted protection from the invisible hand (forces of market competition). AbbVie also has been granted 14 market and data exclusivities for Humira®. Eight of these exclusivities relate to ‘orphan’ designations it has received, which provide additional years of exclusive rights to the U.S. market but also a 25% tax credit for

expensed incurred during clinical trials performed more than a quarter-century ago.<sup>68</sup>

Emerging research suggests these state-actor generated and enforced incentives have altered the global pharmaceutical research and development pipeline as some manufacturers evaluate development investment decisions based on the likelihood of securing not only patent, but also exclusivity protections.<sup>69</sup> Similarly, highly profitable medicines on the market seek special designations to generate additional profits without incurring significant expenses. While such national pharmaceutical (innovation) policies are not universal, their presence in large and leading pharmaceutical markets – like the U.S. and Europe – grant these national policies outsized global relevance.

#### **4.4 The Complicated Domestic Politics of Biomedicine**

Global pharmaceutical spending and use trends are not independent factors; they are made complex by underlying changes in the practice of medicine (i.e., increasing toward ‘biomedicine’ and reliance on pharmacological treatment, per Chapter 2.1) and the global pharmaceutical market (e.g., impact of specialty medicines, biological products, and new therapies, including cell and gene therapies, per Chapters 4.1 and 4.2). Specialty and innovative products comprise a significant and growing portion of the pharmaceutical development pipeline, suggesting these medicines will play an outsized role in pricing and market access decisions in the years to come.<sup>70</sup> Higher market

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<sup>68</sup> The U.S. Orphan Drug Act, 1983 was enacted into law to incentivize pharmaceutical manufacturers to develop medicines use to treat rare diseases, or diseases for ‘orphan’ designations. In addition to a seven-year exclusivity period per indication, manufacturers may also receive a 25% tax credit for expenses incurred during clinical testing and have their New Drug Application fees waived.

<sup>69</sup> Padula et al. (2020) find that a total of 432 branded drugs were approved for 615 orphan indications, of which 108 had multiple indications. Market exclusivity, beyond the initial seven years, increased by 4.7 years with two orphan approvals, and there were 3.1-, 2.7-, and 2.9-year extensions for three, four, and five approvals. Medicines with five approvals averaged 13.4 additional years of exclusivity. Sixteen of the analyzed medicines had exclusivity periods extending at least 10 years beyond the original exclusivity period. The 2020 study estimated a potential U.S. (federal) budget impact of these additional exclusivities of 91 billion USD for the seven years following the end of the primary patent. See Padula et al., “Market Exclusivity for Drugs with Multiple Orphan Approvals (1983–2017) and Associated Budget Impact in the US.”

<sup>70</sup> Specialty and innovative products are projected to account for 40% of global spending in 2024. In developed markets, 44% of spending is on specialty products and is expected to reach 52% in 2024. See Kleinrock and Munoz, “Global Medicine Spending and Usage Trends: Outlook to 2024.” Exhibit 5.

prevalence and patient use of these medicines, which accounted for 36% of global pharmaceutical spending in 2019, is driving recently experienced and projected spending increases. Spending by advanced economies on specialty pharmaceuticals – typically defined in terms of their complexity to manufacturer (because of living cells, for example), specialized patient monitoring requirements, or exceedingly high costs<sup>71</sup> – is expected to reach 52% of total pharmaceutical spending in 2024.

While specialty spending in emerging economies is 90% smaller in absolute terms than advanced economies, the impact of even marginal growth in the uptake of specialty pharmaceuticals, which are universally more expensive than non-specialty pharmaceuticals, would be substantial. The highest rates of increase in medicine use and spending have been concentrated in emerging economies, defined as countries with per capita income below 30,000 USD per year and pharmaceutical spending growth above 1 billion USD over five years. Amidst already-high and rising levels of spending, compounded by broad use, the nonstop pace of ever-more expensive therapies coming to market makes frequent those pricing-and-access conundrums once reserved for the occasional breakthrough or curative therapy.

#### 4.4.1 High Consumption, High Spending: A Good Problem to Have?

Such growth among emerging economies is in some ways a good problem to have, but a problem all the same: mostly driven by access expansions, leading to improved access to medicines and health care broadly, these same countries are least able to competitively respond to and afford medicine spending increases. Former IMF Fiscal Policy and Surveillance Chief Benedict Clements articulated well the high stakes and benefit-cost dichotomy of rising health and medicine spending:

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<sup>71</sup> Per Ian Spatz, “Although there is no accepted definition of specialty pharmaceuticals, they generally are drugs and biologics (medicines derived from living cells cultured in a laboratory) that are complex to manufacture, can be difficult to administer, may require special patient monitoring, and sometimes have Food and Drug Administration (FDA)-mandated strategies to control and monitor their use. Increasingly, specialty pharmaceuticals have come to be defined by exceeding a certain threshold cost, such as \$600 per month, which may place such drugs on higher cost-sharing tiers.” See Spatz, “Specialty Pharmaceuticals.”

On the one hand, providing access to affordable health care is of paramount importance. But spending on health care is putting enormous pressure on public purses all over the world, and it is only getting worse... In advanced economies, spending alone accounted for about half of the rise in government budgets in the past 40 years. If we do nothing, these costs will continue to soar.<sup>72</sup>

For advanced and emerging economies over the coming years, moderating the growth of public health spending, including on pharmaceuticals, “will have to be a major element of the fiscal consolidation strategy.”<sup>73</sup> And for many emerging economies, balancing further expansions to health care and medicine access and increases in public health spending “will be by no means easy.”<sup>74</sup> The 2012 IMF model suggests the “cumulative fiscal burden” of projected increases in public health spending over the 2011-50 period to be 98% of GDP in 2012.<sup>75</sup>

As discussed earlier in this chapter, taken together, the pace of pharmaceutical innovation and rising levels of global use and spending emphasize pharmaceuticals’ increasing centrality to achieving global health goals, whether the eradication of global disease pandemics or the end of preventable illness. But these trends are not without their detractors and political complications. For example, the implications for macroeconomic and fiscal policy of an 100% of GDP growth in health care and pharmaceutical spending for any country are potentially severe. Such rates of growth create unsustainable fiscal pressures that create natural tensions in terms of other public investment and policy priorities and, thusly, demand political trade-offs.<sup>76</sup>

The inherent good of high and rising pharmaceutical spending as an indicator of improved access to health care can quickly turn into an expressly difficult-to-solve political problem. When

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<sup>72</sup> Op. cit., Clements, Coady, and Gupta, *The Economics of Public Health Care Reform in Advanced and Emerging Economies*. Appendix Table 3.3, Pages 37-38 and 51.

<sup>73</sup> Ibid.

<sup>74</sup> Ibid., Page v.

<sup>75</sup> International Monetary Fund, “World Economic Outlook Update, January 2021: Policy Support and Vaccines Expected to Lift Activity.”

<sup>76</sup> O’Neill, “Inflation Rate of the Main Industrialized and Emerging Countries 2020.”

contrasted with other public goods and priorities, how much reliance on pharmaceuticals can the global ‘we’ afford and for how long?

#### 4.4.2 Medicine Insecurity and the Political Response

Because of the “special economics of health care,” including demand being fairly price inelastic, higher medicine prices do not always restrain demand as for other market goods.<sup>77</sup> And, when they do, such restraint can impart a complex interplay of positive and negative externalities. For example, a medicine to treat a chronic disease (i.e., recurrent or lifelong), health care delayed may not mean the proverbial dollar saved. While the health care payor’s costs – whether borne by a state or commercial actor, like an employer – may be less in the short term, the patient foregoing care may have far greater overall costs.

If a patient defers or foregoes care, that patient’s condition may worsen, leading to an even costlier medical intervention or in its absence resulting in disability or death. Price sensitivities are troublesome for patients already in worse health, whom are twice as likely to delay or go without care due to cost, likely compounding their own already-fragile health status.<sup>78</sup> Pharmaceuticals are amongst the top three categories of health care services most commonly foregone or rationed due to price, despite their being essential to treat many common health care conditions.<sup>79</sup> For example, because many pharmaceuticals treat chronic conditions and used daily, patients may take half a dose or skip doses to extend the prescription, or else leave a prescription unfilled at the pharmacy counter because of affordability concerns.

In this way, chronic treatments and expensive curative therapies pose complex decision

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<sup>77</sup> Price inelasticity for health care services is just one amongst several other distinctions of what goes on in the healthcare market as compared to other markets for goods and services. These are explored in greater detail in sub-chapter 3.4. See also Mankiw, *The Economics of Healthcare*.

<sup>78</sup> Amin et al., “How Does Cost Affect Access to Care?”

<sup>79</sup> Op. cit., Amin et al.

points for state actors and individual patients. Several countries have adopted different strategies in response. “Insulin insecurity” in the U.S. is one such example.<sup>80</sup> In the U.S., state attorneys general – responding to an “insulin crisis,” where diabetics have died because of the high cost of a 100-plus-year-old pharmaceutical – have called on regulatory authorities to limit U.S. intellectual property protections to engender competition in the global insulin market.<sup>81</sup> In response, manufacturers asserted such action would endanger global pharmaceutical research and development, “ultimately harming patients and health systems, alike.”<sup>82</sup>

These decision points for state actors are not consistent and are driven by political pressures. An example is the case of Keytruda. In the Netherlands, the national government stopped paying for pembrolizumab (Keytruda), an immuno-oncology drug, it had helped develop because it was too expensive. The list price of Keytruda is approximately 13,000 USD per month.<sup>83,84</sup> Yet on other hand, in the U.K., the National Institute for Health and Care Excellence (NICE), an advisory body to the National Health Service, approved public funding for a 15.2 million USD per-person treatment for a rare blood disorder.

In response to political pressure, some advanced economies have implemented strategic, social purchasing of prescription drugs.<sup>85</sup> Others are evaluating such policies. For example, in the U.S., policymakers once, and largely still, detest to consider directly regulating the pharmaceutical market have annually introduced measures that would adopt collective purchasing tactics in all but name—proposing initiatives that would allow for the government to directly negotiate purchase

<sup>80</sup> Willner, Whittemore, and Keene, “Life or Death? Experiences of Insulin Insecurity among Adults with Type 1 Diabetes in the United States.”

<sup>81</sup> Belluz, “The Absurdly High Cost of Insulin, Explained.”

<sup>82</sup> Pharmaceutical Research and Manufacturers of America, “International Advocacy: Market Access”

<sup>83</sup> Economist Staff, “The Global Battle Over High Drug Prices.”

<sup>84</sup> The list price is 19,448 USD for a six-week course of treatment. This figure has been adjusted to estimate a monthly cost.

<sup>85</sup> In select high-income countries, national price and market access committees consider a product’s price in other countries (markets) when determining the recommended or actual price of the product for their own market. This is commonly known as external reference pricing. See Schuler et al., “The International Price Referencing (IPR) Conundrum: Strategic Approaches for Practical Implementation.”

prices even if commercial entities, like private health insurance plans and employers, are the ones actually purchasing the pharmaceuticals.<sup>86</sup> The dissonance between political pressure and party ideology is nothing new, particularly, with health care. Americans enacted a social-insurance scheme for the public purchasing of discounted pharmaceuticals in 1990 (Medicaid Drug Rebate Program, or MDRP)<sup>87</sup> and, in 2003, expanded another social-insurance program, Medicare, to include coverage of certain pharmaceuticals (Medicare Prescription Drug Program, or Medicare Part D).<sup>88</sup> Same story, different decade.<sup>89</sup>

In early 2019, former Italian health minister Giulia Grillo proposed a draft resolution to the WHO, which was backed by many other WHO member states, calling for global governance of pharmaceuticals.<sup>90</sup> The proposal would have required the divulsion of proprietary pricing strategies, research and development spending, and manufacturing costs, which pharmaceutical manufacturers claimed would “threaten innovation and access” within those countries adopting such policies.<sup>91</sup> Ultimately, Grillo’s proposal was not implemented.

The examples briefly presented here – including the public purchasing of discounted pharmaceuticals established in the U.S. and the global pharmaceutical regulation framework proposed at the WHO – illustrate three premises essential to this research. *First*, health is political because power is exercised over it.<sup>92</sup> Determining who gets what, when, and how inevitably involves

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<sup>86</sup> Former U.S. President Donald Trump proposed variations of external reference pricing and pharmaceutical importation models. See Department of Health and Human Services (U.S.), “American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.”

<sup>87</sup> Congress (U.S.), Omnibus Budget Reconciliation Act. See Berman, “A Legislative History of the Medicaid Drug Rebate Law: The Drug Industry and the Crusade of Senator David Pryor.”

<sup>88</sup> Congress (U.S.), Medicare Prescription Drug, Improvement, and Modernization Act. See Oliver, Lee, and Lipton, “A Political History of Medicare and Prescription Drug Coverage.”

<sup>89</sup> Reinhardt, “Perspectives On The Pharmaceutical Industry?”

<sup>90</sup> Grillo, “Transparency of Medicines’ Prices - Draft Resolution Proposed to WHO.” See archival copies of the letter, resolution, and background on the measure at Knowledge Ecology International, “Italy’s Draft WHO Resolution: Improving the Transparency of Markets for Drugs, Vaccines and Other Health-Related Technologies.”

<sup>91</sup> Taylor, “Government-Imposed Price Controls Threaten Innovation and Access.”

<sup>92</sup> Bambra, Fox, and Scott-Samuel, “Towards a Politics of Health.”

power and politics. U.S. policymakers made a *political* decision to structurally favor access to affordable pharmaceuticals by older and lower-income Americans.

*Second*, like any other resource or commodity in a market, some have greater access to a scarce good (like quality health care and medicines) than others. But these distribution imbalances depend on political action and, amenable to political intervention if the sources of power and the motivations and context behind such power and/or its expression are well understood. The U.S. example shows how these imbalances can be remedied through political action. The WHO example, though unsuccessful, demonstrates that balances of power (or, imbalances) are sustained or renegotiated through political intervention. The Grillo proposal suggests power can be used also to push back against established imbalances and related systems, structures, and processes.

*Third*, power influences health at multiple levels of political action. While unsuccessful, the Grillo proposal demonstrates the striking significance of power and politics on health not only within and beyond countries, but also on global governance for health. Last, it demonstrates that the power and politics of global health are dynamic. These are two-level games, with actors evolving their strategy and approach. As the following section discusses, the response of multinational pharmaceutical corporations (MNPCs) to pricing regulation and intellectual property frameworks is just one clear example.

4.4.3 “The pharmaceutical industry has been remarkably successful in the past five years, due to an intense commercialization arms race”<sup>93</sup>

Over the past three decades-plus, the commercial model of pharmaceutical sales has been driven by a relatively simple convention: sales representatives for MNPCs hitting the pavement to deliver their messages to health care providers, often with less than 10 minutes to support why a

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<sup>93</sup> EURACTIV Media, “Pharmaceuticals: Winning the Commercial Arms Race.”



physician should favor their company's medicine over another ("physician detailing"). McKinsey and Company, a global consulting firm with a dedicated pharmaceutical advisory practice, points to the proliferation of these so-called "drug reps" and their tactics as emblematic of the term "pharmaceutical arms race."<sup>94</sup>

A commercial term referring to marketing practices, there are analogous and practical corollaries to rising pharmaceutical spending, use, and the interconnected political challenges. As law and technology writer Sally Wang (2012) explains, using certain pricing and marketing tactics create a Prisoner's Dilemma:<sup>95</sup> a circuitous loop of higher and higher marketing expenses (and thus higher business costs for pharmaceutical companies) where unilateral actions create a zero-sum dynamic of unilateral gain or harm to one actor over another.<sup>96</sup>

Drug marketing faces the problem of an arms race — competitors attempt to out-compete each other by boosting their marketing efforts, at great expense, only to find that the baseline level of marketing needed to maintain the status quo has increased accordingly. These inefficiencies are costly and often harmful to the stakeholders — drug companies, patients, payors ... and physicians.<sup>97</sup>

Under this example of pharmaceuticals-meet-Prisoner's Dilemma, actors' unilateral or collective success results in higher pharmaceutical sales (i.e., higher use of certain medicines and thus greater market share for certain corporations), which drive total spending on expensive medicines and excess cost growth from market concentrations, both of which are borne disproportionately by the public.

As Wang explains, the pharmaceutical marketing arms race is hurting the supplier (multinational pharmaceutical corporation), inquirer (patients), and payors (countries and their

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<sup>94</sup> O'Neill, "Inflation Rate of the Main Industrialized and Emerging Countries 2020."

<sup>95</sup> Wagner, "The Theory of Games and the Problem of International Cooperation."

<sup>96</sup> Wang, "Let the Arms Race End: Opening the Door to Flexible Drug Marketing Regulation through an IP Justification."

<sup>97</sup> Wang, "Let the Arms Race End: Opening the Door to Flexible Drug Marketing Regulation through an IP Justification."

economies, and other critical economic actors such as employers).<sup>98</sup> While Wang suggests this prisoner's dilemma could be mitigated by another game theory construct (Jean-Jacques Rousseau's story of the Stag Hunt,<sup>99</sup> where actors cooperate for collective gain), such a market-meets-policy solution has yet to be widely pursued, let alone adopted.<sup>100</sup> Rather, state actors in advanced and emerging economies have perceived an inability within the pharmaceutical market to self-regulate pricing and access and therefore are attempting political regulation.

#### 4.4.4 Types of National Policies, Rules, and Standards Regulating Pharmaceuticals

Since at least the 1980s, state actors have enacted a range of reforms to regulate their respective pharmaceutical markets, interacting with a host of other market actors – from payors, including health insurers and other state agencies, to customers (i.e., individual patients) and suppliers (i.e., drug-makers) – with the intent to better balance and share market power as political power between state actors and their constituencies and the pharmaceutical industry. For a visual representation of these interactions (Figure 4.4)<sup>101</sup> and for a list of the discussed and other common national policies and rules regulating pharmaceuticals (Table 4.4). Acting primarily through national policies but also through rules and practical standards, these forms of pharmaceutical regulation generally have insulated the pharmaceutical market from competition (for “supporting” innovation in research and drug development) and, increasingly, have turned attention to questions of cost, volume, and quality of health services supplied. Here are five such strategies.

##### Policy No. 1: Formularies

First, state actors and other drug coverage sponsors, including firms and employers, may limit the pharmaceutical benefits catalogue through establishment of a coverage formulary, with

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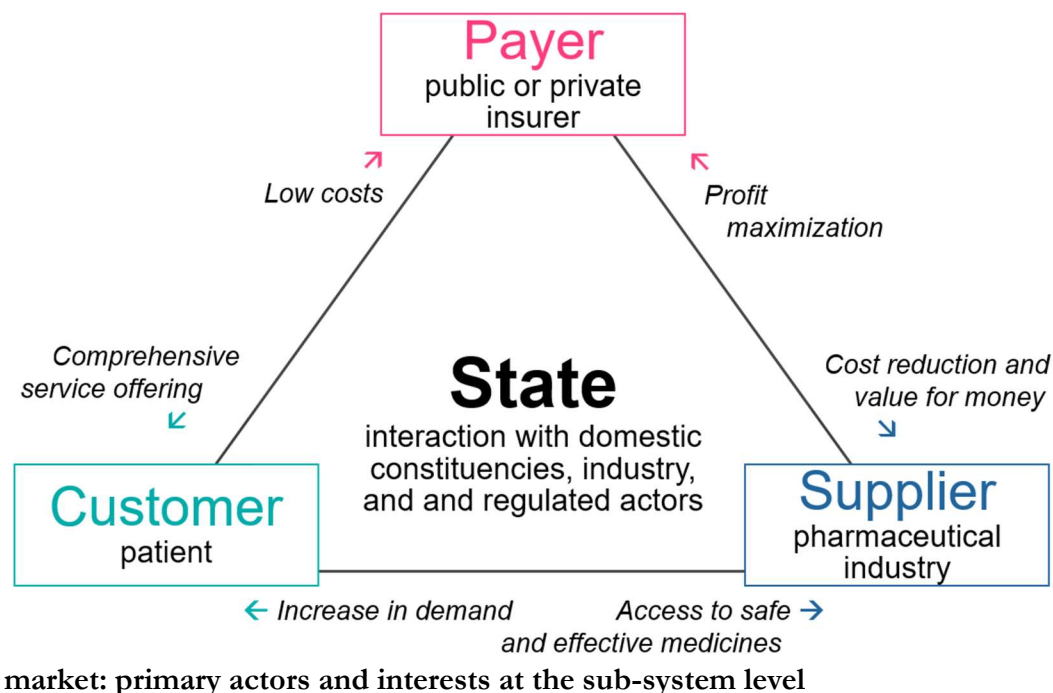
<sup>98</sup> Op. cit., Busse and Schlette, “Chapter 8: Drug Policies and Pricing”

<sup>99</sup> Rousseau, *A Discourse on Inequality*.

<sup>100</sup> Wang, “Let the Arms Race End: Opening the Door to Flexible Drug Marketing Regulation through an IP Justification.”

<sup>101</sup> Busse and Schlette, “Chapter 8: Drug Policies and Pricing”

**Figure 4.4. Political decision-making in the domestic regulation of the pharmaceutical**



Adapted with changes from Busse and Schlette (2007), 76, Figure 3.

particular pharmaceuticals tiered or placed within the formulary based on patient cost-sharing requirements. This formulary – or a list of which medicines are available sorted by the cost sharing required of patients – aims to support improved purchasing power parity to secure more favorable pricing between products within a pharmaceutical class.

#### Policy No. 2: Utilization Management

A *second* such approach is called utilization management, where drug coverage sponsors seek to curb the prescribing behavior of health care professionals. Such policies often build on both formularies and generic substitution policies and share common goals of reducing excess cost growth by promoting use of more cost-effective medicines. Examples include requiring first-line therapies (“step therapy”) or pre-approval (“prior authorization”) before a particular pharmaceutical

**Table 4.4. Common national policies or rules regulating pharmaceuticals**

<u>Intent of Regulation</u>	<u>Example</u>
Improve purchasing power parity to secure more favorable pricing	<ul style="list-style-type: none"> <li>• Formulary, drug coverage catalogue, or select list</li> <li>• Commercial competition</li> <li>• Discount or rebate negotiation</li> </ul>
Curb overuse and inappropriate use of high-cost medicines when therapeutically equivalent and more cost-effective alternatives are available	<ul style="list-style-type: none"> <li>• Limits on direct-to-consumer advertising and other patient-oriented marketing, including discount and coupon programs</li> <li>• Internal reference pricing, which establishes a maximum price for a class of drugs inclusive of brands and generics, biosimilars and biologicals, with the price aligned with the most cost-effective treatment in that drug class</li> <li>• Generic prescribing targets established directly for prescribers by the government, or indirectly through requirements on insurers or payers (or nonstate actors establishing directly through payment incentives)</li> </ul>
Support pharmaceutical research, innovation, development, and manufacturing	Intellectual property rights
Curb incentives for high prices at product launch and annual or semiannual increases in the product's price	<ul style="list-style-type: none"> <li>• Profit controls</li> <li>• Maximum allowable costs</li> <li>• External reference pricing</li> <li>• Health technology and pharmaceutical assessment and evaluation pricing ("value-based pricing")</li> </ul>
Improve clinically appropriate prescribing practices based on current standards of treatment	Computer assisted prescribing support systems (e.g., PRODIGY)
Assure product safety, efficacy, and quality	<ul style="list-style-type: none"> <li>• Product liability directive</li> <li>• Pre-market approval or licensure paradigms</li> <li>• Post-market surveillance and reporting requirements</li> </ul>

may be dispensed and reimbursed.

#### Policy No. 3: Maximum Allowable Cost

*Third*, state actors may directly negotiate a maximum allowable cost for pharmaceuticals in a competitive class, including through internal reference pricing (i.e., comparison to prices of equivalent or similar products) and health technology assessment (or “value-based pricing,” where a price is derived based on the relative or comparative value or efficacy of the product) systems, to drive medicine use to more cost-effective therapies by setting the price paid for expensive medicines within a specific class to that of the more cost-effective alternative.

#### Policy No. 4: Price Controls

*Fourth*, state actors may employ direct price controls through statutory pricing or public procurement for pharmaceuticals protected by intellectual property (IP) rights, whether patent or holding market exclusivity. Such approaches include external reference pricing (ERP), which may set prices based on a comparison to international prices; profit controls; rate of return regulation; or other mechanisms for setting either a fixed maximum price or the parameters that can influence the final price of a pharmaceutical.

#### Policy No. 5: Restrictions on Pharmaceutical Advertising

*Fifth*, and last, state actors and other sponsors may restrict direct-to-consumer advertising of pharmaceuticals, which, as Wang (2012) notes, represents an out-sized portion of pharmaceutical manufacturers’ expenses and have no practical benefit in terms of the quality of the manufactured product, technological innovation in pharmaceutical therapy or delivery, or the improvement of patient’s clinical outcomes or access.

#### 4.4.5 Health as a Deviant Case: A Constructed Global Market Rife with Politics, Power, and Public Goods

As these five examples illustrate, the state actors who often foot the bill of rising use of and spending on pharmaceuticals are rightfully looking closely, pursuing a range of pharmaceutical regulation options. Given the complex interplay between access to health care, population health and wellness, and pharmaceutical pricing, however, states and politicians must do more than balance the books. In an increasingly globalized and interdependent, but also localized and fragmented world, they also must balance the market (competition and access), economic (cost), and political (health) consequences of the growing relevance of pharmaceuticals to human health writ large and the global political economy.

This chapter explored how the benefits of biopharmaceutical innovation are unevenly distributed based on power, versus equity or collective will. The chapter also commented on the “special economics of health care” and implications of high and rising pharmaceutical spending for political action. It also clarified that, while patients worldwide are experiencing greater access to medicines, especially for rare diseases and cancer, these innovations and the collective reliance on medicine to address global health priorities come at a cost.

Patients’ access to medicines and health care broadly depends on their countries’ domestic health care payment and reimbursement policies, including what portion is publicly funded and the pharmaceutical pricing and market access policies. Historically, pharmaceutical access, cost, and affordability have been determined at the domestic level, which in some ways clarified routes of political action and influence on health. Consider other implications of pharmaceuticals and their outsized role in health and wellness. What does their outsized role suggest for select state and nonstate actors in global health governance? Which actors and interests are motivated by sustaining the politico-economic systems that elevate them to such relevance, or are motivated by

countervailing interests and forces? And what does this mean for political action and the ability to influence pharmaceutical pricing in this global economic system?

## CHAPTER 5

# ALL HEALTH POLITICS IS GLOBAL: REVIEW OF THE INTERNATIONAL POLITICAL ECONOMY, MEDICAL SOCIOLOGY, AND PUBLIC HEALTH LITERATURE

“Neither health nor disease in modern society is simply a local phenomenon.”

—Geoffrey B. Cockerham and William B. Cockerham (2010)<sup>1</sup>

The title of this chapter is a play on Daniel W. Drezner’s *All Politics is Global* (2007),<sup>2</sup> which itself is a play on the well-known aphorism (and book title) of former Speaker of the U.S. House of Representatives Tip O’Neill (1994): “all politics is local.”<sup>3</sup> Speaker O’Neill coined this now-ubiquitous phrase to describe the principle that a politician’s success depends on their ability to understand and influence favorably the political advancement of their constituents’ interests—the simple, everyday issues of those back at home (i.e., local issues). Citing the emergence of global rules and regulatory standards on labor, the environment, intellectual property (IP) rights, Internet protocols, food safety, and “how much medicine will cost,” Drezner argues that “for many issues that comprise the daily substance of our lives... the politics have gone global.”<sup>4</sup>

The World Health Organization (WHO, 1994) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”<sup>5</sup> Perceiving health beyond the typical biomedical bounds, though assuredly more complex, is a closer approximation to the actual richness of the human experience, the cross-sectorial “origins of good

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<sup>1</sup> Cockerham and Cockerham, *Health and Globalization*, 2.

<sup>2</sup> Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*.

<sup>3</sup> O’Neill and Hymel, *All Politics Is Local, and Other Rules of the Game*.

<sup>4</sup> *Op. cit.*, Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*, 4.

<sup>5</sup> World Health Organization, *Constitution of the World Health Organization*.



health,” and the interconnectedness of health and social systems, whether they be political or economic.<sup>6</sup> Echoing the underpinnings of population health, the WHO’s definition frames health as greater than the sum of its parts, like the production of health (medical care) and individual behaviors and genetic makeup. Rather, the sum of “health can be seen to depend not only on medical care, but also on... social and economic conditions.”<sup>7</sup> These “social and economic conditions” do not self-manifest; they are constructed, sustained or unraveled, and changed under the preferences of powerful actors. Social and economic conditions (‘determinants’ of health), which are driven by both global forces and local (national) and regional politics, are products of political processes, oftentimes global processes. Reflecting the socio-economic determinants of health, health inevitably involves politics, or exercising power and the mechanisms for constructing and distributing ‘good health’ locally. In an age of global market integration, all health politics is global.

This chapter begins with an exploration of the typologies of globalization, culminating in a literature-informed definition reflecting the combined concepts of modernity, rationality, power, and risk (Chapter 5.1). The significant extant literature establishing the strong influence of globalization,<sup>8</sup> specifically the globalizing of capitalism and Flexnerianism, on health is explored, the practical results of which include some health gains<sup>9</sup> but also significant losses and, increasingly, the slowing or elimination of prior gains (Chapter 5.2).<sup>10</sup> Next, the interrelation of health with systems, actors, and interests and its implications for the global governance of health is explored. ‘Global governance,’ included for health, is defined as encompassing international regulation (e.g., treats,

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<sup>6</sup> Chapter 2 in Dorch, Bailey, and Stoto, *Understanding Health and Its Determinants*.

<sup>7</sup> Dorch, Bailey, and Stoto.

<sup>8</sup> For context, the influence of globalization – of politico-economic structures at the global level, which shape their peers at the national, regional, and local levels, and also ‘individual governance’ – informs the socio-political construction of rules and norms that govern the global-local distribution of health.

<sup>9</sup> Examples include longevity; reduction in the global prevalence of communicable, maternal, perinatal, and nutritional (CMPN) diseases; some pharmacological cures; and vaccines against certain infectious diseases.

<sup>10</sup> And by losses, these often mean harmful consequences for individual and collective (‘global’) health, including the global prevalence of noncommunicable diseases (NCDs).

trade agreements, international legal instruments) as well as de facto or quasi global governance through international regulatory coordination, policy convergence, harmonization, and other formal power-sharing frameworks, even domestic policies, with global implications. Governance of health is examined in complexity, what James N. Rosenau (2018 [1990]) calls “framegration” (Chapter 5.3).<sup>11</sup>

Health has not been considered a core issue of International Political Economy (IPE) and persistently has been marginalized by this discipline and by its peer, International Relations (IR). “Deconstructing Health’s Long Absence from IPE” (Chapter 5.4) examines the contextual and within-field disputes that have shaped the contemporary discipline of IPE and its limited health scholarship. It also discusses the legacy of positivism within the discipline for determining which topics are ontologically appropriate to IPE—despite the discipline’s inherent focus on systems of social relations (albeit economic and politico-economic), which imply normative issues.

The chapter concludes with the literature-based assessment that, although social, political, economic, cultural, and ethical factors are acknowledged as influences on health, exercising power ex ante across levels of analysis and interaction – on system, community, and individual preferences, and outcomes – are far less well explored in Public Health and Health Policy scholarship, just as health continues to be marginalized in IPE and IR despite its significance and richness (in terms of experiences, structures, and political interactions worthy of study) (Chapter 5.5).

## 5.1 Globalization: A Primer

What is globalization and what is so special about it? Is it old, or is it new? Does it have roots and causalities, or is it self-evident? Does it reinforce the primacy of the state, the anarchic nature of the international system, the preeminent role of power—or are these expected norms of

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<sup>11</sup> Rosenau, *Turbulence in World Politics: A Theory of Change and Continuity*, 39.

the global system shifting, evolving, and reconstituting? And what of health? Does health, as a human condition, acquire a global dimension and “transworld solidarity” shirking the “territorialist thinking” of yesterday’s world?<sup>12</sup> Does health, too, absorb globalization’s “focus on its economic context,” and what are the practical implications for individual and collective health, for the role of power in global and local health?<sup>13</sup>

Scholarly debates of the nature, impacts, and politico-economic implications of the global economy, and of globalization have been central to the study of IPE since its reemergence in the 20th century. Particularly since the end of the Cold War triggered dramatic geopolitical and global economic shifts, the discipline has been dominated by debates of the nature, impacts, and implications, and the very definition, of globalization. This section begins the discussion of globalization and health with a primer on contemporary globalization before discussing the extant literature on the relationship between these two integral forces.

#### 5.1.1 Globalization as Global Politico-economic Integration

In 2005, the World Health Organization (WHO) defined globalization (per Rhys Jenkins (2004)) as “a process of greater integration within the world economy through movements of goods and services, capital, technology, and (to a lesser extent), labor, which lead increasingly to economic decisions being influenced by global conditions”). While this research appreciates the Jenkins definition and its relevance to the WHO and broader efforts to understand globalization’s effects on material goods, the definition demonstrates how amorphous ‘globalization’ as a taxonomy has become, reflecting unique, case-specific definitions across the scholarly landscape – within and beyond IPE and IR – that focus on particularities or dynamics found within globalization’s *economic*

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<sup>12</sup> See chart on Page 58 and page 86 in Scholte, *Globalization: A Critical Introduction*.

<sup>13</sup> Cockerham and Cockerham, *Health and Globalization*.

context, including Jenkins and others.<sup>14</sup>

Other economics-oriented definitions of globalization focus on select social experiences and storytelling that relate directly to processes of commercialization, trade, and economic integration.<sup>15</sup> besides its economic context, other definitions have focused on globalization's socio-economic and supraterritorial aspects. Jenkins' definition reflects an approach common to definitions of globalization: centering the phenomenon in terms of its economic *determinants*.

In *Globalization and Its Discontents* (2003), Joseph E. Stiglitz defines globalization as the "closer integration of the countries and peoples of the world."<sup>16</sup> So, too, do Joseph S. Nye, Jr. and John D. Donohue (2000), who define globalization as an increase in *globalism*, reflecting these socio-economic and supraterritorial dynamics. Nye and Donohue, however, contextualize the dynamics in terms of linkage politics, rather than Stiglitz's and others' focus on barrier reduction, and expand the frame of reference to include other facets of the global political economy, like health and the environment.<sup>17</sup> Jan Aart Scholte (2000) advances a breadth in approach similar to Stiglitz, Nye, and Donohue but introduces periodization besides supraterritoriality as conditions of contemporary globalization, particularly, the extent to which the human condition has recently acquired both a global dimension and "transworld solidarity."<sup>18</sup>

Framing the socio-economic integrative dynamics of globalization temporally, Scholte suggests that the post-1960 period, more than before, demonstrated the inappropriateness of applying "territorialist thinking... to today's world." While 1960 is helpful as a constructed starting

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<sup>14</sup> See, for example, Gilpin, Global Political Economy and Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*. For Drezner, globalization as "the cluster of technological, economic, and political processes that reduce the barriers to global economic exchange."

<sup>15</sup> Friedman, *The World Is Flat 3.0: A Brief History of the Twenty-First Century*.

<sup>16</sup> Stiglitz, *Globalization and Its Discontents*, 9.

<sup>17</sup> Nye, Jr. and Donohue, *Governance in a Globalizing World*.

<sup>18</sup> Scholte, *Globalization: A Critical Introduction*, 58, chart 2.

point, to Scholte it is more the accelerant rather than the true go-live date of globalization, or the “periodization of globalization,”<sup>19</sup> but that “large-scale, accelerated globalization” under which “global relations have... proliferated and attained their greatest significance” is a far more recent construct.<sup>20</sup> This temporal-spatial framing is similarly reflected in the historical contextualizing of modernity by Historians Stephen Kern (2003 [1983])<sup>21</sup> and Paul Johnson (1996 [1991]),<sup>22</sup> who agree that developing modern supraterritorial circumstances can be traced to historical events, particularly, the early-to-mid 19th century. Scholte finds commonality with Kern and Johnson, referring to the 18th century’s “global imagination” as taking root in the 19th and mid-20th centuries as “incipient globalization.”

Contemporary globalization, Scholte argues, differs from these prior periods of global politico-economic integration: we have arrived at “full-scale globalization,” where “‘supraterritorial’ relations between people” expand and deepen (i.e., “relative deterritorialization”) and collective notions of social space have shifted away from political orientations (“reconfiguration of geography, so that social space is no longer wholly mapped in terms of territorial places, territorial distances[] and territorial borders”).<sup>23</sup> The socio-economic and supraterritorial framing of globalization per Stiglitz, Nye, Donohue, Scholte, and others<sup>24</sup> are helpful because they expand the bounds of globalization scholarship to accommodate analysis of the political, economic, and social processes and outcomes of globalization.

The definitions are always patterned foremost on the visibility of change, specifically, in the politico-economic processes, structures, and actors (or actions) with established relevance in the

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<sup>19</sup> Robertson, “Glocalization: Time-Space and Homogeneity-Heterogeneity,” 36.

<sup>20</sup> Op. cit., Scholte, 62-64.

<sup>21</sup> Kern, *The Culture of Time and Space, 1880-1918: With a New Preface*.

<sup>22</sup> Johnson, *The Birth of the Modern: World Society, 1815-1830*.

<sup>23</sup> Scholte, *Globalization: A Critical Introduction*, 16 and 46.

<sup>24</sup> Waltz, “Globalization and Governance.” See also Lee, “The Spatial Dimension of Global Health.”

disciplines of Economics, IR, and International Political Economy. For example, the focus on physical change is prevalent in each of Scholte's, Nye and Donohue's, and Stiglitz's respective definitions, and that of Jenkins (discussed). The variety within and across these definitions demonstrate how specific processes, structures, and existing norms are changing (or have changed). Rather than being exploratory or critical, economic, socio-economic, and spatial-temporal framings reinforce the value of globalization instead of questioning the origins and consequences of its dynamics and modalities:

Scholte: Globalization is the "reconfiguration of geography, so that social space is no longer wholly mapped in terms of territorial places, distances, and borders."<sup>25</sup>

Nye, Jr. & Donohue: Globality refers to the "flows and influences of capital and goods... people and forces."<sup>26</sup>

Stiglitz: Globalization represents "the closer integration ... which has been brought about by the enormous reduction of costs of transportation and communication, and the breaking down of artificial barriers to the flows of goods, services, capital, knowledge, and (to a lesser extent) people across border."<sup>27</sup>

### 5.1.2 Globalization as the Processes of Modernity and Rationality

Focusing on the construction (in terms of its origins) and social consequences (in terms of both outcomes and influences) of globalization, Sociologist Roland Robertson suggests globalization has transformed global consciousness (i.e., the awareness of individuals of the world around them and their place in it), reconstituting the social processes and interactions of the world as smaller, "a single place" that has been "compressed."<sup>28</sup> Robertson rejects definitions that imply a specific normative value, what he calls "global unicity," as "misleading" because they imply globalization

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<sup>25</sup> Op. cit., Scholte, 16.

<sup>26</sup> Nye, Jr. and Donohue (2000) define globalism as "a state of the world involving networks of interdependence at multi-continental distances. These networks of interdependence are linked through flows and influences of capital and goods, information and ideas, people and forces, as well as environmentally and biologically relevant substances." See op. cit., Nye, Jr. and Donohue, *Governance in a Globalizing World*.

<sup>27</sup> Op. cit., Stiglitz, 9.

<sup>28</sup> Robertson, *Globalization: Social Theory and Global Culture*, 6.

constitutes a definitive move toward certain endpoints. Preferring typologies that are “neutral with respect to the risks, costs, benefits, and dangers,”<sup>29</sup> Robertson’s critique is enjoined by and follows that of fellow Sociologist Anthony Giddens (2012 [1990]).

Giddens’ *The Consequences of Modernity* describes globalization – what he calls “globality” – as the processes of modernity (i.e., the socio-political attributes of the modern era<sup>30</sup>) and rationality (i.e., knowledge and behavior are independent of experience, rooted in logic and objectivity)<sup>31</sup> spreading consistently and inconsistently, globally. Globalization is Enlightenment-era modernity and rationality on a global scale. The twin processes of modernity and rationality are “inherently globalizing,” not accidentally, because of four influences that represent helpful factors for examining the origins and consequences of contemporary globalization. These include, *first, differential power*, represented as differential access to ideas, services, goods, outcomes, and other social constructs of value, to actors in positions of power; such actors hold primacy in determining value.

*Second, the role of values is imperative*, changes to which “are not independent of innovations in cognitive orientation created by shifting perspectives on the social world.”<sup>32</sup> Reflecting Robertson’s focus on globalization as global consciousness, this shifting-permanency of values means that Rationalism does not and cannot apply to values, so they can both change and remain based on the shifting social construction of consciousness.

*The third factor, the impact of unintended consequences*, is intimately related to the *fourth factor*, or

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<sup>29</sup> Op. cit., Robertson, 6-8.

<sup>30</sup> For example, Giddens references the Nation-state system, capitalism, state surveillance, and exclusivity of the means of violence as “processes of modernity” that are globalizing. See Giddens, *The Consequences of Modernity*.

<sup>31</sup> Rationalism, or a belief that we come to knowledge through the use of logic and independently of sensory experience, was critical to the debates of the Enlightenment period, when the power of reason was lauded and valued as the only acceptable form of knowledge, versus knowledge that comes from experience. Contemporary tensions between positivist and normative models in Economics, the emerging scholarship of Alexander Wendt (*Quantum Mind and Social Science: Unifying Physical and Social Ontology*, 2015), and even the physicality of common definitions of globalization represent the continued dominance of Rationalism in scholarship and other facets of the human endeavor. See, on Rationalism, Johnston and Callender, “Multiple Perspectives on Economic Rationalism and the New Managerialism: Power and Public Interest?” See, on quantum ontology, Wendt, *Quantum Mind and Social Science*.

<sup>32</sup> Op. cit., Giddens, 42.

what Giddens describes at *the reflexivity of modern social life*. Defined based on modernity and rationality, globalization is rife with an ever-growing scope of unintended consequences that only the vast accumulation of knowledge could curb. Modernity, to the detriment of narrowing unintended consequence, “is directly involved with the continual generating of systematic self-knowledge,” which can neither differentiate between expert and common knowledge, nor account for the “intervention of an observer.”<sup>33</sup> Knowledge is in a constant state of self-production and expansion;<sup>34</sup> however, because of the social construction of knowledge, the expanded knowledge base is simultaneously individualized, influenced, and self-altered, making accumulation of all knowledge deeply impractical.

Globalization defined in terms of the tension inherent to a globalizing modernity, expressed through modernity’s myriad processes, has its roots in facticity and exteriority, or aspects of the modern self that are immutable social norms resistant to change and robust enough to compel or alter behavior. Facticity refers to the intractable conditions of rational existence, or how individual behavior (and collective behavior and constructed social processes) is deeply rooted in social facts. Exteriority refers to the external, the beyond self; Giddens explains that globalization-as-high-modernity expands the tensions between what is “extensional” and “intensional,” or when we begin to be influenced by, or give higher priority to, what is beyond us (i.e., external).<sup>35</sup> The extensional and intensional crises of the self; the inability to predict, control, or curb unintended consequences; and differential power in changing values engender a modern era – globalization – which practically imparts dialectics of personal and collective security-danger and trust-risk.

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<sup>33</sup> Ibid.

<sup>34</sup> If we individually generate a knowledge base, universally unconsciously derived by and through personal experience, Rationalism dictates such knowledge is logical, independent, true, thus driving a knowledge base so large as to make consequence-curbing accumulation impossible.

<sup>35</sup> Op. cit., Giddens, 153.



### 5.1.3 Globalization as a Continuous Global Political Process

In contrast to the socio-economic focus of Scholte and others, Ethan Kapstein (1999,<sup>36</sup> 2000<sup>37</sup>) centers globalization as a political phenomenon that is neither natural nor accidental, but incidental to policy decisions made after World War II among the western allies, particularly, at the Bretton Woods Conference of 1944. Kapstein defines globalization as an ongoing, continuous global political process constructing the contemporary world economic order. Specifically, he posits both leading state actors and international financial institutions (IFIs), what he calls “the current institutions of the world economy,” as politically designing and operating a “just economic order” that was intended to achieve two goals: the creation of wealth (by open international markets and free trade) and its equitable distribution (by domestic institutions).

Kapstein considers globalization through a political lens that counters the prior definitions’ emphasis on the practical *outcomes* of globalization. Rather, and reflecting on the Atlantic Charter of 1941 and failure of the Treaty of Versailles, he argues that post-war world leaders “who devised this system [globalization] hoped to reconcile national demands for social justice with global peace and prosperity.”<sup>38</sup> To “promote[] peace through interdependence, while it promoted prosperity through efficiencies that came... [from] free trade,” any unintended negative externalities would be managed through states’ domestic “welfare policies.”<sup>39</sup>

As Kapstein concluded, the “grand design” of compassionate neoliberalism did not live up to its own hype. Because the pace of development among lower-income economies was slower than anticipated, requiring greater direct aid flows from advanced economies than estimated (of at least 15 billion USD in the late 1950s), beginning in the 1970s, the U.S. and Europe adopted a

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<sup>36</sup> Kapstein, “Distributive Justice as an International Public Good: A Historical Perspective.”

<sup>37</sup> Kapstein, “Winners and Losers in the Global Economy.”

<sup>38</sup> Op. cit., Kapstein, 88.

<sup>39</sup> Ibid., 93

complementary policy of economic restructuring to leverage “trade as an engine of growth” to make up the difference. The decades since have demonstrated that neither political strategy was effective longitudinally at achieving global convergence in national incomes. Because of political decisions constituting the global political economy, Kapstein argues that the global poor have seen their share of income fall dramatically.<sup>40</sup>

#### 5.1.4 Redefining Globalization: Origins and Consequences, Rather than Outcomes

Giddens’ reflection on globalization-as-modernity builds on Gabriel García Márquez’s *One Hundred Years of Solitude* (2006 [1970]),<sup>41</sup> a landmark work in magical realism that deftly captures the elements of global structuralism, hegemony, and heterodoxic movements in response to particular outcomes well-noted in contemporary globalization: powerlessness and one-size-fits-all policy convergence. Building on García Márquez’s exploration of the cultural components of development and fragmenting implications for local communities, Giddens suggests globalization is reappropriating the dialects of trust and security within conditions of global risk and danger across modernity.

Consequentially, globalization is a tension-wrought interplay between the interpersonal and the international, between the needs of the local community and the global political-economy (i.e., glocalization and fragmegration) and between trust and risk. Giddens provides these examples: global capitalism has introduced the degrading and often dangerous nature of modern industrial work; the rise of the Surveillance state has empowered totalitarian political systems to grow and expand; state-exclusivity of the means of violence quickens the development speed of military-grade power and weaponry; and the Westphalian Nation-state system has become both overwhelmed and

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<sup>40</sup> Ibid., 100. According to recent estimates, 600 million people still live in extreme income poverty, or on less than 1.90 USD per day, which exceeds 1.3 billion when measured by the UN Multidimensional Poverty Index. Conceição, *Beyond Income, Beyond Averages, Beyond Today: Inequalities in Human Development in the 21st Century*.

<sup>41</sup> García Márquez, *One Hundred Years of Solitude*.

underpowered, allowing for the rise of biological, environmental, and commercial threats that may go unmitigated by official authority channels.

Returning to Kapstein's politically oriented typology, the underlying political processes that reflect Giddens' tension-wrought globality are evident. Political processes constitute the applied aspects of globalization, reflecting and reinforcing the invisible but implicit forces of modernity and rationality that define globality. When defined in terms of modernity and rationality, globalization's origins and consequences can be examined through the broader lens of who holds power and, can determine values and their appropriation; what is acceptable knowledge, particularly, in terms of hegemonic ideas, norms, and beliefs; how values are generated and changed, and by whom; why some processes and outcomes are generated over others (i.e., the unintended consequences that are or are not curbed); and how trust and risk are accumulated, ameliorated, and/or allocated. Each question reflects political conditions and the role of power, per Kapstein, and taken together represent a more meaningful lens through which to examine issues spanning the global political economy, including health.

This research adopts an amended variation of Giddens' and Kapstein's respective typologies of globality and globalization, which this research defines as:

The consistent and inconsistent globalizing of the processes of modernity and rationality, which are simultaneously constructed and applied through political means that magnify asymmetries in power and resources,<sup>42</sup> thereby, both enhancing and lessening the costs, benefits, and trust-risk dynamics of complex interdependence and global consciousness.

While the debate on what is and is not globalization is not settled, this adapted definition is fitting to the purposes of this research. The discussion now turns to the extant literature surveying the particular impact of globalization's more notable consequences – increased international trade and

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<sup>42</sup> Labonté and Schrecker, "Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution."

interdependent economic activity – on health. From there, a practical discussion of these consequences is explored through the lens of two overlapping dynamics of globalization, health, and the ‘Competition state’: the shrinking policy space for health and the shifting international political economy of medicines, the latter of which presents itself as a paradigm case for health, in its own right, being a core issue of the 21st century global political economy.

## 5.2 Health in a Globalized World

As reflected in the working definition of globalization this research applies, globalization is a two-sided, multifactorial assemblage of experiences and outcomes reflecting the political expression of the dual processes of modernity and rationality. The definition is intentionally neutral and presumes that globalization has both costs and benefits and trust-risk dynamics, and their binary expression (i.e., good or bad) is ultimately a political decision, construct, and outcome. Rather than narrowly focus on the particular consequences of economic development (or its absence) on health, this section examines somewhat holistically the range of consequential dimensions of the globalization-health nexus. Here the global adoption of ‘Flexnerianism’<sup>43</sup> as demonstrated by the ‘globalization of’ western medical practice standards (or the ‘westernization’ of medicine), and the practical consequences for health, are examined. Also examined are other systems of medical practice, including holism and traditionalism, and the practice of medicine, which collectively have adopted a mechanistic and individualist bent. The subchapter then turns to the slowing, if not stalling, health gains and rising health losses observed with particular attention over the past decade. The subchapter closes with an examination of how Flexnerianism, the shifting global burden of

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<sup>43</sup> Refers to the *Flexner Report* by Abraham Flexner, which critiqued medical schools in the U.S. and Canada at the turn of the 20th century for not following ‘laboratory’ medicine, which the American Medical Association (AMA), Johns Hopkins University, and other medical thought leaders strongly supported. Teaching institutions closed, merged with others, or were wholly restructured to adopt Flexnerianism approaches. According to Waitzkin, “the closure of many medical schools not based in laboratory science led to fundamental changes in the class composition of the profession, changes that went hand in hand with reduced competition and higher individual incomes for doctors.” See Waitzkin, “The Marxist Paradigm in Medicine,” 686.

disease, and the marketization of health complicates, rather than make efficient and addressable efforts to achieve a disease-free world.<sup>44</sup>

### 5.2.1 Globalization of Flexnerianism: The Individualist-Mechanistic Ideology of Medicine

As Sneha Mantri (2003) notes, rationalism-based scientific explorations, often called pathologic or morbid anatomy, in the 17th century gave rise to gross and microscopic anatomy, the cataloguing of diseases, etiological connections of illness to specific anatomical locations, and, ultimately, the technological advancement of treatment reflecting a “‘foci of interest’ in organ systems” and rooting in “scientific validity.”<sup>45</sup> the medical practice regimes of China, Egypt, and India did not develop under a similar model of scientific determinism and Rationalism, because, as Porter argues, “religious and cultural beliefs discouraged such inquiry.”<sup>46</sup> As Vicente Navarro (1976) notes, the science of medical practice and its individualization are not coincidental, but an outgrowth of rationalism:

Medicine is indeed socially useful to the degree that the majority of people believe and accept the proposition that what are actually politically caused conditions can be individually solved by medical intervention. From the point of view of the [global] capitalist system, this is the actual utility of the medicine—it contributes to the legitimation of capitalism.<sup>47</sup>

Besides Giddens’ examination of the primacy of rationality as a co-constitutive force of globalization (along with modernity), Max Weber (2013 [1922])<sup>48</sup> similarly explored the role of Enlightenment-era Rationalism in the rise of capitalism and Industrial Revolution across Europe and the Americas. While Weber’s analysis did not incorporate health in terms of the practice of medicine, it was intended to establish a theoretical framework for activities, goods, services, and other modes of

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<sup>44</sup> *World Health Statistics 2020: Monitoring Health for the SDGs, Sustainable Development Goals.*

<sup>45</sup> Mantri, “Holistic Medicine and the Western Medical Tradition.”

<sup>46</sup> *Ibid.*, 25.

<sup>47</sup> Navarro, *Medicine Under Capitalism*, 208.

<sup>48</sup> Weber, *Economy and Society*.

economic activity associated with the ‘free market.’ Specifically, Weber argued that Rationalism represents a framing of knowledge, ideas, and beliefs that has been particular to the West from Enlightenment to the modern era. Formal rationality, per Weber, economically constructs higher valuations of practical outcomes and efficiencies that can be proceduralized and quantified, over abstract or communal notions (e.g., Fordist modes of factory).

The European vision of scientific medicine carried forward from the Enlightenment into the contemporary “ideology of medicine” was not isolated to that portion of the north Atlantic. The ideas and beliefs about science and its role in health was paralleled in the U.S. with the “victory of Flexnerianism.”<sup>49</sup> Flexnerianism, as introduced by Thomas McKeown (1971), regards “a living organism... as a *machine* which might be taken apart and reassembled if its structure and functions were fully understood.”<sup>50</sup> Reflected in the rationalism-based scientific practices of pathology and morbid anatomy, Vicente Navarro (1976) argues that Flexnerianism imparts a “mechanistic conception of medicine, in which it is assumed that disease is the imbalance of the components of the *machine-like body*” (emphasis added), an approach that implicitly *individualizes the cause of disease* and the clinical treatment of it.<sup>51</sup>

This individualist-mechanistic view, Navarro notes, structures the individualization and, *depoliticization* of health, absolving politico-economic responsibility for *actual health*—save for “those health programs, such as health education, that are aimed at bringing about *changes in the individual* but not in the economic or political environment,” akin to the 19th century working-class diseases

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<sup>49</sup> Op. cit., Navarro, 206-207.

<sup>50</sup> McKeown, “A Historical Appraisal of the Medical Task.”

<sup>51</sup> Op. cit., Navarro, 206. Notably, ideas that the working class of 19th century England experienced significant disease prevalence because of poor diets and malnutrition has been debunked; see Clayton and Rowbotham, “An Unsuitable and Degraded Diet? Part One: Public Health Lessons from the Mid-Victorian Working Class Diet.” The concept of public health education, also referred to as behavioral health promotion, has been extensively evaluated. Baum and Fisher, “Why Behavioral Health Promotion Endures despite Its Failure to Reduce Health Inequities.”

associated with ‘immorality’<sup>52</sup> and ‘poor moral fibre’ and calls for ‘self-care’ of 1970s U.S. and Canadian public health efforts.<sup>53</sup>

The individualist-mechanistic vision of health compares sharply to the environmentalist-structuralist approach of historical public health and medical sociology practitioners, including those of 19th century public health reformers “Virchow in Silesia, Engels and Chadwick in the U.K., and Villermé in France.”<sup>54</sup> Indeed, Friedrich Engels’ seminal 1844 account, *The Condition of the Working Class in England*, describing the effects of the Industrial Revolution, as a politico-economic system, on the workplace and living conditions of the poor—and their health.<sup>55</sup> Reflecting the observations of Engels and his peers, the environmentalist-structuralist approach reflects a “triple helix” of public health, referring to a tri-part focus on “genetics, organism, and environment” (i.e., biology, behavior, and the social, economic, and political systemic determinants) as interactively producing health or driving illness.<sup>56</sup>

Recent literature has explored resurfaced variants of ‘biomedical’ practice and public health *defined by* an exclusive focus on individual ‘at-risk’ behaviors and the necessity of ‘self-care’ ([Chapter 5.2.4](#)’s discussion of synergy and co-production). The contemporaneous individualist-mechanistic view of health similarly has been critiqued (Richard Levins 2000; Daniel Weber 2016; John Bellamy Foster et al. 2021; Jennifer Dohrn and Eleanor Stein 2021);<sup>57</sup> linked to structural issues of systemic racism, patriarchy, and colonialism (Paul Farmer 2003, 2020;<sup>58</sup> Richard Lewontin and Levins 2007);<sup>59</sup>

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<sup>52</sup> R. Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity* (*The Norton History of Science*).

<sup>53</sup> Navarro, *Medicine Under Capitalism*, 208. See also Lalonde, “A New Perspective on the Health of Canadians;” Kickbusch, “Self-Care in Health Promotion;” and National Research Council Panel on Race, Ethnicity, and Health in Later Life (U.S.), *Behavioral Health Interventions: What Works and Why?*

<sup>54</sup> Op. cit., Baum and Fisher, 214.

<sup>55</sup> Engels, *The Condition of the Working Class in England*.

<sup>56</sup> Lewontin and Levins, *Biology Under the Influence: Dialectical Essays on the Coevolution of Nature and Society*.

<sup>57</sup> See, for example, Dohrn and Stein, “Epidemic Review;” Weber, “Medical Hegemony;” Levins, “Is Capitalism a Disease?” and Foster, Clark, and Holleman, “Capital and the Ecology of Disease.”

<sup>58</sup> See, for example, Farmer, *Pathologies of Power*; “A Critique of Market-Based Medicine;” and *Fever, Feuds, and Diamonds: Ebola and the Ravages of History*.

<sup>59</sup> Op. cit., Lewontin and Levins.

and persistent not only in western public health and general medical practices, but also in globally and across the physical sciences, including epidemiology (Eugene T. Richardson 2020)<sup>60</sup> and genetics (Lewontin and Levins).<sup>61</sup> As demonstrated by Engels et al., McKeown, Navarro, Levins, Weber, Foster et al., Dohrn and Stein, Farmer, Richardson, and others, western medical practice, in the Flexnerian style, has a demonstrated and extensive relationship to the market, and capitalism in particular—even *under systems of public financing*.

### 5.2.2 Globalization of Western Medical Practice Standards: The Hegemony of Biomedicine

Drawing on Roy Porter's (1997)<sup>62</sup> analysis of the history of medicine, Geoffrey B. Cockerham and William C. Cockerham (2010) find that transferring western medicine is not only a fixture of contemporary globalization but, more important, a product of discursive power framing this style of medical practice as "the most effective type of treatment for disease."<sup>63</sup> To Cockerham and Cockerham's point, the title of Porter's analysis, *The Greatest Benefit to Mankind: A Medical History of Humanity* is an on-the-nose example of narrative as reinforcing specific norms over others. Here, the value of western medicine. To Cockerham and Cockerham's thesis, Porter states that western medicine "has developed in ways which have made it uniquely powerful and led it to become uniquely global," referring to the systematic scientific investigation of the body, diagnoses of illness, and their treatment.<sup>64</sup>

Reflecting on the premised globalization of Flexnerianism (Chapter 5.2.1), it is possible to apply Weber's findings on Rationalism to understand Porter's conclusion of the 'victory' of western medical practice standards *due to the globalization of Flexnerianism*. This discursive construction can be

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<sup>60</sup> Richardson, *Epidemic Illusions*.

<sup>61</sup> Op. cit., Lewontin and Levins.

<sup>62</sup> Op. cit., R. Porter.

<sup>63</sup> Cockerham and Cockerham, *Health and Globalization*, 25.

<sup>64</sup> Op. cit., R. Porter, 6.



observed in the dichotomy expressed in Porter's (1999) historical accounting of the recent and nascent interconnection of global health and western medical practice:

Before the 20th century, the health problems of the industrial world were largely distinct and independent from those of the colonized; in many respects, the 'West' and the 'Rest' were still just making contact. During the 20th century all grew interlocked, through the transformation of empires, gigantic population migrations, the changes wrought by multinational capitalism, communications revolutions, world war, and global politics.<sup>65</sup>

Per Navarro (1975, 1976),<sup>66</sup> western medicine is a hegemonic "ideology of medicine which complements, rather than conflicts, with the ideology of capitalism, i.e., liberalism and individualism."<sup>67</sup>

Through the lens of globalization and discursive power, this account can be examined as problematic in at least two ways. *First*, reflecting Rationalism, it presumes neutral value: that is, 'western medicine' is better because it is scientifically valid and reflects technological advancement over 'traditional medicine,' so it should dominate the making of global health. As the discussion of Giddens and Robertson illuminated, awareness, consciousness, knowledge, ideas, and beliefs – including of the relative value of scientific process, styles of medical or healing practices, and the importance of logical, efficient systems and outcomes – are social constructs furthered as the systemic generation of 'real' self-knowledge. Knowledge is individually and socially constituted, resulting in the potential for personal, cultural, political, and other biases that, unless resolved, persist as 'logical' under modes of rationality.

The accounting reflects cultural biases that "traditional medicine and healing" are "superstitious practices that hinder evidence-based therapy [and] cause harm to the patient."<sup>68</sup>

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<sup>65</sup> Op. cit., R. Porter, 483.

<sup>66</sup> Navarro, "The Political Economy of Medical Care: An Explanation of the Composition, Nature, and Functions of the Present Health Sector of the United States."

<sup>67</sup> Op. cit., Navarro, 206.

<sup>68</sup> Li, "Indigenous Identity and Traditional Medicine: Pharmacy at the Crossroads," 279.

Conversely, as Reanne Li (2017), Deborah Lupton (2012),<sup>69</sup> and others in the Medical Sociology and Anthropology fields suggest, such styles of medicine and healing practices are culturally rooted and, following political decisions that forcibly applied western medicine practices on Indigenous communities, are viewed as tools of power “integral [to] regaining their autonomy and empowerment.”<sup>70</sup>

Reflecting this hegemony of western medical practice, *second*, the account lacks historical context, failing to explain the significant and complicated (in terms of health and many other facets) interactions between, as Porter describes, the “west and the rest,” including the extensive pre-20th century colonization of much of the world outside of Europe – from the Americas to Asia, Australia, and Africa – and, often, the association of western medical practice with introducing disease, lifestyles, and health care treatments that oppressed, marginalized, and destabilized Indigenous populations. While this research cannot articulate so it is meaningful and appropriate to the extensive history of colonialism and systemic discrimination, including “attempts to propagate western medicine,”<sup>71</sup> introduction of foreign disease, and use of these practices – called the hegemony<sup>72</sup> of the “biomedical tradition”<sup>73</sup> – the argument here is that western medical practices contributed to the politically engineered ostracism and destruction of Indigenous cultures in colonized countries around the world.

As explored in Chapter 2, contemporary medical practice standards, to the detail of treatment guidelines, essential medicine lists (EML), and even what is considered good clinical practice (in terms of pharmaceutical clinical trials), have been politico-economically constituted as ‘policy best

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<sup>69</sup> Lupton, *Medicine as Culture: Illness, Disease And The Body*.

<sup>70</sup> Op. cit., Li, 279.

<sup>71</sup> Verma, “Western Medicine, Indigenous Doctors and Colonial Medical Education: A Case of Desire for ‘Hegemony’ in Conflict with Demands of ‘Colonial Partiality.’”

<sup>72</sup> For a discussion of Gramsci and the roots of hegemonic theory, see Bates, “Gramsci and the Theory of Hegemony.”

<sup>73</sup> Garcia Vazquez, “Indigenous Medical Tradition and Biomedical Tradition: A Historical Relation of Hegemony.”

practices,' packaged and prepared for the consumption of select, usually less powerful, state actors as part of international development commitments. The earlier discussion of Tanzania and the role and influence of international institutions in recommending a specific EML and corresponding treatment guidelines as part of the state's structural adjustment program (SAP) requirements highlight how power frames western medical practice, discursively, as a scientific good and necessity to be protected and advanced through systemic processes of policy coordination and convergence.

Dani Filc (2004),<sup>74</sup> Deborah Lupton (2012),<sup>75</sup> Daniel Weber (2016),<sup>76</sup> and Strüver V. Ibeneme et. al. (2017),<sup>77</sup> among others in the extant literature on medical practice and hegemony, similarly discuss how systems of medical practice "represent, and are influenced by, the cultural environment in which they exist,"<sup>78</sup> including individual experiences, the experiences of communities, customs, traditions, other norms, and intuitions. The value of one medical system of practice is socially constructed, versus pre-determined. Returning to Lupton (2012), she notes such processes have explicit consequences for individual perceptions of health and illness, and for the differential power of certain forms of health (and associated industries and actors) over others:

Western societies in the early 21st century are characterized by people's increasing disillusionment with scientific medicine. Paradoxically, there is also an increasing dependence upon medicine to provide the answers to social as well as medical problems...

With the current obsession for locating the genetic precursor of illness, diseases, and behaviors, the knowledge base of western medicine has encroached even further into defining the limits of normality and the proper functioning and deportment of the human body...

The dependence on rationality and individualism... the turn to biomedicine and science as the ultimate weapons against illness, disease, and premature death have all generated ideas and practices which tend to deny the fragility and mortality of the

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<sup>74</sup> Filc, "The Medical Text: Between Biomedicine and Hegemony?"

<sup>75</sup> Op. cit., Lupton.

<sup>76</sup> Weber, "Medical Hegemony."

<sup>77</sup> Ibeneme et al., "Roads to Health in Developing Countries: Understanding the Intersection of Culture and Healing"

<sup>78</sup> Op. cit., Ibeneme et. al., 13.

human body. For the populations of western societies, serious illness and death are strange, mysterious, frightening, and unexpected events.<sup>79</sup>

The western system of ‘biomedical’ practice – inclusive of Flexnerianism, the individualist-mechanist ideology of medicine, and now ‘biopharmaceutical’ reliance – is complicated in its own right, including in terms of its own patients, historical mistreatment of globally marginalized communities of other medical systems’ patients, and its role as a constructed instrument of hegemonic power. Similarly, the processes of globalization reconstitute western medical practices as informal global health governance of the ideas, norms, and standards governing the everyday experience of health care between doctors and patients, and what is considered ‘health’—meaning the production and distribution of health. This complex interplay of coercive and discursive power introduces select health gains and the potential for unevenness and numerous risks, including the elevation of medical science, bio-pharmaceutical innovation, and other health technologies alongside deterioration in key indicators of health, systems-based public health interventions, community health norms and ideologies of medicine and collective versus individual responsibility for health.

### 5.2.3 Globalization of Disease: The Global State of Incomplete Health

The globalization of Flexnerianism and western systems of medical practice are important and interconnected aspects of health in a globalized world. But what does it mean for *actual* health: for the state of global disease burden, considered illness as compared to health, and how to care for ourselves and each other? From the lens of global health governance theorists and IPE scholars, it means the rise of global pandemics of infectious disease, as noted by Howard Waitzkin, referring to the core components of infectious disease, epidemiology, and Medical Sociology pioneer Rudolph Virchow:

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<sup>79</sup> Op. cit., Lupton, 1-2.

First, the etiology of disease is multifactorial. Among the most important factors in causation are the material conditions of people's everyday lives. Second, an effective health care system cannot limit itself to treating the pathophysiological disturbances of individual patients.<sup>80</sup>

From the perspective of global governance scholars, at the turn of the 21st century, the economic consequences of globalization were accelerating significantly, yielding 'spill-over,' cross-border risks; namely, the spread of infectious disease (Table 5.2-A). The frequency and severity of global infectious disease pandemics have accelerated in the prior two decades, and much IPE scholarship has been devoted to exploring the "transcendence of geography"<sup>81</sup> that was characterizing a growing range of social issues—including global health—by rendering states' territorial boundaries irrelevant. How would the globe self-manage infectious disease flows in an anarchic international system? What global government would step in to help states "address effectively what state institutions alone"<sup>82</sup> could not? Much ink has been spilled exploring these questions through the lens of governance, particularly, international regulatory coordination around ports of entry and similar barriers to disease flow, and security, including implications of global infectious disease flows for states' military forces.<sup>83</sup> What this body of scholarship did not address, however, were the characteristics and consequences of globalization for health, versus the politico-economic consequences of a particular disease.<sup>84</sup>

For example, in 2001 the World Health Organization (WHO) established the Commission on Macroeconomics and Health to examine the interplay global economic integration and related social processes, including health. The Commission's specific focus was to consider the intersection

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<sup>80</sup> Waitzkin, "The Marxist Paradigm in Medicine."

<sup>81</sup> Dodgson, Lee, and Drager, "Global Health Governance, A Conceptual Review," 5 in Kirton, *Global Health* (2009).

<sup>82</sup> Op. cit., Dodgson, Lee, and Drager, 5.

<sup>83</sup> Op. cit., Elbe. See also Elbe, "Should HIV/AIDS Be Securitized? The Ethical Dilemmas in Linking HIV/AIDS and Security," Chapter 26 in, op. cit., Kirton (2009).

<sup>84</sup> Framing health in terms of politico-economic risks has extended beyond the bounds of infectious disease, including to noncommunicable diseases (NCDs), which are diseases that may not as easily be transmitted from person to person (though some NCDs have infectious components).

**Table 5.2-A. Brief accounting of global infectious disease pandemics, by century**

<u>21st Century</u>	<u>20th Century</u>	<u>19th Century</u>	<u>18th Century &amp; Earlier</u>
<i>SARS-CoV-1</i> 2002-03 813 est.	<i>Polio</i> 1916-54 6,000	<i>Russian Flu</i> (H2N2 or A/H3N8) 1889-93 1 million	<i>Plague of Justinian</i> 541-543 100 million est.
<i>Swine Flu (H1N1)</i> 2009-10 151,700-575,400 est.512F <sup>85</sup>	<i>Spanish Flu (H1N1)</i> 1918-20 100 million	<i>Third Plague</i> (China and India) 1855-1960 12 million	<i>Bubonic Plague</i> 1334-51, with waves into the 19th century 200 million est.
<i>Bird Flu 2 (H7N9)</i> 2013 to Present 1,568	<i>Asian Flu (H2N2)</i> 1957-59 1.1 million	<i>Cholera 1-6</i> 1817-1923 Unknown, but high, with mortality rates exceeding 11%514F <sup>87</sup>	<i>Smallpox</i> 1520-1972 56 million
<i>Ebola</i> 2014-16 11,325	<i>Cholera 7</i> 1961-75 155,000	<i>Yellow Fever (U.S.)</i> 1800-79 100,000-150,000 est.	<i>17th and 18th Century Great Plagues</i> 1665-1817 3.6 million
<i>MERS-CoV</i> 2015 to Present 866	<i>Hong Kong Flu (H3N2)</i> 1968-70 1 million		
<i>ZIKA</i> 2015 to Present 51	<i>Bird Flu (A/H5N1)</i> 1998 to Present 350		
<i>Covid-19</i> (SARS-CoV-2) 2019 to Present 3.2 million513F <sup>86</sup>	<i>HIV/AIDS</i> 1981 to Present 40 million est.		

Compiled from LePan, Routley, and Schell, "Visualizing the History of Pandemics;" Paul and Pal, "A Brief History of Pandemics;" Piret and Boivin, "Pandemics Throughout History;" Snyder and Ravi, "1818, 1918, 2018: Two Centuries of Pandemics;" and Cardona-Ospina et al., "Fatal Zika Virus Infection in the Americas."

<sup>85</sup> Centers for Disease Control and Prevention, "2009 H1N1 Pandemic (H1N1pdm09 Virus)."

<sup>86</sup> The WHO estimates mortality of 3.23 million as of May 13, 2021. See "WHO Coronavirus (Covid-19) Dashboard."

<sup>87</sup> For example, some estimates of the pandemic in India suggest annual mortality of 1.3 million between 1817 and 1924. An analysis of the pandemic in Italy suggests a mortality rate of 11.1%; see Imperato, Imperato, and Imperato, "The Second World Cholera Pandemic (1826-1849) in the Kingdom of the Two Sicilies with Special Reference to the Towns of San Prisco and Forio d'Ischia."

of health and economic development for the global poor, intended to inform practices and policies to achieve the health-related targets of the United Nations 2000 Millennium Development Goals (MDGs). The Final Report described states of ill health as engendering “medical poverty traps,” acknowledging a complex interdependence between health and economic development that is bidirectional. That is, health is indispensable to economic development, but health is *not* being improved by the processes, policies, and outcomes associated with global economic growth and development.<sup>88</sup> The Commission observed that globalization’s “benefits are not reaching hundreds of millions of the world’s poor” and health is one of the “new kinds of international challenges” of global interdependence.

The Commission’s report was considered groundbreaking for international development efforts, laying the groundwork for further inquiry into the dynamic relationship between health, global market integration, and interdependent political processes. Specifically, the 2001 report would charter a course of extensive evidence generation, research, and action within the WHO, including a 2005 follow-up Commission premised on identifying the structural barriers to global health equity and potential mechanisms of action. Charged with examining the determinants of health articulated by the Commission on Macroeconomics and Health, the Commission on Social Determinants of Health (CSDH) set out to map those areas that, if addressed, were likeliest to reduce observed inequities in global health.<sup>89</sup>

These Globalization Knowledge Networks (GKNs) did not, at the outset, firmly establish corollaries between health and the dynamics of globalization. The GKNs did, however, define the leading determinants of health for the purposes, *first*, of generating evidence and analysis and, *second*,

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<sup>88</sup> World Health Organization, “Macroeconomics and Health: Investing in Health for Economic Development.”

<sup>89</sup> Irwin et al., “The Commission on Social Determinants of Health: Tackling the Social Roots of Health Inequities.”

informing implementation of a responsive global strategy. The nine GKNs include globalization,<sup>90</sup> employment conditions, social exclusion, priority public health conditions, women and gender equity, early childhood development, urbanization, health systems, and measurement and evidence. To assist in the issue identification and analysis of health determinants along the nine GKNs, the WHO partnered with the University of Ottawa Institute of Population Health.<sup>91</sup> Separately, the Norwegian Agency for Development Cooperation, other agencies of the Norwegian government, and philanthropic support of the University of Oslo and Harvard Global Institute at Harvard University (U.S.) sponsored The Lancet-Oslo Commission on Global Governance for Health (2014). In their respective final reports, the Ottawa Institute GKN (2007)<sup>92</sup> and the Lancet-Oslo Commission (2014)<sup>93</sup> found not only corollaries between health and global politico-economic systems, but structural causalities: notably the “political origins of inequity” (Table 5.2-B).<sup>94</sup>

For example, the Ottawa Institute GKN, led by Ronald Labonté and Ted Schrecker, found that “globalization policy-driven changes,” including structural adjustment programs (SAPs), financial market liberalization, “collapse of public institutions and safety nets,” and other policies to maximize trade openness “reduced potential gains in life expectancy at birth (LEB) by 1.23 years, due primarily to increases in income inequalities.”<sup>95</sup> The declines in LEB were more acute in sub-

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<sup>90</sup> For the purposes of the GKNs, globalization is defined as “a process of greater integration within the world economy through movements of goods and services, capital, technology, and (to a lesser extent), labor, which lead increasingly to economic decisions being influenced by global conditions.” See Jenkins, “Globalization, Production, Employment and Poverty: Debates and Evidence.”

<sup>91</sup> This partnership generated dozens of issue papers, literature reviews, and reports on a spectrum of health-globalization issues, including regulations, redistribution, governance, social determinants of health, impact of trade and investment agreements, and many others. For a sampling, see Labonté and Schrecker, “Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution,” Labonté et al., *Globalization and Health: Pathways, Evidence and Policy*; Labonté and Torgerson, “Frameworks for Analyzing the Links Between Globalization and Health,” Labonté and Schrecker, “Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution,” “Globalization and Social Determinants of Health: Introduction and Methodological Background,” “Globalization and Social Determinants of Health: Analytic and Strategic Review Paper,” Correa, “Intellectual Property Rights and Inequalities in Health Outcomes,” Gleeson et al., “Analyzing the Impact of Trade and Investment Agreements on Pharmaceutical Policy: Provisions, Pathways and Potential Impacts,” and Lister and Labonté, “Globalization and Health Systems Change.”

<sup>92</sup> Op. cit., Labonté and Schrecker (2007).

<sup>93</sup> Ottersen et al., “The Political Origins of Health Inequity: Prospects for Change.”

<sup>94</sup> Op. cit., Ottersen et al.

<sup>95</sup> Op. cit., Labonté and Schrecker (2007), 9-10.



**Table 5.2-B. Findings of the UN Commission on Social Determinants of Health and The Lancet-University of Oslo Commission on Global Governance for Health**

<u>Categories of Interrelation</u>	<u>University of Ottawa Institute of Population Health (2007)</u>	<u>The Lancet-University of Oslo Commission on Global Governance for Health (2014)</u>
Health Impacts	<p>Improves <i>and</i> impairs life expectancy at birth, including gains of 1.45 years globally over the 1980-2000 period and losses of 1.23 years for 1960-80 period</p> <p>Contributes to improvements in traditional and new measures of global health—but here, too, the declines are slowing<sup>96</sup></p> <p>Marketizes health via neoliberal reforms, which “have contributed to health care resource scarcities”<sup>97</sup></p> <p>Contributes to progress in health technology, which may produce technology-facilitated health gains</p> <p>Increases global trade in and the transnational production of food, which is associated with nutritional transition from home-produced to store-bought foods and obesogenic (“toxic”) food environments<sup>98</sup></p>	<p>Embeds and deepens disparities in health outcomes</p> <p>Sustains systemic barriers and inequities, including racism, sexism, and poverty, which diminish “their [individuals affected by disparities] control over their own life circumstances”</p> <p>Emphasizes the biomedical model, including the individualization of health, Flexnerianism, and focus on “the substantial technological advances” of modern medicine</p> <p>Depoliticizes health by construing “inequities as problems of technocratic or medical management”<sup>99</sup></p>

<sup>96</sup> Such measures include the U5MR, maternal mortality rate, prevalence of infectious diseases, and premature NCD-affiliated mortality. The yearly percent-change in premature NCD mortality, which had been declining at a rate of -1.6% since 2000, slowed to a decline of -1.1% beginning in 2010. See, op. cit., Adhanom Ghebreyesus (2021).

<sup>97</sup> Privatizes and marketizes health “on the open market as the normative baseline” for the world.

<sup>98</sup> Refers to the settings (“built environments”) in which we live and eat, our food environments, whether our homes, neighborhoods, worksites, or schools, and how such environments influence which foods are available, how much they cost, and whether the people in those settings are eating healthy diets. Numerous literature articulates the occurrence of this transition and its health impacts, both within developing and emerging economies and advanced economies. See Lake and Townshend, “Obesogenic Environments: Exploring the Built and Food Environments;” Mustajoki, “Obesogenic Food Environment Explains Most of the Obesity Epidemic;” Hobbs and Radley, “Obesogenic Environments and Obesity: A Comment on ‘Are Environmental Area Characteristics at Birth Associated with Overweight and Obesity in School-Aged Children? Findings from the SLOPE (Studying Life course Obesity Predictors) Population-Based Cohort in the South of England;” Larson and Story, “A Review of Environmental Influences on Food Choices;” Swinburn, Egger, and Raza, “Dissecting Obesogenic Environments: The Development and Application of a Framework for Identifying and Prioritizing Environmental Interventions for Obesity;” Booth et al., “Environmental and Societal Factors Affect Food Choice and Physical Activity: Rationale, Influences, and Leverage Points;” and Lovasi et al., “Built Environments and Obesity in Disadvantaged Populations.”

<sup>99</sup> In so doing, as Ottersen et al. (2014) note, health and other “social and political ills” are “depoliticize[d] ... and can pave the way for magic-bullet solutions that often deal with symptoms rather than causes.” Ibid., Ottersen et al., 636.

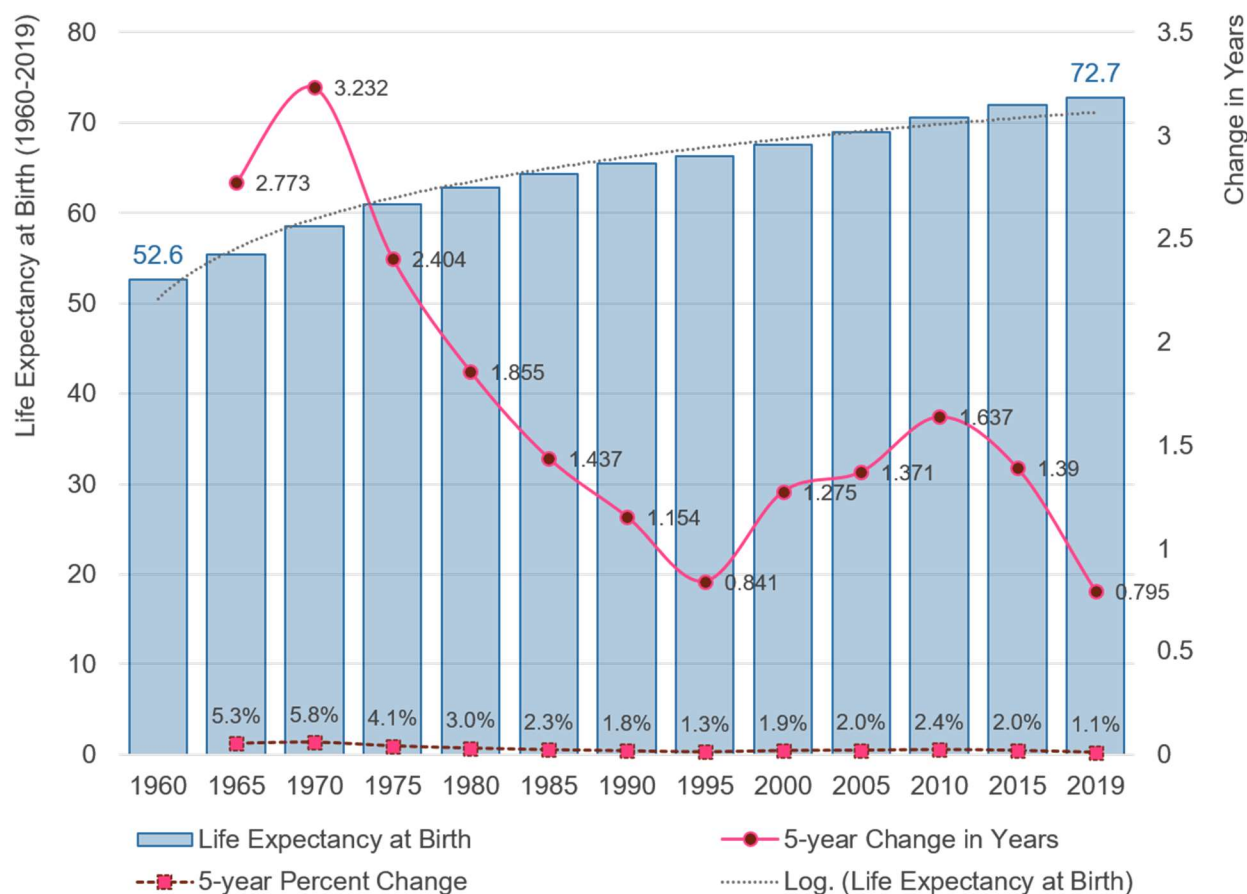
Table 5.2-B, Continued

<u>Categories of Interrelation</u>	<u>University of Ottawa Institute of Population Health (2007)</u>	<u>The Lancet-University of Oslo Commission on Global Governance for Health</u>
Economic Determinants	<p>Reproduces gender hierarchies through a “global political economy of care work... done by women”<sup>100</sup></p> <p>Drives “labor ‘flexibility,’” which favors firms over workers and imparts negative externalities as firms and national economies compete for lowest net costs and highest efficiencies</p>	<p>Produces asymmetrical growth within and between economies, “creating winners, losers, and growing inequities”</p> <p>Increases income inequality sharply both between and within countries</p>
Political Determinants	<p>Ties domestic policymaking on health to international financial institution-established performance criteria</p> <p>Weakens the universal rights of many, including “to the progressive realization of their right to health”</p> <p>Shrinks the national policy space, by prioritizing economic competitiveness and market liberalization, subordinating other policy areas to economic concerns, limiting policy choices,<sup>101</sup> or excluding them entirely</p> <p>Limits “the range of choices and constrain action on health inequity” because political determinants of health are “reinforced by systemic global governance dysfunctions”</p>	<p>Defines ‘political determinants of health’ as the “norms, policies, and practices that arise from transnational interaction” which “cause and maintain health inequities”</p> <p>Trades off health, social systems, and ecosystems against economic interests and market forces</p> <p>Operates through global norm generation to guide societal interaction, including how issues are constructed and contextualized and what solutions can be proposed and accepted</p> <p>Shapes <i>processes</i> of global governance in alignment with dominant interests</p> <p>Requires global political solutions and “vigilance across all policy arenas” to advance improvements to global health</p>

<sup>100</sup> Labonté and Schrecker conclude that “[o]ne of the most important barriers to women’s ability to participate as full economic actors in the global economy is their domestic responsibilities and, for a large subgroup, their childcare responsibilities. These responsibilities, in turn, and the lower pay accorded women workers throughout the world, reflect deeply entrenched patterns of gender discrimination. Policy priority should be given to providing all women with access to childcare, free or at minimal cost, through the appropriate combination of labor standards and direct public expenditure by national governments and development assistance providers.” See op. cit., Labonté and Schrecker (2007), 11.

<sup>101</sup> Though traditionally concerned a problem of the global South, Labonté and Schrecker demonstrate how the ease and speed with which large-scale investors (e.g., firms, Venture Capital) “can shift funds around the world in response to the prospect of economic instability or higher taxation also reduces

**Figure 5.2-A. Global life expectancy at birth, in Total years with trends (1960-2019)**



Author data construction and logarithmic analysis of World Bank Group, *DataBank* | *Life Expectancy at Birth, Total (Years)*, 1960-2019.

Saharan African and Latin American countries and the former Soviet Union. The report notes that the 1960-80 declines in life expectancy were reversed across the 1980-2000 period through observable average annual gains of 1.45 years. These gains, note Labonté and Schrecker, were driven primarily by “progress in health technology,” or improvements in biomedical technologies and innovations including the heightened use of and innovation within pharmaceuticals—instead of improvements brought by the collective reduction in total health risk. (The authors also note reductions in global HIV/AIDS prevalence and mortality and in the under-five mortality rate

(U5MR) reversed the prior two-decade losses.<sup>522</sup>F102) 2019 tells a slightly different, and slightly worse, story (Figure 5.2-A). Global life expectancy improved quickly and meaningfully between 1960 and 1970, from 52.6 years to 58.6 years—a total gain of 11.4% and average five-year gain of 5.6% in a single decade.<sup>523</sup>F103 Within the UN Commission on Social Determinants of Health’s final report (2007), the Commission itself notes that “globalization policy-driven changes reduced potential gains in life expectancy at birth by 1.23 years, due primarily to increases in income inequalities.”<sup>530</sup>F104 Though global life expectancy gains since 1970 have sustained in terms of total years, from 52.6 to 72.7 years (1960-2019), the pace and significance of these gains fell sharply between 1970 and 1975, when global market integration first accelerated. Life expectancy gains continued to slow through 1995 and, following a pick-up between 1995 and 2010, appear to be on a similar declining path for 2010 and beyond. Overall, after five-year average gains of 5.6% between 1960 and 1970, gains in LEB slowed dramatically each successive decade (excluding the early 2000s): 1970-80, 4.3%; 1980-90, 2.4%; 1990-2000, 1.7%; 2000-10, 2.1%; and 2010-19, 1.8%. The latest five-year average increase, for the 2015-19 period, is the slowest rate of LEB gains yet at 1.1%. And that is before the potentially significant impact of Covid-19 on global life expectancy rates for the 2020-22 period, which have the potential to further the decline in gains or reverse gains.

In the past quarter-century of accelerated global market integration, however, health improvements have slowed or reversed, according to Labonté and Schrecker. In part this can be observed by recalling the global commitment to health, as a condition of global economic development, which was embedded in the United Nation’s 2000 Millennium Development Goals and its follow-on 2015 Sustainable Development Goals. The shifting health risks also can be

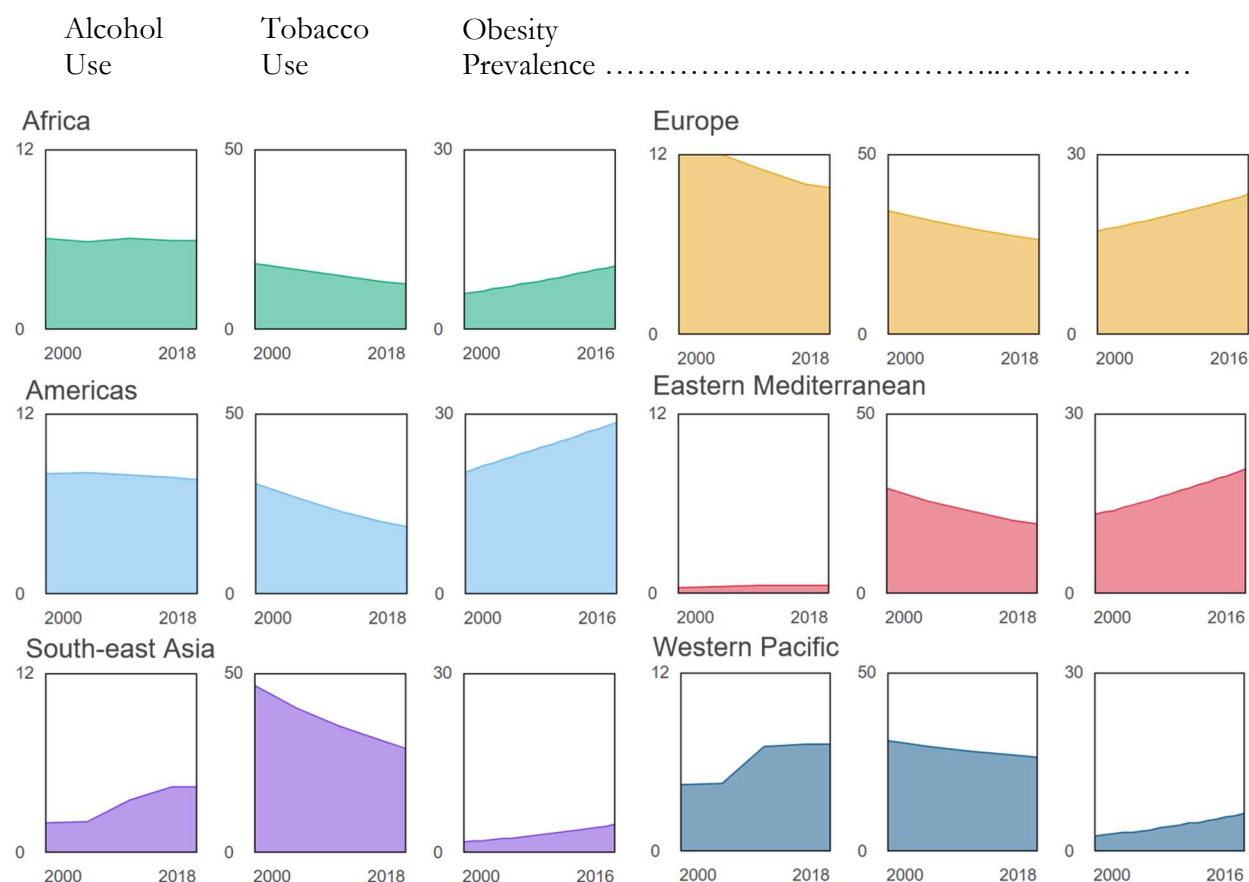
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<sup>102</sup> Ibid.

<sup>103</sup> World Bank Group, *DataBank | Life Expectancy at Birth, Total (Years), 1960-2019*.

<sup>104</sup> Labonté and Schrecker, “Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution” (2007), 10.

**Figure 5.2-B. Dramatic increases in NCD risk factors, including alcohol consumption, tobacco use, and obesity prevalence in regions all over the world (2000-18)**



As measured in alcohol consumption per capita among adults 15 years of age and older (liters of pure alcohol); prevalence of tobacco use among adults 15 years of age and older (%); and prevalence of obesity among adults 18 years of age and older (%). Tobacco and obesity reflect age-standardized prevalence. Data and image from Adhanom Ghebreyesus, “World Health Statistics 2021: Monitoring Health for the SDGs, Sustainable Development Goals.”

considered in relation to the changing global burden of disease, or the collection of diseases and illness that drive global mortality. Increasingly, the burden of death among advanced economies is ‘trickling down’ to communities and regions of the world in which ill health was defined by communicable diseases, infectious viruses—not lifelong health conditions correlated with politico-economic and other social determinants of health (Figure 5.2-B).

Traditional measures of health, including under-five mortality, maternal mortality, and

prevalence of infection disease – though directionally moving favorably – cannot and do not capture the contemporary state of health. The contemporary state of global health is one of quasi-health that prioritizes the palliation of noncommunicable diseases (NCDs), which represent the drivers the diseases of the global ‘North’ (i.e., of “medicine under capitalism,”<sup>105</sup> health under globalization). Considering the basic meaning of ‘political economy,’ economic and political relations, operating within a social system, are interactive and dynamically shaped by the system of social relations in which they operate (i.e., macro level of analysis). In a politico-economic system of globalization, social determinants – whether “specific exposure” at the intermediary level or “social position” based one’s own relative “social position” – create linkages and have consequences for health.

Despite significant advancements in the collective ability to prevent, treat, and even cure diseases; select global progress on life expectancy and maternal, infant, and under-five mortality; and improvements in access to care and indicators of health and wellness associated with infectious disease, distributing health gains versus risks within and between states “remains extremely and unacceptably uneven.”<sup>106</sup> And increasingly on the decline—if not reversing sometimes. This unevenness should come as no surprise when examined through the lens of power and health’s place within contemporary politico-economic systems, including global neoliberalism,<sup>107</sup> the “fragmented and thin” global health system,<sup>108</sup> and the increasingly fragmenting world order.<sup>109</sup> Nor

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<sup>105</sup> Navarro, “The Political Economy of Medical Care: An Explanation of the Composition, Nature, and Functions of the Present Health Sector of the United states.”

<sup>106</sup> Op. cit., Ottersen et al.

<sup>107</sup> “Neoliberalism” refers to market-oriented policies, whether international, national, or local, such as privatization, deregulation, and trade liberalization. While the research examines the term and its explicit and implicit meanings and relevance to health equity and global health governance at greater detail in chapter 3, a cursory overview of the concept can be found in Iber, “Worlds Apart: How Neoliberalism Shapes the Global Economy and Limits the Power of Democracies.” A fulsome history of neoliberalism can be found in Slobodian, *Globalists: The End of Empire and the Birth of Neoliberalism*.

<sup>108</sup> Op. cit., Moon, Rottingen, and Frenk, “Global Public Goods for Health.”

<sup>109</sup> Center for Strategic and International Studies (CSIS) Risk and Foresight Group Director Sam Brannen discussed with CSIS advisors Seth G. Jones, Rebecca Hersman, and Todd Harrison the post-Covid-19 world order. The panel concluded that Covid-19 would accelerate the transition to a more fragmented world order in which the “future organizing principles,” or the values and norms that will

should the declines, given the earlier discussion of the perverse incentives that the *marketization of health* precipitates for individual and collective health.

#### 5.2.4 Globalization of Health System Norms: Synergist Ideas of the Co-production and Individualization of Health

Improving health may involve deceptively complex, though superficially simple, solutions.<sup>110</sup> The original language proposed by Dr. Henry Sigerist, noted in brackets, for the charter of the World Health Organization Charter (1986 [1946]) states that “health is a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity [and individuals will want to take responsible for their own health].”<sup>111</sup> As discussed, this similarly is the case when examining health risks, which often have their roots in complex, interdependent, and inter-sectoral relationships—including systems of power relations at the global-local levels. In his discussion of ways to improve health organizational integration, or the “inter-agency governance” of health,<sup>112</sup> Morton Warner describes a scientific process with its origins in the social world: synergy. Warner notes that synergy as a typology reflects a long history of process-oriented thinking in metaphysics<sup>113</sup> that is often expressed in philosophical ethics as ‘the whole being greater than the sum of its parts.’<sup>114</sup>

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establish political order in the international system, are unclear. The panel also suggested that the experience would improve the geopolitical position of neither China nor the United States, resulting in, at minimum, the continued quasi bi-polar balance of power system. See Jones, Hersman, and Harrison, “World Order after Covid-19.”

<sup>110</sup> Warner, “Synergies,” Chapter 10 in Marinker, *Constructive Conversations about Health: Policy and Values*.

<sup>111</sup> World Health Organization, *Ottawa Charter for Health Promotion*.

<sup>112</sup> Op. cit., Marinker, 4.

<sup>113</sup> There is dispute whether Aristotle or Hesiod coined this common phrase. For example, per Aristotle, “Concerning the challenge we just faced about how to describe things in numbers and definitions, *What is the reason for a unity/ oneness? For however many things have a plurality of parts and are not merely a complete aggregate but instead some kind of a whole beyond its parts*, there is some cause of it since even in bodies, for some the fact that there is contact is the cause of a unity/ oneness while for others there is viscosity or some other characteristic of this sort. But a definition [which is an] explanation is one [thing] not because it is bound-together, like the Iliad, but because it is a definition of a single thing.” See Aristotle, *The Metaphysics*. See also Upton, Janeka, and Ferraro, “The Whole Is More than the Sum of Its Parts: Aristotle, Metaphysical.”

<sup>114</sup> The original Hesiod quote is, “For we have already divided up our inheritance, but you made off with much more as you kowtowed to bribe-taking kings, the men who long judge this kind of case. The fools, they do not know how much *half is greater than the whole* nor how much wealth is in mallow and asphodel.” See West, *Works and Days* and Bartlett, “An Introduction to Hesiod’s ‘Works and Days.’”

As in IPE, IR, and Comparative Politics, which describe the near-identical concept of interdependence as the embedded autonomy and reciprocity of complex relationships, Warner describes synergy as a “coming together of different elements to produce unique powerful effects.”<sup>115</sup> Though a fundamental process of the natural world and a descriptive term originating in the physical sciences, it has been applied elsewhere, including business administration and corporate environments.<sup>116</sup> In its scientific use, synergy is exemplified in naturally occurring processes lacking an obvious source of motivation, such as an animal’s primitive drive toward self-preservation. Warner notes other related scientific concepts, including “ordering (quantum physics), cooperation and coordination (biophysics and developmental biology), functional integration (biochemistry), mutualism and cooperation (ecology and behavioral biology), [and] cooperation (anthropology),” have been developed and used to explain the ordering and interacting of the natural world. These concepts have similar application in the social sciences, especially IPE and IR, where typologies of cooperation and interdependence have been used to examine the ordering of the global politico-economic system and interactions within, whether synergistic or competitive.

Warner’s conceptualization and contextualization of synergy pertains to the ‘co-production’ of health in terms of narrative or discursive construction and the establishment and reinforcement of global norms. Synergistic activity in the (human) social world is not value-neutral as it may appear to be in the natural world: it “positively buzzes with values—they underpin our thoughts and heavily influence the actions of individuals and organizations alike.”<sup>117</sup> Synergy and synergistic relationships – across space, time, actors, or processes – represent the essentialness of incorporating the “value of

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<sup>115</sup> Op. cit., Warner, 113. For a review of the term’s use in Comparative Politics, for example, see also Schneider, “Elusive Synergy: Business-Government Relations and Development,” and, in particular, Evans, *Embedded Autonomy: states and Industrial Transformation*.

<sup>116</sup> Gould and Campbell, “Desperately Seeking Synergy.”

<sup>117</sup> Op. cit., Warner, 117.



values”<sup>118</sup> in the analysis of complex systems, whether the global political economy or other “phenomenal human”<sup>119</sup> systems. The concept of the ‘co-production’ of health<sup>120</sup> is a helpful example of the interplay between values and synergies that generate norms, and their practical implications for the everyday experience of health, its organization, and global governance.

Originating with Medical Historian and physician Henry Sigerist, co-production at its most narrow definition refers to the patient-physician relationship: models promoting patient engagement and individualization of the health care experience, through “individualized care paths,”<sup>121</sup> “individualization of service delivery,”<sup>122</sup> and ‘self-care’ (Chapter 5.2.2). The typology has relevance beyond such models, however, and also has been constituted to refer to patient responsibility for or ‘ownership’ of health. For example, co-production was reflected in the original WHO definition of health<sup>123</sup> and the “social production of disease.”<sup>124</sup> As Elizabeth Fee (1989) notes, ideas like co-production of health and the social production of disease generate global norms with local and individual implications beyond medical management and individual care models.<sup>125</sup>

Co-production is more narrowly defined within contemporary literature as “the voluntary or involuntary involvement of public service users in any of the design, management, delivery and/or evaluation of public services,”<sup>126</sup> and it originates in Public Service Administration literature as part

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<sup>118</sup> Danzon, “The Value of Values,” 17–19, Chapter 2 in, op. cit., Marinker, *Constructive Conversations about Health: Policy and Values*.

<sup>119</sup> Op. cit., Warner, 118.

<sup>120</sup> Op. cit., Warner, 116-117.

<sup>121</sup> Graffigna et al., “Co-Production Compass’ (COCO): An Analytical Framework for Monitoring Patient Preferences in Co-Production of Healthcare Services in Mental Health Settings.”

<sup>122</sup> Loeffler et al., *Co-Production of Health and Wellbeing in Scotland*.

<sup>123</sup> Larsen, “Not Merely the Absence of Disease: A Genealogy of the WHO’s Positive Health Definition.”

<sup>124</sup> Fee, “Henry E. Sigerist: From the Social Production of Disease to Medical Management and Scientific Socialism.”

<sup>125</sup> Op. cit., Fee, 127-128.

<sup>126</sup> Stephen P. Osborne, Zoe Radnor, and Kirsty Strokosch (2016) note a broader dialogue within the Public Administration and Public Policy fields of whether this definition should be refined to the point of excluding “the broader involvement of citizens.” While Osborne et al. do not resolve this line of questioning, it is important to note the extant discourse in these fields on the scope of ‘user’ in the co-production of public services. For Osborne et al., see Osborne, Radnor, and Strokosch, “Co-Production and the Co-Creation of Value in Public Services: A Suitable Case for Treatment?,” 639-640.

of the public service logic (PSL).<sup>127</sup> As compared to concepts of collaborative partnership whereby service users, like patients, guide health care service delivery and its processes, or form their care teams, the PSL concept of co-production refers to the material and ideational contributions of individuals (e.g., taxpayers) to the public service (e.g., the co-production of public goods). Such an approach is materially different from traditional models of public service, where state regulators are exclusively responsible for “designing and providing services to citizens, who in turn only demand, consume and evaluate them.”<sup>128</sup>

According to Osborne, Radnor, and Strokosch (2016), this shift reflects the potential, if designed well, to capture global synergies associated with health. Specifically, to achieve meaningful “public service reform,” “respond to the democratic deficit,” and promote “active citizenship and active communities.”<sup>129</sup> Presented as synergy, as the natural alignment of interests and the co-production of outcomes, however, denotes such processes are rational, and neutral and value-free—there is not a hand leaning on the scales of outcomes. Revisiting the concepts of Critical Constructivism (Chapter 3.2.1) and Flexnerianism (Chapter 5.2.2), however, all concepts – even those originating in the value-free world of the Natural Sciences – impart meaning and reinforce ideas when applied in social systems. Mechanisms like co-production of health care services, whether at the collective level (e.g., social insurance programs) or the patient level (“individualized care paths”) are narrative parts of a collective discourse that health, disease, and treatment are the responsibility of the individual patient as they reflect patient ‘risk’ and ‘behavior.’

Co-production of health and individualized care delivery have much in common with the concept of behaviorism in public health promotion, or that the public role in health should be

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<sup>127</sup> Eriksson, “Representative Co-Production: Broadening the Scope of the Public Service Logic.”

<sup>128</sup> Pestoff, “Citizens and Co-Production of Welfare Services: Childcare in Eight European Countries,” 506.

<sup>129</sup> Op. cit., Osborne, Radnor, and Strokosch, 640-641.

limited to education about ‘good’ health choices because, ultimately, health itself is within the individual’s realm of control and responsibility.<sup>130</sup> A peer concept to co-production and behaviorism is individual responsibility, or “the roles of individuals in determining their lifestyle,”<sup>131</sup> including their “individual behavioral choices and access to medical treatment.”<sup>132</sup> Similar to assumptions of market behavior (Chapter 4.3), each presume the self-regulation of health, where differences in outcomes and experiences are the product of choices—just as differences determine and explain variation in economic status and outcomes.<sup>133</sup> With adequate information (market transparency and choice) and incentive (demand and ease of market entry), individuals will choose health over sickness. In all three concepts, the patient is empowered and autonomous, ‘takes control’ of their own health care, and reaps either the benefits or faces the consequences.

Rather than a “triple helix” view of health being dynamically produced and influenced by an array of inputs, including social relations and politico-economic systems, ‘health’ as an idea (biomedicine), a network of individual decisions that comprise it (choice and risky behaviors), and the mechanisms through which it is effectuated as a ‘health care service’ (or good). Health, as individual responsibility and reflecting behavioral choices, is therefore not a matter of public interest. Returning to Dr. Sigerist and the early WHO definition of health that began this discussion, Warner (2006) notes that global public health authorities have trouble conceptualizing health *beyond the hegemonic idea of health* in terms of medical system and individual behavioral interventions:

This was somewhat anticipated by the medical historian Henry Sigerist in 1942 when he presaged the WHO slogan of total physician and social wellbeing and added ‘and individuals will want to take responsibility for their own health.’ But how are they to do this? Engagement with health professionals as partners to achieve higher levels of

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<sup>130</sup> Baum and Fisher, “Why Behavioral Health Promotion Endures despite Its Failure to Reduce Health Inequities.”

<sup>131</sup> Ullrich et al., “Cancer prevention in a political arena: The WHO perspective.”

<sup>132</sup> Robert et al., “Public views on determinants of health, interventions to improve health, and priorities of government.”

<sup>133</sup> Harvey, *A Brief History of Neoliberalism*.

health literacy is one way. The use of the Internet by patient supports groups is another.<sup>134</sup>

The extant Public Health literature on behavioral health promotion, co-production, and individual wellness initiatives (by employers) is expanding to reflect critical analyses of power and interest. As Baum and Fisher note, there are strong incentives for state actors to reject the structural determinants of health, which may engender system change(s) at the political or economic levels like to incur costs to adjacent politico-economic interests. Rather, individualism enables right-sized state involvement (in terms of system accommodation) in health while simultaneously legitimizing, reinforcing, and narratively making sense of the depoliticization of health.

As the findings of the Ottawa Institute and *The Lancet*-Oslo Commission clarify, however, achieving health equity requires policies designed to change the *systemic conditions* under which individual patients make their harmful choices: “Construing socially and politically created health inequities as problems of technocratic or medical management depoliticizes social and political ills.”<sup>135</sup> Lack of political will and action however, has as much to say about the embeddedness of the globalization of individual health as it does about the policy space afforded health in domestic and global decision-making processes.

#### 5.2.5 Globalization as Depoliticization: Shrinking the Policy Space for Health

The policy priorities of state actors are called their respective ‘policy space’ or the relative prioritization of a state actor’s public policy objectives and interests. The literature on ‘policy space’ is complex. Definitions alone vary significantly, from economics-centered conceptualizations of the relative prioritization of a state actor’s public policy objectives and interests,<sup>136</sup> including those

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<sup>134</sup> Op. cit., Warner, 116-117.

<sup>135</sup> Op. cit., Ottersen et al., 646.

<sup>136</sup> Jackson, “The Purpose of Policy Space for Developing and Developed Countries in a Changing Global Economic System,” Chang,

advanced by the UN,<sup>137</sup> other intergovernmental organizations (IGOs), and international financial institutions (IFIs), to issue-agnostic definitions that assert the salience of global politico-economic forces to constrain state behavior.<sup>138</sup>

The former often has centered on the relative room for certain policy conversations in relation to international trade and economic development, growth, or recovery policies and priorities.<sup>139</sup> This economics-centered definition was constituted as part of global norms by the 2014 UN Conference on Trade and Development (UNCTAD), which defined policy space as “the freedom and ability of a government to identify and pursue the most appropriate mix of economic and social policies to achieve equitable and sustainable development that is best suited to its particular national context.”<sup>140</sup> Conversely, the latter is exemplified by Ronald Labonté et al. (2009), who define policy space in non-economic terms in their evaluation of socio-political determinants of health for the WHO: as those situations in which the international system constrains the ability of state actors to adopt policies that promote a particular issue. In health, this research borrows Labonté and Schrecker’s (2007b) policy space definition:

[Policy space is] the extent to which national decisions for health and on social determinants of health can be made on the basis of health policy concerns and priorities as distinct from other priorities, such as economic growth, maintaining payments to external creditors, or complying with trade agreement disciplines.<sup>141</sup>

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“Policy Space in Historical Perspective with Special Reference to Trade and Industrial Policies;” Mayer, “Policy Space: What, for What, and Where?;” Shadlen, “Exchanging Development for Market Access? Deep Integration and Industrial Policy under Multilateral and Regional-Bilateral Trade Agreements.”

<sup>137</sup> “Policy Space and Global Governance: Issues at Stake;” “Fiscal Space for Stability and Development: Contemporary Challenges.” New York: United Nations (2014).

<sup>138</sup> Labonté and Schrecker, “Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution.”

<sup>139</sup> See, for example, Shadlen, “Exchanging Development for Market Access? Deep Integration and Industrial Policy under Multilateral and Regional-Bilateral Trade Agreements;” Chang, “Policy Space in Historical Perspective with Special Reference to Trade and Industrial Policies;” Mayer, “Policy Space: What, for What, and Where?;” Jackson, “The Purpose of Policy Space for Developing and Developed Countries in a Changing Global Economic System.”

<sup>140</sup> “Policy Space and Global Governance: Issues at Stake;” “Fiscal Space for Stability and Development: Contemporary Challenges.” New York: United Nations (2014).

<sup>141</sup> Labonté and Schrecker, “Towards Health-Equitable Globalisation: Rights, Regulation and Redistribution.”

This definition was prepared for the WHO Commission on Social Determinants of Health; it is more appropriate to this research because of the definition's inherent complexity and comprehensiveness, and it better reflects the complexity of the politico-economics of health. As the contrast between the UN and WHO definitions of policy space demonstrate well, globalization effectively shrinks the national and global policy spaces<sup>142</sup> to subordinate, or co-opt, health to other policy priorities, primarily: economic growth and security, enhancement of the private sector, and the spread of beliefs and ideas in ways that grant legitimacy to certain norms and their practical outputs over others (e.g., capitalism, valuation, assetization).

Returning to the Drezner v. O'Neill dichotomy at this chapter's open, Drezner's thesis that "all politics is [now] global" rests on the argument that, though domestic factors explain state actors' preference formation, such 'local politics' neither account for the outcomes of international bargaining, nor the global normative context within which ideas and state actors' interests, beliefs, and priorities – each of which underpin preferences – are constructed. They are prioritized, shaped, and resolved by global systems, structures, processes, and preferences, including those reflected through international regulatory coordination (e.g., multilateral trade agreements, treaties) and informal global governance systems, like national pharmaceutical policies that interrelate with those of other state actors for guidance and oversight.<sup>143</sup> This is the inherent challenge of such a reality. Domestic constituencies lack political influence at the global table. This means less civil society oversight and engagement of kitchen-table issues and less policy space for the prioritization of related public policies, of which there is none more consequential than health. The issues that matter to constituents back home are beyond their political control.

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<sup>142</sup> Radhika Gore and Richard Parker. "Analyzing Power and Politics in Health Policies and Systems." *Global Public Health* 14, no. 4 (April 3, 2019): 481–88.

<sup>143</sup> Bevir, *Governance: A Very Short Introduction*, 1.

### 5.3 The Global-Local Nexus and the Interdependence of Regulation

The post-Cold War era has unfolded to encompass a myriad of complex and interconnected forces, most notably globalization. But dynamics adjacent to and beyond globalization also are present and similarly exacerbated by power and politics, forming the proverbial why-and-how behind globalization's most challenging externalities especially those related to health. One such set of complementary dynamics – the tension and interrelation between the local and the global – simultaneously drive and complicate efforts to temper these externalities through global regulation or global governance, as James N. Rosenau (1997) notes:

To speak of an uneven frammegrative worldview is to conjure up processes and arrangements undergoing continual fluctuations in every country and region between globalizing and localizing tendencies, between expanding coherence and contracting solidarity. It suggests the tensions fostered by the compelling lure of both distant and immediate horizons.<sup>144</sup>

To illustrate this set of dynamics, let us return to the consequences of globalization for health. While infectious disease is a more obvious example of the long-standing global-local nexus magnified by contemporary globalization, Public Health experts since at least the 19th century have understood that good and ill health, including NCDs and access to health care services, are affected by macro, meso, and micro structures that often interrelate.<sup>145</sup> called the neighborhood effect, linkage politics, frammegration, global regulatory coordination, and countless other terms<sup>146</sup> – from 'diffusion' (Strange 1996), spatial clustering analysis, political geography, linkage politics, and strategic political economy – the idea is simple: ideas, preferences, and policies move and are transferred between

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<sup>144</sup> Page 99 of Rosenau, "Frammegration." Chapter 6 in James N. Rosenau, ed., *Along the Domestic-Foreign Frontier: Exploring Governance in a Turbulent World* (Cambridge: Cambridge University Press, 1997).

<sup>145</sup> Henry Mayhew, *London Labour and the London Poor: A Cyclopaedia of the Condition and Earnings of Those That Will Work, Those That Cannot Work, and Those That Will Not Work*, 3rd ed. (New York: Cornell University Press, 2009 [1851]).

<sup>146</sup> For a comprehensive discussion of the terms used and their expression in International Relations, U.S. Foreign Policy, and IPE scholarship, see Bruce Bueno de Mesquita and Alastair Smith, "Domestic Explanations of International Relations," *Annual Review of Political Science* 15, no. 1 (2012): 161–81.

levels of socio-political action and interaction; so, too, do the processes and expected outcomes that come with them.

This section explores select variations of this set of dynamics, including William Julius Wilson's (2012 [1987]) neighborhood effect, James N. Rosenau's (2018 [1990]) fragmentation, Paul Dimaggio and Walter Powell's (1983) isomorphism (or Kenneth N. Waltz's (1999) 'best practices' micro-theory), and the transfer of political preference formation from the local to the global—Daniel W. Drezner's (2007) Revisionist Model that “all politics is global.” The section then concludes with an explanation of how together these dynamics generate a global politics of health. First, however, the discussion must begin with a brief examination of the sometimes conflicting and amorphous typologies of globalization, global governance, and regulation, and the forms of global regulation.

### 5.3.1 Defining Terms: Making Sense of Governance

Particularly relevant to this discussion of global governance is Deborah D. Avant, Martha Finnemore, and Susan K. Sell's (2010) description of globalization as shifting “the spatial reach of social action and organization toward the interregional, intercontinental, or global scale” and weakening the “correspondence between social action” (i.e., political action) “and the territory enclosed by state borders.”<sup>147</sup> It is a delinking of political issues from their sovereign-border ties. Central to this delinking are changes in the concepts of power and of politics – what some have

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<sup>147</sup> Avant, Finnemore, and Sell, *Who Governs the Globe?*, 4.



called the ‘new world order’<sup>148</sup> – and of governance, regulation, and authority.<sup>149</sup> Acutely present in post-Cold War IPE and IR scholarship, globalization has invited a rich literature of explanations and theory-making reconsidering what is power and who wields it in a unipolar or multipolar world; the role and autonomy of the Westphalian-era Nation-state; the rise and influence of nonstate actors like non-governmental organizations (NGOs), intergovernmental organizations (IGOs, e.g., United Nations (UN), European Union (EU)), transnational and multinational corporations (TNCs/MNCs), and international institutions; and whether and how anarchy persists in an era of “complex interdependence.”<sup>150</sup>

These structuring components of global life have been transformed by globalization, particularly, its politico-economic effects, to create a ‘new world order’ or ‘new global order.’ As with the concepts of ‘globalization’ and ‘global health’ earlier explored (and typologies of global governance), what is meant by new world order varies, but is generally associated with the shift from a bipolar balance of power (i.e., the U.S. and Soviet Union) to a hegemonic world order (the U.S. being a hegemon); the heightened “interaction of the market and powerful actors,” per Robert Gilpin (2001);<sup>151</sup> and the need to regulate globalization (i.e., Drezner (2007), which refers to the

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<sup>148</sup> The term new world order originates with U.S. President Woodrow Wilson in the aftermath of the First World War, which he used to describe a “new world order of democratic nations” that would be codified in the postwar League of Nations, the precursor to the modern UN. See Ambrosius, “Woodrow Wilson, Alliances, and the League of Nations,” 141; Referring to the eras of U.S. Presidents George H. W. Bush and George W. Bush, the term refers to the former’s vision of a post-Cold War world and, more immediately, to the latter’s post-9/11 geopolitical landscape. See also the perspectives of Samuel P. Huntington (2011 [1993]) and Francis Fukuyama (1989, 2006 [1992]), and the ongoing debate of their views of the “new global order,” including: Huntington, *The Clash of Civilizations and the Remaking of World Order*; Fukuyama, “The End of History?”; Fukuyama, *The End of History and the Last Man*; Rose et al., “The Clash of Civilizations? The Debate: 20th Anniversary Edition.”

<sup>149</sup> See, for example, the role of transnational and multinational corporations as explored in Haufler, *A Public Role for the Private Sector: Industry Self-Regulation in a Global Economy*.

<sup>150</sup> Robert O. Keohane’s and Joseph S. Nye, Jr.’s landmark theoretical contribution is perhaps, with the benefit of approximately a half century of experience, too optimistic of a framework, but its notions of power politics and complex interdependence continue to dominate modern understandings of globalization and actor interrelations in the global political economy. See Keohane and Nye, Jr., *Power and Interdependence* See also; Keohane and Nye, Jr., “Power and Interdependence in the Information Age.”

<sup>151</sup> Gilpin, *Global Political Economy*, 45.

“regulation of the global economy”<sup>152</sup>) to address, first, the global challenges that exceed the capability of individual state actors and, second, the impact on domestic constituencies of “forces that readily cross territorial space to affect all of our lives.”<sup>153</sup>

## Governance

The pace and processes of globalization accelerated in the late 20th and into the early 21st centuries, coinciding with geopolitics shifts following the end of the Cold War and the post-9/11 period. Specifically, globalization’s externalities, or fringes, emerged on a host of macroeconomics issues, including health. The WHO Commission on Macroeconomics and Health, while focused on health as its name suggests, observed that globalization’s “benefits” referring not only to health but also to income, employment, safety, and prosperity, “are not reaching hundreds of millions of the world’s poor,” introducing “new kinds of international challenges.” Similar to the role of states themselves in determining the ‘rules of the road’ within their domestic frontiers, governance – whether at the global, national, or local levels – refers to the agreed-upon approach to collective action on an issue.<sup>154</sup>

Reflecting this research’s focus on forms of governance across the spectrum of formality, nature of agreement, and levels of analysis, governance as the way rules, requirements, norms, and actions are structured, sanctioned, sustained, regulated, and held accountable by a group of actors. Borrowing from Dodgson, Scholte, and others, this operational definition implies that governance can occur at different levels of social relations, including the individual, local, national, regional, and supranational or global levels. This definition presumes governance need not originate with a state actor or collective of states but can be established by a variety of actors.

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<sup>152</sup> Drezner (2007) notes that “the existing literature has missed the mark in assessing the regulation of the global economy.” See Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*, 11.

<sup>153</sup> Lee, “The Spatial Dimension of Global Health,” 61.

<sup>154</sup> Dodgson, Lee, and Drager, “Global Health Governance, A Conceptual Review.”

## Global Governance

Jan Aart Scholte (2000, 2011) places global governance within a similar context of social interaction (versus politico-economic processes) as this research's operating definition of governance. Alike all aspects of social interaction, global social relations require global governance, or the policies, rules, and standards (collectively, regulation, defined below) that reflect global norms and the mechanisms and/or institutions for their implementation, administration, and enforcement. Responding both to the inherent anarchy of the international system and increasing complexity of daily life wrought by globalization, Scholte (2011) notes that:

As any arena of human collective life becomes significant [,] frameworks of governance develop to bring a certain order and predictability to that sphere. Rules are set, maintained, adjusted, and enforced.<sup>155</sup>

Global governance is critical for its potential to mediate the negative externalities of globalization that state actors are ill-equipped to manage. In their 2014 report on the political origins of health inequity, *The Lancet*-University of Oslo Commission on Global Governance for Health recommend global governance *for health* as a mechanism for addressing the political determinants of health, which are intimately linked, the report notes, with domestic policymaking and structures but also, because of globalization, “to transnational activity and global political interaction.”<sup>156</sup> Ole Petter Ottersen et al. employ Thomas G. Weiss and Ramesh Thakur's (2010) definition of global governance in their examination of the United Nations, specifically, that *global governance* is:

The complex of formal and informal institutions, mechanisms, [authority] relationships, and processes between and among states, markets, citizens, and organizations, both intergovernmental and non-governmental, through which collective interests on the global plane are articulated, rights and obligations are established, and differences are mediated.<sup>157</sup>

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<sup>155</sup> Scholte, “Global Governance, Accountability and Civil Society,” 8.

<sup>156</sup> Ottersen et al., “The Political Origins of Health Inequity: Prospects for Change.”

<sup>157</sup> Weiss and Thakur, *Global Governance and the UN: An Unfinished Journey*, 31–32.

The Weiss-Thakur definition is helpful for its emphasis on the complex web of relationships, decision-making mechanisms, and political forums through which norms and interests are both established and expressed. This sentiment is similar rooted in Scholte's conceptualization of governance and this research's own operating definition of governance. It also aptly reflects the sometimes-informal mechanisms of influence. As globalization drives issue de-linking and also linkage politics, with domestic challenges and preferences increasingly informed by supraterritorial dynamics, Scholte explains that global governance "involves not only nation-states, but also other types of actors, such as business enterprises," which helpfully separates global governance from global government or the structuration of a global state.<sup>158</sup> Conceptualizing global governance differently eschews the central and necessary premise that, in a globalized world of complex interdependence, governance can take many forms and work through numerous levels and types of authorities, including the absence of centralized state or institutional authority.

Building on Scholte (2011) and Drezner (2007), the research defines global governance as the collection of authority relationships designed to establish, monitor, enforce, sustain, and amend or restrict any international rules and regulations, including hard law treaties, soft law declarations, private orders, recommended codes of conduct, generally accepted standards, and other formal global norms and practices upheld in the global political economy.

Specific to the framework of health, the nuance between *global health governance* and *global governance for health*, particularly, as this research examines and discusses both and the two systems are interactive and dynamic. Returning to Ottersen et al., *global governance for health* accepts this broader construct of inputs and outputs for global health policy and systems, referring to any formal or

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<sup>158</sup> As Scholte (2000) notes, "[t]o speak of global governance is not to suggest the existence, emergence, or goal of a world state," but rather "global-scale regulation" that is developed and "can operate in the absence of a centralized, sovereign, public entity that is elevated from a national to a planetary scale." See Scholte, *Globalization: A Critical Introduction*, 10.

informal governance (i.e., “institutions, rules, and processes by states, intergovernmental institutions, and nonstate actors”) which affects the determinants of health, and those coordinating bodies, institutions, and practices of governance specifically created “to deal with challenges to health that require cross-border collective action to address effectively.”<sup>159</sup> This conceptualization allows for the examination of forms of governance, and the actors and interests that drive them, beyond the boundaries of governance mechanisms *defined in terms of specific actors and institutions*, an approach which is, itself, biased for formal power-sharing-as-governance arrangements.

### Regulation-As-Governance

Before discussing specific forms of global regulation-as-governance, it is important to briefly define regulation, as this research intentionally borrows from Scholte to reflect a typology of global governance contextualized in terms of its immediate outputs, rather than actual or potential outcomes (i.e., those broad and vague notions of what governance can or may achieve): the actual collection of policies, rules, and standards. Reflecting Virginia Haufler’s (2001) construct of ‘social regulation,’ this research defines regulation as “the formal rules or standards that dictate what is acceptable and required behavior, putting limits on what is permissible,” which can exist beyond the purely domestic and/or governmental context.<sup>160</sup> In this way, regulations’ norm-affirming and compliance roles are not exclusive domains of state actors. That definition provides the basis to examine the forms of global governance, of Drezner’s “regulation of the global economy.”

#### 5.3.2 Forms of Global Regulation

As the scholarship of Rosenau (1990), Strange (1996), Haufler (2001), Drezner (2007), and others reflects, there are a multitude of typologies seeking to explain the processes of global

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<sup>159</sup> Op. cit., Ottersen, 633.

<sup>160</sup> Haufler, A Public Role for the Private Sector: Industry Self-Regulation in a Global Economy, 8.

regulation designed to temper anarchy, establish “the global rules of the game,”<sup>161</sup> and promote power sharing. Three reflect the continuum of level of political action and policy coordination amongst the participating actors: international regulatory coordination, policy convergence, policy harmonization, and international regulation (Table 5.3-A).<sup>162</sup>

### International Regulatory Coordination

Beginning with international regulatory coordination, this form of global regulation refers to the codified adjustment of states’ national standards, policies, and rules to recognize or accommodate other states’ regulatory frameworks. One example is the International Generic Drug Regulators Program (IGDRP) Information Sharing Pilot, as explored further in Chapter 6.

### Policy Convergence & Harmonization

Policy convergence reflects a heightened standard, policy, or rule coordination across states, or “the narrowing of national policy differentiations or gaps in national standards over time.”<sup>163</sup> Policy convergence makes possible additional forms of international cooperation and collaboration. When coordination and convergence result in the adoption of the “the same harmonized technical guidance documents, standards, and scientific principles,” and “similar regulatory practices and procedures are introduced,” including policies and rules, state-to-state dialogue, collaboration, and regulatory accommodation has aligned to the point of policy harmonization, creating de facto or actual global rules (“regulatory standards”) for those harmonized policy issue areas.

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<sup>161</sup> Op. cit., Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*, 11.

<sup>162</sup> We do not include policy coordination, or the mutual adjustment of national rules and regulations in recognition of regulatory frameworks of other countries, given the informal and tacit nature of such processes, which can range from information sharing and best practices to coordination on policy development and/or national policy adjustment in practice versus statute or other formal codification of such accommodation. Chapter 1’s discussion of WHO and World Bank Group health policies, including essential medicine lists, formularies, and treatment guidelines in developing countries, are helpful examples of policy coordination, though once such ‘best practices’ are tied to development financing, including through structural adjustment policies, they become formalized and move up the continuum into formal global regulations.

<sup>163</sup> Op. cit., Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*, 11.

**Table 5.3-A. Forms of global regulation, defined and ordered by policy convergence**

<u>Form of Global Regulation</u>	<u>Definition</u>	<u>Health-related Example</u>
<div style="display: flex; align-items: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); font-weight: bold; margin-right: 10px;">             ▲ Greatest to Least Policy Alignment ▲ ▼ International to Domestic Level of Political Action ▼           </div> <div>             International Regulatory Coordination           </div> </div>	The codified mutual adjustment of national standards, policies, and rules to recognize or accommodate other countries' regulatory frameworks	IGDRP Pilot, IPRF, and IPRP on pharmaceutical review  Australia-Canada-Singapore-Switzerland Consortium on pharmaceutical marketing review, registration, evaluation, and post-market surveillance <sup>164</sup>
Policy Convergence	The narrowing of national policy differentiations or gaps in national standards and rules	External reference pricing, used by more than 50 countries, and incorporates pharmaceutical prices from over 90 countries
Policy Harmonization	Policy convergence of national standards, policies, or rules to the same harmonized regulatory practice and procedure, resulting in a single, global regulatory standard	Global antidoping regime <sup>165</sup>  Single marketing authorization process for pharmaceuticals (e.g., European Medicines Agency, Mexico's Comisión Federal para la Protección contra Riesgos Sanitarios <sup>166</sup> )
International Regulation	The elevation of converged or harmonized policy to the level of international rules and obligations upheld in the global political economy, whether by states themselves or nonstate actors, including international institutions, IGOs, and NGOs	TRIPS Agreement of 1994, which establishes minimum intellectual property protections  International Health Regulations of 2005, which establish public health requirements <sup>167</sup>

Rosenau, "The Governance of Fragmegration: Neither a World Republic nor a Global Interstate System," fig. 1 (table).

<sup>164</sup> Specifically, the ACSS, since 2007, has explored opportunities for international regulatory coordination styled as increasing policy convergence around pharmaceuticals (including generics) approval and licensure, registration, assessment and evaluation reports for new-to-market pharmaceuticals and new active substances, post-market surveillance, and technical guidelines for pharmaceutical market approval. See Wood and Cuff, *Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators*, fig. Box 2-2.

<sup>165</sup> Houlihan, "Policy Harmonization: The Example of Global Antidoping Policy."

<sup>166</sup> Op. cit., Wood and Cuff, *Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators*, 31–32.

<sup>167</sup> World Health Organization, "International Health Regulations."

## International Regulation

When issue areas and standards are elevated from the domestic, or national, to the international and policy harmonization is codified, national policy coordination, convergence, and harmonization has shifted dramatically to the realm of international regulation. This definition includes international regulation as the elevation of converged or harmonized policy to the level of international rules and obligations, including hard law treaties, soft law declarations, private orders and codes of conduct, and other formalized global norms and practices upheld in the global political economy, whether by states themselves or nonstate actors, including international institutions, IGOs, and NGOs. The WHO's International Health Regulations (IHRs) are such an example.<sup>168</sup>

### Example: International Health Regulations, 2005

Effective June 15, 2007, the current and revised IHRs are codified in international law and legally binding on 196 countries across the globe, including all member states of the WHO. They supported global disease and acute public health and risk management. Specifically, the IHRs establish WHO's responsibility for "global public health security," and require signatory countries to: establish and maintain minimum public health capacities, including core capacities for surveillance and response at designated points of entry; report certain disease outbreaks and public health events to the WHO; designate a National IHR Focal Point for coordination and communication with the WHO; and adhere to privacy and confidentiality safeguards to protect the rights of travelers and other persons in relation to the treatment of personal data, informed consent, and non-discrimination in applying health measures under the IHRs, among other provisions.<sup>169</sup>

For example, states party to the IHRs must report certain metrics to the WHO; outside of

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<sup>168</sup> World Health Organization, "Implementation of the International Health Regulations (2005): Annual Report by the Director-General."

<sup>169</sup> Op. cit., World Health Organization, "International Health Regulations."



emergency and acute public health risks, such reports are annual self-assessments of public health risks of domestic and global concern. The WHO aggregates the surveys to produce a real-time public health Index for Risk Management and a global public health security dashboard (i.e., Electronic State Parties Self-Assessment Annual Reporting Tool (e-SPAR)), both of which deepen global and local norms related to public health, the significance of international coordination, and at least some domestic investment in public health preparedness, surveillance, risk management, and response. It also creates, sustains, and reinforces expectations for public health preparedness.

The IHR framework not only regulates public health surveillance at the international level but also establishes global norms of domestic investment and support of public health and risk management. For example, states party to the IHR must report certain metrics to the WHO; outside of emergency and acute public health risks, such reports are annual self-assessments of public health risks of domestic and global concern. The WHO aggregates the surveys to produce a real-time public health Index for Risk Management and a global public health security dashboard (i.e., Electronic state Parties Self-Assessment Annual Reporting Tool (e-SPAR)), both of which deepen global and local norms related to public health, the significance of international coordination, and at least some domestic investment in public health preparedness, surveillance, risk management, and response. It also creates, sustains, and reinforces expectations for public health preparedness.

The capacity of global regulation, however, to reinforce and sustain such norms depends on the efficacy of such regulation, specifically, how much states and other actors party to the regulation implement and comply with the regulation. The May 2021 report of the WHO Review Committee on the Functioning of the IHRs (2005) during the Covid-19 Response is such an example. The Review Committee, led by Dr. Lothar H. Wieler, president of the Robert Koch Institute in Berlin (i.e., Germany's national public health institute), concluded that, "in the context of a pandemic, countries that in 2005 approved the IHR, in 2020 only applied the Regulations in part, health risk

prevention, surveillance, preparedness, and response specific to supraterritorial risk (e.g., pandemics). For a review of these forms of global regulation, return to Table 5.3-A.<sup>170</sup>

Within the sphere of health and other crucial global issues, globalization's dynamics simultaneously drive international regulatory coordination and global governance and detract from it, simultaneously elevating domestic priorities and preferences and overriding them. The tensions between global-local and interdependence-independence are strikingly complex, and make collective action and coordination on global health, including pharmaceutical market regulation, a far greater challenge. It is reasonable to hypothesize these tensions driving greater international regulatory coordination, policy convergence, and policy harmonization – each of which allow for state-specific tailoring – and detracting from international regulation (e.g., treaties, trade agreements).

### 5.3.3 Drivers and Detractors of Global Regulation

Global-local forces can simultaneously drive and complicate global regulation, particularly, of health, and the resultant consequences of globalization for health. While infectious disease is a more obvious example of the long-standing global-meets-local and politico-economic relevance of health, which globalization has magnified (Chapter 5.1), Public Health experts since at least the 19th century have understood that good and ill health, including NCDs and access to health care services, are affected by macro and micro structures that often interrelate.<sup>171</sup> called the neighborhood effect, the theory contends that neighborhoods have a direct or indirect effect on individual behaviors and outcomes.

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<sup>170</sup> Significant criticism and scrutiny have been levied against the WHO for its response to the Covid-19 pandemic, which necessitated the formation of this Committee and requires this report. Notably, however, the failure appears less to be of the WHO itself than of actual, practical alignment with the IHR that all sovereign countries in the world now are party to. Specifically, the Committee goes on to note that, “unless this report leads to change and greater international collaboration, we shall be no better protected from the next pandemic than we were from this one.” See World Health Organization, “WHO’s Work in Health Emergencies - Strengthening Preparedness for Health Emergencies: Implementation of the International Health Regulations (2005),” 7.

<sup>171</sup> Henry Mayhew, *London Labour and the London Poor: A Cyclopaedia of the Condition and Earnings of Those That Will Work, Those That Cannot Work, and Those That Will Not Work*, 3rd ed. (New York: Cornell University Press, 2009 [1851]).

## Neighborhood Effect

The neighborhood effect<sup>172</sup> has been explored in Political Science, Economics, Epidemiology, Gerontology, Psychology, and Urban Design to explain a range of individual outcomes, including health and wellness,<sup>173</sup> voting patterns,<sup>174</sup> education and cognitive ability,<sup>175</sup> poverty and inequality,<sup>176</sup> and employment.<sup>177</sup> It also has been applied extensively in IR, U.S. Foreign Policy, and IPE to explain differences in the level of conflict or integration in regions of the world,<sup>178</sup> the “institutional variation across states,”<sup>179</sup> and the adoption of particular policies or politico-economic systems by state actors—in this last way, it can drive and sustain forms of global regulation.<sup>180</sup> The terminology referring to the neighborhood effect theory is varied and no terms are used consistently, particularly, within IPE and IR. Say, taken together, the terminology and related scholarship reflect a body of theory known as linkage research or linkage politics.

It is reasonable to assert that the larger a neighborhood grows (i.e., the more interdependent that the proverbial ‘global neighborhood’ becomes), the more global the neighborhood effect becomes. To paraphrase Public Health scholars Sally Macintyre and Anne Ellaway (2003):

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<sup>172</sup> For the foundational literature on the neighborhood effect, see William Julius Wilson, *The Truly Disadvantaged*, 2nd ed. (Chicago, Illinois: University of Chicago Press, 2012). For a comprehensive discussion of the contemporary literature on neighborhood effects, see J. Michael Oakes et al., “Twenty Years of Neighborhood Effect Research: An Assessment,” *Current Epidemiology Reports* 2, no. 1 (March 1, 2015): 80–87.

<sup>173</sup> Op. cit., Macintyre and Ellaway (2003). See also Stephen Jivraj et al., “The Impact of Life Course Exposures to Neighbourhood Deprivation on Health and Well-Being: A Review of the Long-Term Neighbourhood Effects Literature,” *European Journal of Public Health* 30, no. 5 (October 1, 2020): 922–28.

<sup>174</sup> K.R. Cox, “The Voting Decision in a Spatial Context,” *Progress in Geography* 1 (1969): 81–117.

<sup>175</sup> Milton Friedman, “The Role of Government in Education,” in *Economics and the Public Interest*, ed. Robert A. Solo (New Jersey: Rutgers University Press, 1955), 14.

<sup>176</sup> Robert J. Sampson, “Neighbourhood Effects and beyond: Explaining the Paradoxes of Inequality in the Changing American Metropolis,” *Urban Studies* 56, no. 1 (January 1, 2019): 3–32.

<sup>177</sup> Emily T. Murray et al., “Linking Local Labour Market Conditions across the Life Course to Retirement Age: Pathways of Health, Employment Status, Occupational Class and Educational Achievement, Using 60 Years of the 1946 British Birth Cohort,” *Social Science & Medicine* 226 (April 1, 2019): 113–22.

<sup>178</sup> Kristian Skrede Gleditsch, *All International Politics Is Local: The Diffusion of Conflict, Integration, and Democratization* (Ann Arbor: University of Michigan Press, 2002).

<sup>179</sup> Op. cit., Bueno de Mesquita and Smith (2012).

<sup>180</sup> Kristian Skrede Gleditsch and Michael D. Ward, “Diffusion and the International Context of Democratization,” *International Organization* 60, no. 4 (October 2006): 911–933.

“Neighborhoods make people, and people make neighborhoods. It is not composition or context, but composition and contexts.”<sup>181</sup> In this way, so, too, does the global neighborhood – or global political economy – make actors; and actors, particularly, powerful ones, make the global neighborhood. The forces of frammigration and institutional isomorphism complement the neighborhood effect’s capacity for driving linkage politics and policy transfer or coordination.

### Frammigration

In *Turbulence in World Politics: A Theory of Change and Continuity*, Rosenau (2018 [1990]) coined the term ‘frammigration’<sup>182</sup> to precisely capture this global neighborhood effect. Rosenau later described such an effect as “the central tensions” of the modern era: “three overlapping polarities between globalization and localization, centralization and decentralization, and integration and fragmentation.” These polarities, which Rosenau elsewhere describes as “distant proximities,”<sup>183</sup> continuously interact, whether through cooperation or conflict, to beget complexities that shape global norms, systems, and actors as central dynamics of the global political economy beyond globalization itself.<sup>184</sup>

Frammigration is the contraction of these polarities, an ongoing process whereby the “diverse and contradictory forces that can be summarized in the clash between globalization, centralization, and integration on the one hand and localization, decentralization and fragmentation on the other.”<sup>185</sup> Notably, this continuous, ongoing process globalizes national economies, which practically complicates state actors’ interaction with, and oversight of, markets. Such complexity in macro-macro relationships is occurring simultaneous to the reinforcement of state-firm relationships

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<sup>181</sup> Sally Macintyre and Anne Ellaway, “Neighborhoods and Health: An Overview,” in Ichiro Kawachi and Lisa F. Berkman, eds., *Neighborhoods and Health*, (Oxford University Press, 2003).

<sup>182</sup> Rosenau, *Turbulence in World Politics: A Theory of Change and Continuity* (2018 [1990]).

<sup>183</sup> See chapters 1, 9, and 19 in Rosenau, *Distant Proximities: Dynamics Beyond Globalization* (2003).

<sup>184</sup> Rosenau, “The Governance of Frammigration: Neither a World Republic nor a Global Interstate System” (1990).

<sup>185</sup> Op. cit., Rosenau (1990).

(“business alliances”), the intensification of international trade and investment conflicts, and expectation by constituencies that government will perform, even though their ability to frame and implement policies also is weakened.

Though the sources and consequences of frammegration are many and manifest differently depending on the micro or macro level of action, as Rosenau (2003) explains in the Four Levels of Aggregation (Table 5.3-B),<sup>186</sup> a consequence relevant to this review of linkage politics to the global political economy is this: the complexities of the globalized world are so great as to simultaneously divide and combine the local and the global to downplay the traditional tools of power reserved to state actors, as Rosenau notes:

The inordinate complexities of the emergent epoch—the continuing privatization of economies; the widening porosity of traditional boundaries, the endless proliferation of organizations; and the mounting flow of people, ideas, networks, goods, currencies, and technologies across borders—may have diminished the extent to which state, provincial, city, or other territorial leaders can control the course of events.<sup>187</sup>

This interplay of the near and far, the local and the global, the distant and the proximate, which has been discussed extensively and described differently in the literature, requires each of us, and the authorities that govern us all – including the policymakers of states – to cope simultaneously with the remote and the close-at-hand.

While the defining characteristics of globalization as increased volume and intensity of global trade flows are well appreciated, the notions of insecurity and turbulence arising from “the vortex of frammegration” are less obvious but equally pernicious. Policymakers, including state actors, are likely to be caught in this vortex – pushed and pulled to decide policy priorities overall or else a particular policy, whereby a decision favoring one polarity (or ‘proximity,’ such as globalization)

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<sup>186</sup> Ibid., Rosenau, Table 1.

<sup>187</sup> Op. cit., Rosenau (2003), 149.

**Table 5.3-B. Rosenau's Four Levels of Aggregation: Examples of frammegration**

Sources of Frammegration ▼	Levels of Aggregation ►			
	MICRO	MACRO	MACRO- MACRO	MICRO- MACRO
Skill Revolution	expands people's horizons on a global scale; sensitizes to the relevance of distant events; reverts to local concerns	enlarges the capacity of government agencies to think "out of the box," seize opportunities, and analyze challenges	multiplies quantity and enhances quality of political linkages among state actors; solidifies their alliances and enmities	constrains policy making through increased capacity of individuals to know when, where, and how to engage in collective action
Authority Crises	redirect loyalties: encourage individuals to replace traditional criteria of legitimacy with performance criteria	weakens ability of governments and other organizations to frame and implement policies	enlarges the competence of some IFIs, IGOs, and non-governmental organizations; encourages wariness in negotiations	facilitates the capacity of publics to press and/or paralyze their governments and international organizations
Bifurcation of Global Structures	adds to role conflicts, divides loyalties, and foments tensions among individuals; orients people toward local spheres of authority	facilitates formation of new spheres of authority and consolidation of existing spheres in the multi-centric world	generates institutional arrangements for cooperation on major global issues	empowers transnational advocacy groups and special interests to pursue influence through diverse channels
Organizational Explosion	facilitates multiple identities, sub-groupism, and affiliation with transnational networks	increases capacity of opposition groups to press for altered policies; divides the public from elites	renders the global stage transnational and denser with nonstate actors	contributes to the pluralism and dispersion of authority; heightens the probability of authority crises

Table 5.3-B, Continued

	MICRO	MACRO	MACRO-MACRO	MICRO-MACRO
Mobility Upheaval	stimulates imaginations and provides more contact with other cultures; heightens political salience of the outsider	enlarges the size and relevance of sub-cultures, diasporas, and ethnic conflicts	heightens need for international cooperation to control the flow of drugs, money, people, and conflict	increases movement across borders that lessens capacity of governments to control territorial boundaries
Microelectronic Technologies	enables like-minded people to be in touch with each other anywhere in the world	empowers states to mobilize support; renders their secrets vulnerable to spying	accelerates diplomatic processes; facilitates electronic surveillance and intelligence work	Constrains actors by enabling opposition groups to mobilize more effectively
Weakening of Territoriality, states, and Sovereignty	undermines national loyalties and increases distrust of states and other institutions	adds to the porosity of territorial boundaries and the difficulty of framing national policies	increases need for interstate cooperation on global issues; lessens control over cascading events	lessens confidence in states and other institutions; renders nationwide consensus difficult to achieve and maintain
Globalization of National Economies	swells ranks of consumers; promotes uniform tastes; heightens concerns for jobs	complicate tasks of state governments vis-à-vis markets; promotes business alliances	intensifies trade and investment conflicts; generates incentives for building global financial institutions	increases efforts to protect local cultures and industries; facilitates vigor of protest movements

imparts negative consequences for the other (localization) – of zero-sum dynamics. It is possible to imagine scenarios where state leaders face impossible choices – “mutually exclusive alternatives in which they either serve distant needs and negate close-at-hand or vice versa”<sup>188</sup> – that result in political trade-offs and, at worst, winners and losers.

Returning to the research’s central case of pharmaceuticals, the signing by the U.S. and countless other advanced, pharmerging, and lower-income countries of the multilateral Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement<sup>189</sup> was an international backstop to open markets, the promotion of innovation, and the goals of neoliberal economic policies—even as economies of all sizes have since struggled under the heavy burden of high pharmaceutical prices that extended monopolies engender. Alike the neighborhood effect, fragmentation and other variations of linkage politics can advance both good and ill effects.

The bidirectional influence of policy and politics can be helpful but, more often, it results in complexities and zero-sum dynamics that, to Rosenau’s credit, are expressly difficult for traditional political actors (states) to address. This cynicism, however, discounts the inherent privilege of select actors – again, enormously powerful state actors – over others that is built into and sustained by the very international regimes that states have constructed to temper globalization’s most troublesome dynamics. Market-based nonstate actors, whose respective businesses state actors rely on for economic growth and development, also benefit from just such privilege.

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<sup>188</sup> Ibid., Rosenau (2003), 150.

<sup>189</sup> As a reminder, the TRIPS agreement introduced IP law into the multilateral trading system for the first time and remains the most comprehensive multilateral agreement on IP to date. In 2001, low- and middle-income countries, concerned by high-income countries’, where the pharmaceutical industry is a leading economic actor, reading of TRIPS, initiated a round of talks that resulted in the Doha Declaration. The Doha Declaration (November 2001) is a WTO statement that clarifies the scope of TRIPS, including that the Agreement can and should be interpreted in light of the goal “to promote access to medicines for all,” and allows for compulsory licensing



## Isomorphism and The Privileging of Powerful Actors

As Drezner explains in *All Politics is Global* (2007), though the processes of global regulation may promote power sharing, the practical outputs differ.<sup>190</sup> The processes of global regulation are intentionally designed to privilege the “great powers”<sup>191</sup> in ways that coerce and contextualize less powerful actors’ engagement in global governance systems and structures, but also may constrain actors’ scope of permissible or domestic policy choices.<sup>192</sup>

Here, the dynamics of fragmentation can be observed once more: state actors’ preferences, first, flow from their respective domestic priorities but are actualized, second, as a “function of the adjustment costs” or the calculations created by different outcomes, including whether to cooperate regulatorily or changing their international engagement or level of support.<sup>193</sup> More often than not, Drezner asserts, the market size of these powerful state actors alters the nature of the outcomes of international regulatory cooperation and/or global governance, which can make all the difference between the outcomes that the process generated or the actual outcomes.

Less powerful actors are not only less likely to realize the gains (from power sharing) or equity (from a global level-playing field), but they also are more likely to be motivated or coerced to support certain rules and regulations over others that they otherwise may not be inclined to support, or institutional isomorphism. According to both Neorealism<sup>194</sup> and the World Society Approach,<sup>195</sup>

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<sup>190</sup> Drezner, *All Politics Is Global: Explaining International Regulatory Regimes* (2007), 11.

<sup>191</sup> Ibid. For Drezner, the only great powers worth mentioning are the U.S. and the European Union (EU), but other powerful state and non-state actors could be swapped in depending on the particular issue under examination and one’s comfort with non-state centric approaches. For example, it should not be unreasonable to survey the global political economy, inquire which industrial sectors dominate economic growth, development, and recovery, and evaluate whether those firms have “great power,” too.

<sup>192</sup> Op. cit., Drezner (2007), 35-36.

<sup>193</sup> Ibid., Drezner, 5.

<sup>194</sup> In discussing globalization, Waltz (1999) asserts that powerful state actors continue to have autonomy, but states will adopt the best practices of other leading states, leading to policy convergence. See Waltz, “Globalization and Governance,” 697.

<sup>195</sup> For a comprehensive discussion of isomorphic processes, see DiMaggio and Powell, “The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields”; Finnemore, “Norms, Culture, and World Politics: Insights from Sociology’s Institutionalism”; Meyer et al., “World Society and the Nation-state”; Boli and Thomas, “World Culture in the World Polity: A Century of International Non-Governmental Organization”; Voeten, “Making Sense of the Design of International Institutions.”

isomorphism foregoes the economic and market aspects of globalization by focusing instead on globalization's ideational dynamics: the spread of new norms; the "expansive structuration" of the state; the development of new rules and regulatory frameworks; and the transfer to other state actors of certain policies and political approaches, including through the prior discussed processes of policy coordination, convergence, and harmonization.

Isomorphism not only privileges outcomes but also the processes and choices of powerful actors.<sup>196</sup> Through isomorphism, the forces of globalization drive the design of processes that, reflecting market size and capacity, generate outcomes favorable to powerful state (really, leading market) actors, but also shape the policy ideas, preferences, and choices available to all state actors to the primary benefit of powerful state actors—and often "through coercive, normative, and mimetic... processes."<sup>197</sup> (Cogently, such preference shaping is not solely to the benefit of powerful states. It also preserves the very market-oriented structures that contemporary neoliberal-styled globalization relies on.)

Though Drezner himself does not align with either Structural Neorealism or the World Society Approach, his Revisionist Model requires isomorphism to functionally deliver on its promise of a cogent theory of power and politics in preference formation and influence over international regulatory coordination and resultant standards. Rather than contextualizing isomorphism in the international institutions, bureaucracies, and intergovernmental bodies established to "structurate" the globe, Drezner's Revisionist Models depends on an isomorphic-light approach that centers powerful state actors (instead of international organizations), helps coordinate and converge the preferences and priorities of less powerful state and nonstate actors, and – ultimately and still – secures the preferred outcomes of powerful state actors. Waltz (1999) aptly captures the nexus

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<sup>196</sup> Drezner, "Globalization and Policy Convergence" (2001), 61.

<sup>197</sup> Op. cit., Voeten, "Making Sense of the Design of International Institutions," 152.

between the Neorealist-World Society isomorphism and Revisionist Model of global regulation: “In a competitive system, the winners are imitated by the losers, or they continue to lose.”<sup>198</sup>

### The Pathologies of Governance

The drivers of regulatory governance frame the dialogue within the broader geopolitical and politico-economic landscape, which prominently features nonstate actors, including multinational corporations and other large firms, alongside international financial institutions and states. Despite being promoted as harbinger of efficiency, the shift from *government* to *governance* (including public-private regulatory coordination mechanisms) entails critical pathologies and “massive failures of governance at the global and national levels,” which the Covid-19 pandemic brutally exposed.<sup>199</sup>

Some have argued that the ‘Regulatory state’<sup>200</sup> has been reconfigured, both politically (in terms of its weakened connection to the citizenry through party and representative politics) and bureaucratically (capacity to manage widening social inequities),<sup>201</sup> resulting in structural cuts in democratic contestation, or deregulation, that both promoted select economic interests while simultaneously, and quite fundamentally, altering the relationship between regulatory governance from an extension of the citizenry to one of potential interest capture.<sup>202</sup>

What does this mean for governance within the context of global health? Lee Jones and Shahar Hameiri (2021) suggest that Regulatory states cannot marshal the resources to prepare for, let alone respond to, global health needs—whether in times of crisis or the risk management of the everyday.<sup>203</sup> (the report of the World Health Organization (WHO) Review Committee on the

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<sup>198</sup> Op. cit., Waltz, “Globalization and Governance,” 695.

<sup>199</sup> Jones and Hameiri, “COVID-19 and the Failure of the Neoliberal Regulatory state.”

<sup>200</sup> Leibfried, Huber, Lange, Nullmeier, and Stephens, eds, *The Oxford Handbook of Transformations of the state*.

<sup>201</sup> Mair, *Ruling the Void*.

<sup>202</sup> Potter, Olejarski, and Pfister, “Capture Theory and the Public Interest: Balancing Competing Values to Ensure Regulatory Effectiveness.”

<sup>203</sup> Op. cit., Jones and Hameiri, 20.

Functioning of the International Health Regulations (IHRs) During the Covid-19 Response found that the majority of participatory member states had not actualized their commitment to the IHRs.<sup>204</sup>) To make sense of these changes and encourage a reconsideration by states of how best to promote governance Jones and Hameiri articulate four pathologies of the shift from government to governance. *First*, the dynamic reflected in the IHR challenge suggests a *pathology of meta-governance*, or deferral to an international or intergovernmental body. *Second*, Regulatory states reflect an inherently fragmentary character, which expresses itself as the privatization and dispersal of authority *downwards* (to sub-national systems, like state actors' regional or local governments), *upwards* (to intergovernmental bodies), and *horizontally* (to quasi-independent regulatory authorities (RAs)).

The *third* structural flaw in the Regulatory state is that it shifts the burden of enforcing laws and regulations away from state agencies and *to the entities being regulated*—reflecting dynamics both of interest capture and of rising corporate self-governance. Practically, the dispersal of authority in these ways makes it exceedingly difficult for RAs to secure, let alone enforce, desired regulatory policy outcomes. Jones and Hameiri suggest this results in practical *governance*, referring to the outcome of regulatory oversight, which is “reduce[d]... to a ‘box-ticking’ exercise, designed more to demonstrate compliance than to change substantive outcomes” of the entity being regulated.<sup>205</sup> *Fourth*, these constructed weaknesses go hand-in-hand with overall shifts in the *provision of public goods*, or else services provided and paid for by the state. Where the state once directly provided such goods or services, and now it provides oversight of the market provision of that good(s), Mike Raco (2016) suggests this produces an asymmetric, codependent “client-operator contractualism” with the

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<sup>204</sup> The WHO's 2005 IHRs reflect a “shift towards meta-governance,” per Jones and Hameiri, which originates with the 2005 amendments, which came on the heels of the 2003 SARS outbreak. Although the WHO gained additional surveillance capacities to monitor compliance, it did not acquire supranational powers. Moreover, the WHO is not resourced to build member state capacity on health promotion or otherwise, though it attempts with the level of resources we do have. WHO, “Strengthening Preparedness for Health Emergencies: Implementation of the International Health Regulations, 2005.”

<sup>205</sup> Op. cit., Jones and Hameiri, 8-9.

state becoming a “negotiator[] rather than provider”<sup>206</sup> and the firm consulted because the expertise for proper regulatory oversight “is often monopolized by the private sector.”<sup>207</sup>

In terms of codependence, and reflecting on the themes from Chapter 2, these governance interactions between regulatory authorities and the ‘governed’ reconstitute “significant fractions of capital [as] parasitically dependent on states for their survival, but states also depend upon them,” whether to maintain “the most basic of social services” or to meet other state priorities—like those of their recovering economies.<sup>208</sup> Harkening to Strange (1996) and Potter et al. (2014), the implication of the pathologies of governance with a dominating sector of the economy are ripe for producing a particular dynamic: the potential for interest capture, or when firms engage in a politics of contractual and regulatory capture of government interests. Pharmaceutical governance suggests a paradigmatic case of such intertwining forces and interests.

#### 5.3.4 Pharmaceutical Governance and Regulation as a Paradigm Case

Returning to the theme of all politics being global, including the politics of health, Drezner ties the concepts of adjustment costs, policy convergence, and idea isomorphism together in case studies, which hold up well—with one exception. He describes the World Trade Organization’s 1994 TRIPS Agreement, earlier discussed, as a “semi-deviant case,” reminding that the U.S. and EU softened their stance on enforcement in response to international concern over the pricing and availability of HIV/AIDS medicines. This public pressure campaign culminated in the 2001 signing of the Doha Declaration and the 2005 codification by member states of the World Trade Organization of this and an earlier clarification as permanent amendments to TRIPS:

The TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted

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<sup>206</sup> Raco, *state-Led Privatisation and the Demise of the Democratic state: Welfare*, 3 and 98.

<sup>207</sup> Jones and Hameiri, “COVID-19 and the Failure of the Neoliberal Regulatory state,” 9.

<sup>208</sup> Op. cit., Raco, 46-47.

and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.<sup>209</sup>

The positional softening of the U.S. and EU, Drezner argues, is not a reflection of the capacity of global civil society (GCS) and related nonstate actors to raise public health issues to the fore of the global public dialogue, nor of their power to turn collective concern for public health into effected global change (i.e., Doha). Rather, the Doha Declaration was an adjustment cost worth paying for several reasons: *first*, to guarantee, once again, preferred regulatory outputs (i.e., the U.S. and EU acted to ensure the amendment “fit with their preference”); *second*, to protect against reputational risk and liability (i.e., by “appropriate[ing] the normative frame of improving public health,” the U.S. and EU were able to avoid the blowback-by-proximity of globally negative publicity that the pharmaceutical sector garnered); and *third*, to preserve policy flexibilities to maintain national security (i.e., then-and-now, U.S. national security strategies emphasize public health in direct response to infectious disease as a global security risk).

Doha was not a response to GCS pressure but, according to Drezner, a power-play by the U.S. and EU to advance their own policy objectives, which inherently reflected domestic political considerations even if not the preferences of everyday Americans and Europeans. Drezner notes two caveats of linkage politics, one of which is “the possibility that nonstate actors have a longer-run plan of action that is commonly thought.” He notes that the spread of global norms “is a lengthy process” and GCS’ interest in states’ adoption of even more favorable terms may inherently require a longer time horizon. Though Drezner can neither validate nor falsify this potentiality, the implicit reference to nonstate actors is far too narrow in its scope. Were ‘pharmaceutical manufacturer’ incorporated into the case-specific definition of ‘nonstate actor’ (or even ‘great power’), it could be

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<sup>209</sup> World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); See also Kerry and Lee, “TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?”

argued that the global pharmaceutical market – mindful the political winds were not at its back – calculated its *own* adjustment costs, concluding Doha was far less costly than the whole-cloth loss of TRIPS.

Similarly, it is possible to reframe the rationale of the U.S. and the EU not only in terms of practical power preservation (i.e., the first consideration, above), reputational risk management, and national security policy. If bio-pharmaceutical innovation is a powerful narrative backed by drug-makers for preserving the international pharmaceutical market, so, too, is global health – backed by powerful state actors – for preserving growth in the very same international pharmaceutical market that so buoys their economies. It is odd that the discipline established to account for the significance of economic relationships on their own, and distinct from being a component of national power, in IR continues to marginalize this significant area of global economic and political activity except for security and trade-adjacent issues.

#### 5.4 Deconstructing Health's Long Absence from IPE

Health long has been reserved to “the domestic sphere of national governments,” with primary decision-makers, interests, and influences at the level of national competence and thusly considered beyond the boundaries of IPE<sup>210</sup> and IR, with rare exceptions (e.g., pandemics).<sup>211</sup> In their account of the historical absence and 21st century emergence of health within IPE, Jappe Eckhardt and Kelley Lee (2019) assert the discipline's traditional focus on issues facing the global economy (e.g., international trade, monetary policy, role of multinational corporations and other

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<sup>210</sup> Paraphrasing Balaam and Dillman, and consistent with the field, throughout the research we intend to make a distinction between the term ‘international political economy’ (and also both ‘global political economy’ and ‘global economy’) and the acronym ‘IPE.’ The former refers to the subject area of the discipline’s field of inquiry, or object of study. The latter, then, is the discipline itself. See David N. Balaam and Bradford Dillman, “What Is International Political Economy?” Chapter 1 in Balaam and Dillman, *Introduction to International Political Economy*.

<sup>211</sup> Health in terms of global security is a preeminent exception, as this chapter explores later. For an extensive conversation on the securitization of health literature or, as Elbe describes it, the “medicalization of security,” see Elbe, *Security and Global Health*.

non-state economic actors, economic development) excluded consideration of domestic (and social policy, in particular) issues like health.<sup>212</sup> Writing a decade earlier, Adrian Kay and Owen David Williams (2009) share Eckhardt and Lee's conclusion, noting "a striking poverty of International Political Economy approaches to this fundamental area of globality and human life."<sup>213</sup>

Throughout the 20th century, when IPE reemerged as a discipline, health remained a question reserved to either Public Health researchers whom "rarely incorporated insights from IPE or IPE-related questions," or Health Policy analysis, "which was studied almost exclusively as a domestic concern of national and sub-national government, with 'international' providing comparative analysis of national contexts."<sup>214</sup> When examined, rare as it was, through the prism of political economics, Eckhardt and Lee note health was associated with "alternative" economic perspectives, including Marxism<sup>215</sup>, and thusly was neither incorporated into the "mainstream analysis of health policy"<sup>216</sup> nor "explicitly rooted in IPE."<sup>217</sup> The field of IPE has prioritized positivist issues, like trade imbalances and economic growth, and marginalize normative issues, like health, despite normative issues often holding deeply equal primacy, impact, and relevance to societies and operating and influencing interactively between structures, systems, and state and nonstate actors.

This historical penchant for exclusion of normative issues and alternative economic perspectives, however, is not, as some have argued, unique to the particular ontology of the American or Harvard School of IPE; it can be found across the discipline's continuum of epistemologies and ontologies. Within-discipline finger-pointing aside, the absence of a mature IPE

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<sup>212</sup> See, for example, Oatley, *International Political Economy*; Ravenhill, *Global Political Economy*.

<sup>213</sup> Kay and Williams, *Global Health Governance: Crisis, Institutions and Political Economy*, 8.

<sup>214</sup> Jappe Eckhardt and Kelley Lee, "The International Political Economy of Health," Chapter 41 in Shaw et al., *The Palgrave Handbook of Contemporary International Political Economy*.

<sup>215</sup> Navarro, *Medicine Under Capitalism*.

<sup>216</sup> Shaw et al., *The Palgrave Handbook of Contemporary International Political Economy*. Page 662.

<sup>217</sup> Kay and Williams, *Global Health Governance: Crisis, Institutions and Political Economy*. Page 1.



sub-discipline focused on health is a poor reflection of the parameters that IPE set out for itself: examining the political, economic, and social dimensions of the global political economy, which includes health right along with security and currency flows.<sup>218</sup> Physician, neuroscientist, professor of medicine, and rector of the Karolinska Institute in Sweden Ole Petter Ottersen (2014) articulates the inexorable gap between this absence and the reality of health and systems:

Great strides have been made over the past decades when it comes to prevention and cure. All these initiatives are carried out in a political landscape in which many decisions made outside the global health system interfere with or undermine efforts undertaken within the global health system.<sup>219</sup>

How should health remaining so long on the discipline's margins be explained?<sup>220</sup> Or, amidst the academic and political fervor for global health courtesy of the Covid-19 pandemic, has health “ascended from the ‘low’ politics to the ranks of ‘high’ politics in IR,” become relevant because of its proximity to “high politics,” rather than in its own right?<sup>221</sup>

#### 5.4.1 The Legacies of Realism and Neoclassical Economics

Concerned with the complex interplay of politics and economics<sup>222</sup> and “the interaction of the market and powerful actors,”<sup>223</sup> IPE reemerged as a significant field of study in the post-World War I era in response to global developments, namely the rise of “complex [economic]

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<sup>218</sup> Balaam and Dillman, Introduction to International Political Economy.

<sup>219</sup> Holmes, “Profile | Ole Petter Ottersen.”

<sup>220</sup> For a discussion of the American and British schools of IPE, see Cohen, “The Transatlantic Divide: Why Are American and British IPE so Different?” For a conversation exploring whether the American School is appropriately characterized as such, or if these are unique to a further subset of the discipline within the United States (i.e., Harvard School), see Germain, “The ‘American’ School of IPE? A Dissenting View.”

<sup>221</sup> Youde, “High Politics, Low Politics, and Global Health.”

<sup>222</sup> Jackson and Sørensen, Introduction to International Relations: Theories and Approaches.

<sup>223</sup> Gilpin, Global Political Economy. Page 45.

interdependence.”<sup>224</sup> Existing theories were ill-equipped to explain these developments.<sup>225</sup> In their respective historical discussions of the intellectual roots of IPE, both Benjamin J. Cohen (2008) and John Ravenhill (2010) emphasize the field’s reemergence, noting IPE’s lineage is rooted in 19th century and 20th century scholarship, including that of classical economists (Adam Smith, David Ricardo, John Stuart Mill), social and economic change theorists (Karl Marx, Emile Durkheim), institutional economists and anthropologists (Thorstein Veblen, Karl Polanyi), and mid-century economists and economic historians (Albert Hirschman, Jacob Viner, and Charles P. Kindleberger).

While rooted in 19th and 20th century scholarship, modern events reexamined many of these assumptions. Following the August 1971 U.S. decision to end the gold-exchange standard that had founded the then-dominant Bretton Woods international monetary regime, questions emerged as to how to account for the significance of economic interactions on their own (and distinct from being a component of national power) in IR. Following the complementary signals of demonstrated global interdependence rooted in economic relations, including the 1973-74 crisis caused by the Organization of Petroleum Exporting Countries (OPEC) imposed oil embargo, economic relations and economic power gained greater recognition in IR, though the discipline lacked the constructs and expertise to make sense of these global political disruptions. In the reemerged field’s early years, Thomas C. Lawton, James N. Rosenau, and Amy C. Verdun (2018)<sup>226</sup> and Robert O. Keohane (2009) explain that the ‘old’ IPE (of the 1960s and 1970s) focused on the political implications of this heightened economic interdependence, framing IPE as an economically minded subdiscipline of

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<sup>224</sup> The term “complex interdependence” was developed by Robert O. Keohane and Joseph S. Nye, Jr. It refers to the various, complex transnational connections (“interdependencies”) between states and societies. Interdependence theorists noted that such relations, particularly, economic ones, were increasing; while the use of military force and power balancing were decreasing (but remained important). It is defined as “the mutual dependence of actors and the reciprocal costs of that relationship.” See Keohane and Nye, Jr., *Power and Interdependence*.

<sup>225</sup> For a fulsome discussion of the intellectual lineage of International Political Economy, see John Ravenhill, “International Political Economy,” Chapter 31 in Reus-Smit and Snidal, *The Oxford Handbook of International Relations*. See also Cohen, *International Political Economy: An Intellectual History*.

<sup>226</sup> Lawton, Rosenau, and Verdun, *Strange Power: Shaping the Parameters of International Relations and International Political Economy*.

IR: “there was no field. Little research was being done. Most economists were ignoring politics, and IR saw political economy as ‘low politics,’ minor, boring and incomprehensible.”<sup>227</sup> Enter IPE.

By investigating the economic instruments of foreign policy, like sanctions and trade agreements, and the economic relations between industrialized and less developed countries, IPE explained “a world of growing interdependence,” in part, by broadening the typologies of power within IR to include “soft power” (the ability to obtain preferred outcomes by attraction rather than coercion or payment), and different forms of “hard power” (use of coercion or payment to achieve preferred outcomes, like sanctions).<sup>228</sup>

Employing the same state-centric approach which then-dominated IR, IPE was framed as the study of state-to-state economic relations (e.g., trade negotiations, economic sanctions, monetary regimes) as distinct from states’ political relations. It reflected a research agenda broader than the confines of International Relations’ dominant theoretical paradigm at the time (and to a degree still): Realism, which emphasized not only the centrality of state actors, power (primarily defined in terms of the preponderance of military force), and anarchy (the absence of a global government), but also that the political sphere is autonomous from socio-economics.<sup>229</sup> While socio-economics remained distinct, it clearly was growing as part of a broader discussion of the interaction between international politics and economics.

Given its focus on the politics of international economic exchange – the international politico-economic relations (versus international political relations), IPE scholars have been influenced by two sets of questions, per David Lake (2009): “what are the political determinants of globalization,” and “how does integration (or not) into the international economy affect the interests

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<sup>227</sup> Keohane, “The Old IPE and the New,” 35.

<sup>228</sup> Nye, Jr., *Bound to Lead: The Changing Nature of American Power*.

<sup>229</sup> Morgenthau, *Politics Among Nations*.

of individuals, sectors, factors of production, or countries and, in turn, national policies?”<sup>230</sup> If IPE begins with the assumption that market openness is rare – protectionism characterized most states’ trade policies preceding the mid-to-late 20th century – though considered ideal, making sense of the political decisions that either have worked towards or away from that ideal is a crucial starting point. These questions yield four goals for Keohane’s ‘old’ IPE, which are not rooted solely in Realism and Neoclassical Economics but also influenced by the discipline’s contemporary research agenda (Table 5.4). This is evident in the dual-track evolution of “IPE’s split brain”<sup>231</sup>: the American and British Schools.

#### 5.4.2 The American School of IPE

IPE’s scholarly priorities and perspectives shifted after the OPEC embargo, resulting in the emergence of two dominant and different schools of thought. Benjamin J. Cohen (2007) notes that “once born, the field proceeded to develop along separate paths followed by quite different clusters of scholars,” referring to the distinction between the American and British Schools of IPE.<sup>232</sup> The intellectual legacies of Realism and Neoclassical Economics are essential to understanding the IPE, particularly, from the standpoint of the American School. Cohen’s articulation of what is considered the American School of IPE is instructive:

The American School remains determinedly state-centric, privileging sovereign governments above all other units of interest.... For it is essentially a subset of IR [International Relations], sharing the Political Science discipline’s central preoccupation with public policy. The core object of study... is limited to questions of state behavior and system governance. The main purpose of theory is explanation: to identify causality. The driving ambition is problem solving: to explore possible solutions to challenges within the existing system... The American School remains wedded to the principles of positivism and empiricism – the twin pillars of a hard science and model.<sup>233</sup>

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<sup>230</sup> Lake, *Hierarchy in International Relations*, 221.

<sup>231</sup> Weaver, “IPE’s Split Brain.”

<sup>232</sup> Cohen, “The Transatlantic Divide: Why Are American and British IPE so Different?” (2007).

<sup>233</sup> Op. cit., Cohen (2007).

**Table 5.4. Overarching research goals of IPE**

Goal	Description
Emphasize how politics determines the stability and openness of the international economy	Though Neoclassical Economics showed that free trade was optimal, in reality, protectionism historically had dominated states' trade policies. IPE scholars have proposed explanations that are more political to explain such paradoxes created by economic theory.
Explain states' foreign economic policy choices	From a political standpoint, these choices are the most important factor shaping the international economy. In working through these questions, scholars have explored not only international factors, but also domestic ones.
Understand the changing positions of states in the world economy	Economic causes for this change are usually supplemented by political ones, while domestic causes of the rise and decline of states are paired with international factors.
Account for the impact of the international economy on domestic politics	The heightened economic interdependence between state actors is presumed to impact domestic politics, an issue often explored through globalization's influence on national economies.

Author generated examples and explanation.

Though IPE set out to be broader than IR and the confines posed by Realism, particularly, in terms of the typologies of power (to include economic power), the American School was heavily influenced by the 1979 publication of Kenneth Waltz's *Theory of International Politics*.<sup>234</sup> Critiquing arguments of the limiting effects of complex interdependence on leading states (the "great powers"), in *Theory of International Politics*, Waltz reaffirmed Realism as a core theoretical framework, asserted the continued primacy of state actors and called for a scientific approach, "emulating that of economics,"<sup>235</sup> to be advanced across IR and IPE, which should be considered a subdiscipline of the former.

<sup>234</sup> Waltz, *Theory of International Politics*.

<sup>235</sup> Reus-Smit and Snidal, *The Oxford Handbook of International Relations*. Page 546.

Waltz's call for a more scientific approach to IR and IPE was itself informed by "the prevailing ontology of economics." This dominant ontological approach (methods) was influenced by prominent Economics scholarship, specifically, Neoclassical Economics (i.e., a precursor to contemporary neoliberal economics), which focused on the invisible hand of market forces, the role of the private sector, and ways to achieve optimal, technical efficiency in market performance.<sup>236</sup> The earlier discussion and examination of public goods scholarship, in Chapter 3, presented the inherent discomfort among mid-century economists to incorporate political processes and structures, like sources of authority and conflicts between actors and interests, into their economic theories, models, and evaluations—even public policy evaluations.

This discomfort persists within contemporary neoliberal economics, reserving questions of "how the economic pie gets divvied up" to the market itself to resolve distributional allocations, or else to other academic disciplines to make sense of the "scruffy bargaining or political compromise" inherent in political processes.<sup>237</sup> Akin to Realism's distinction between politics and economics, neoclassical economics discouraged scholarship on questions about socio-politics, reserving its focus to the outputs (evaluations and implications) of policy for economic activity rather than to policy's inputs (distribution of power, processes and structures, governing norms). Samuelson, along with other neoclassical and mid-century American economists, acknowledged that market forces could be and often were mediated by states and politics, but high-powered mathematics were ill-suited to explain the proverbial sausage making of policy and, thus, political matters were excluded from the numeracy and abstraction of economic theory. Taking up this mantle, IPE adopted what Cohen describes as a "soft Rational Choice approach" to quantitatively explain state behavior.

Under Rational Choice, state actors remain primary but are viewed as rational actors with

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<sup>236</sup> Cohen, *International Political Economy: An Intellectual History*. Page 39.

<sup>237</sup> Cohen. Pages 39-40.

near-economic efficiency in the identification and pursuit of their interests. Game theory is a prime example of the narrowed ontology characteristic of the American School and, a research agenda that naturally excludes the study of the interaction between international and domestic systems, the role of ideas and other normative analyses, questions of agency and structure, and other research incompatible with an epistemological approach “wedded to the principles of positivism and empiricism.”<sup>238</sup> Most economists demurred from the field based on concerns that empirical methods were ill-equipped to address the imprecise notions of power, dependency, and interests that dominate IR. The resultant epistemology of the American School approximates far more the formal modeling, data rigor, positivism, and statistical technique of economics.<sup>239</sup> The evolution of the British School could not be more different.

#### 5.4.3 The British School of IPE

Arguing that IR theory and scholarship were “inadequate and underdeveloped, from the political side” and subject to “a dollar-biased skew on the economic side,” IPE forerunner Susan Strange (1970) discounted the application of economic assumptions to explain actor behavior (i.e., Rational Choice Theory, or RCT):

My other criticism is that the economists’ contributions to the study of International Economic Relations [IPE] have shown political naiveté. Too often they write on international economic problems as though political factors and attitudes simply did not exist and could be brushed aside as some kind of curious quirk or aberration....

Economic theory continues to assume it is about economic choices, even when descriptive economics has shown how often the rationality is qualified and decisions influenced by non-economic considerations. How much more has international economic history shown that political choices on economic policies have seldom

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<sup>238</sup> Cohen, “The Transatlantic Divide: Why Are American and British IPE so Different?” Page 200.

<sup>239</sup> Cohen also argues the influence of economics’ penchant for rationalism and positivism – collectively referred to as reductionism – now extends beyond the bounds of the American School of International Political Economy and to International Relations, Political Science, and other social sciences: “Political scientists have an inferiority complex when it comes to economics. Even such notables as Katzenstein, Keohane, and Krasner bow their heads, describing economics as ‘the reigning king of the social sciences’ Whether the title is deserved or not, it is certainly true that the methodology of economics now appears to set the standard for what passes for professionalism among social scientists in the US.” See Cohen. Page 206.

been motivated by carefully reasoned assessments of quantifiable economic costs and benefits, but rather by political aims and fears, and sometimes by totally irrelevant considerations and irrational emotions.<sup>240</sup>

Contrary to the epistemology and ontology of the American School, rooted in positivism, rationalism, and reductionism, Strange argued that IPE should be the “middle ground” between political and economic analysis: a heterodox, collaborative, and multivariate approach to the study of “the international system and the interaction between domestic politics and the world political economy”<sup>241</sup> that favors reflectivism over rationalism or reductionism, normativism over positivism.<sup>242</sup>

Strange and Robert Cox are revered for their roles in pioneering the British School which posits that IPE should be multidisciplinary (prioritizing academic openness, inclusiveness, and eclecticism),<sup>243</sup> normative (seeking engagement with social issues, including distributional issues like health and other public goods), and critical (questioning orthodoxy and mainstream thinking).<sup>244</sup> Though each theme – multidisciplinary, normative, and critical – is integral to the British School of IPE, Strange’s and Cox’s advocacy of “normative ambition”<sup>245</sup> highlights the acute divergence from the American School’s affinity for and reliance on realism and its adjacencies, including neorealism and neo-utilitarianism. In “Social Forces, States and World Orders: Beyond International Relations Theory” (1981) and *Production, Power, and World Order* (1987), Cox similarly posited that the changes of the late 20th century reflected the emergence of a new world order driven by the realignment of social forces versus heightened economic interdependence alone. Cox rejected IR’s centrality of state

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<sup>240</sup> Strange, “International Economics and International Relations: A Case of Mutual Neglect.” Emphases added.

<sup>241</sup> Lawton, Rosenau, and Verdun, “Introduction: Looking Beyond the Confines,” Chapter 1 Lawton, Rosenau, and Verdun, Strange Power: Shaping the Parameters of International Relations and International Political Economy.

<sup>242</sup> Strange, “International Economics and International Relations: A Case of Mutual Neglect.”

<sup>243</sup> Strange, *The Retreat of the state: The Diffusion of Power in the World Economy*. Page xv.

<sup>244</sup> Cohen, “The Transatlantic Divide: Why Are American and British IPE so Different?” Page 206.

<sup>245</sup> Cohen. Page 206.



actors, arguing that the state should not be analyzed in isolation but in relation to the structures and the actors with which they interact (“state society complex”).

In stark contrast to the American School, the hallmark of the new world order for the British School is not the global political economy’s heightened economic role but social interdependence: “international production is mobilizing social forces, and it is through these forces that its major political consequences vis-a-vis the nature of states and future world orders may be anticipated.”<sup>246</sup> To understand the then-emergence of a new world order, the British School argued it is imperative to first examine the structures and actors that shape social forces and, second, to support social forces that would “bargain for a better deal within the world economy.”<sup>247</sup> If “the center of gravity in world politics has shifted,” new concepts of power and politics are needed for addressing the much larger ontological problem within IR: the “failure of interconnection.”<sup>248</sup>

The British School’s approach to analyzing power, specifically, “who, or what, is responsible for change” and “who, or what, exercises authority... in the world economy or world society,” seeks to replace Realism’s view of IR and the American School’s state-centric view of the global political economy with a more multivariate, multidisciplinary approach that reflects a “world of multiple, diffused authority.”<sup>249</sup> By blending approaches and perspectives, and synthesizing findings, across disciplines, Strange believed that IPE would likely produce imperfect findings, but such imperfection would approximate far more closely the complexity of the contemporary global political economy than perfect theory and refined, but impractical, models.<sup>250</sup>

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<sup>246</sup> Cox, “Social Forces, states and World Orders: Beyond International Relations Theory.” Page 147.

<sup>247</sup> Cox. Page 151.

<sup>248</sup> Strange, *The Retreat of the state: The Diffusion of Power in the World Economy*. Page 12.

<sup>249</sup> *Ibid.*, Pages 184 and 199.

<sup>250</sup> *Op. cit.*, Lawton, Rosenau, and Verdun, *Strange Power: Shaping the Parameters of International Relations and International Political Economy*.

#### 5.4.4 IPE's Normative Ambitions, Reconsidered

In the research's prior discussion of public goods theory, the epistemology and ontology that a positivist approach imparts were explored. Say, normative approaches, including those advocated by Strange, require engagement with the imprecise, the vague, and the opaque: the social issues, like health, which are not solely economic. By widening the aperture of power and politics to incorporate both nonstate actors and the spectrum of interests and influences (i.e., even those that may not be rational or do not lend themselves to economization), Strange posits a theoretical framework for exploring what Samuelson, who was an Economist rather than an IPE scholar, could not: employing scholarship not only to articulate the wrongs of the world, but also to identify ways to the right them.

According to Strange, IPE “should be about justice, as well as efficiency: about order and national identity and cohesion, even self-respect, as well as about cost and price.”<sup>251</sup> Normative ambition is a mechanism for centering ethics, equity, and values in IPE, opening wide the door to social distributional considerations, particularly, for matters like health. But questions remain whether normative intent aligns with practice in the British School of IPE. To the credit and legacy of Strange, Cox, Robert Gilpin, Robert Keohane, and Joseph Nye, IPE scholars spanning the spectrum between the American and British Schools – and at ontological points between – have employed both positivist and normative approaches, economic models and theoretical frameworks, rigorous data and exploratory cases, to understand and explain issues deeply fundamental to IR, including changes in patterns of international conflict<sup>252</sup> and cooperation,<sup>253</sup> the bifurcation of

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<sup>251</sup> Susan Strange, “Preface,” Pages ix-xi in Strange, *Paths to International Political Economy*.

<sup>252</sup> Huntington, *The Third Wave: Democratization in the Late 20th Century*.

<sup>253</sup> Mansfield and Reinhardt, “International Institutions and the Volatility of International Trade.”

international and domestic matters (e.g., state-in-society approach,<sup>254</sup> two-level games<sup>255</sup>), and what is power and who yields it.<sup>256</sup>

The IPE discipline also has contributed to developing notable theories with implications for the study of a range of political processes, structures, and phenomena relevant to IR, Political Science, Economics, and Public Health, including security, governance, anarchy, and the behavior of states. Relevant to questions of power and power-driven or adjacent processes and interactions (i.e., politics), the discipline has contributed to hegemonic stability theory,<sup>257</sup> development theories,<sup>258</sup> collective action theory,<sup>259</sup> democratic peace theory,<sup>260</sup> and constructivism.<sup>261</sup> In its practical reflection of “inclusiveness and eclecticism above all,” the American and British Schools of IPE have demonstrated the value of crossing academic boundaries to “extend more widely the conventional limits of the study of politics,” the study of power.<sup>262</sup> As this discussion has found, however, such boundary crossing has yet to extend to health, including the power and politics of medicines, despite the growing extant literature directly linking health and globalization.

### **5.5 Summary Findings of Critical Literature Review: Health is a Public Good, Distinctly Political, and a Core Issue of the 21st Century Global Political Economy**

Contemporary IPE reflects a continuum of approaches, rather than a “transatlantic divide,” examining the causes and implications of “key dimensions of the world we live in” through the dual

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<sup>254</sup> Moravcsik, “Taking Preferences Seriously: A Liberal Theory of International Politics.”

<sup>255</sup> See Putnam, “Diplomacy and Domestic Politics: The Logic of Two-Level Games”; Lake, *Hierarchy in International Relations*.

<sup>256</sup> Op. cit., Strange, *The Retreat of the state: The Diffusion of Power in the World Economy*.

<sup>257</sup> Robert O. Keohane, “The theory of hegemonic stability and changes in international economic regimes, 1967-1977,” in Holsti, “The Concept of Power in the Study of International Relations.”

<sup>258</sup> Potter et al., *Geographies of Development: An Introduction to Development Studies*.

<sup>259</sup> Olson, *The Logic of Collective Action*.

<sup>260</sup> Kant, *Toward Perpetual Peace and Other Writings on Politics, Peace, and History*. See also Doyle, “Kant, Liberal Legacies, and Foreign Affairs”; Doyle, “Kant, Liberal Legacies, and Foreign Affairs, Part 2.”

<sup>261</sup> Wendt, “Anarchy Is What states Make of It: The Social Construction of Power Politics.”

<sup>262</sup> Strange, “Wake up, Krasner! The World Has Changed.”

lenses of both politics and economics.<sup>263</sup> Recent special issues of the *Review of International Political Economy* (RIPE) and *New Political Economy* (NPE), for example, “highlight collective blind spots that may dull IPE’s capacity to theorize the current moment.”<sup>264</sup> The 2021 special issue of *RIPE*, for example, encourages topics ranging from racial and gender inequities to corporate power, climate change to expertise-dynamics in global governance, and big tech to “assetization” (the creation of knowledge assets) be pushed “higher up the scholarly agenda.”<sup>265</sup> Topics once excluded from the purview of IPE (like climate change) or else marginalized (like income inequality<sup>266</sup>) increasingly are being centered, held as examples of the discipline’s increasing intellectual diversity and inclusivity. Why not also IPE’s treatment of health? Such a question rightly deserves a critical examination of why it has, to date, been essentially marginalized.

This narrative synthesis of health and the IPE discipline attempts to answer this question by explaining health’s presence, though marginalized, in IPE scholarship pre-dating the Strange, Cox, Keohane, and Nye reformation of the late 20th century. *First*, while this review suggests that health has been marginalized in IPE, it actually has deep roots but through alternative politico-economic frameworks, namely Marxism and Socialism through the works of Engels, Navarro, and others. *Second*, return to the contradiction posed by O’Neill (1994) and Drezner (2007), that all politics is local *and* global, respectively, by explaining the fragmentation of health, a causality of globalization, which drives the politics of health – even those of the local and national levels – to the terrain of what Scholte (2000) calls the “supraterritorial.” This chapter closes by examining the contemporary characterization of health as an “emerging issue”<sup>267</sup> *because* of its proximity to core issues of the

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<sup>263</sup> LeBaron et al., “Blind Spots in IPE: Marginalized Perspectives and Neglected Trends in Contemporary Capitalism.”

<sup>264</sup> Op. cit., LeBaron et al.

<sup>265</sup> Ibid.

<sup>266</sup> Lockwood, “The International Political Economy of Global Inequality.”

<sup>267</sup> As a reminder, core issues include international trading and monetary systems, the role of multinational corporations, and economic

global economy (e.g., trade, development), rather than because health itself is a core issue.

### 5.5.1 Health's Roots in Alternative Political Economy

The continued marginalization of health within IPE scholarship is arbitrary given that “[t]he political economy approach to health has a long pedigree, arguably dating back to the 19th century, with further influential work conducted in the late 1970s.”<sup>268</sup> Both Friedrich Engels’ seminal 1844 account<sup>269</sup> of the health-related externalities generated by industrial capitalism and Vincent Navarro’s 1976 assessment<sup>270</sup> that contemporary capitalism “normalizes” ill health and drives the underdevelopment of health care systems are notable examples. Moving from the national to the international, Lesley Doyal and Imogen Pennell’s 1979 comparative study of health and health care in Britain and East Africa<sup>271</sup> established linkages between health (, ill health) and sociopolitical and economic institutions. Building on the critiques of Engels and Navarro, Doyal and Pennell assert that, rather than being natural or accidental, a particular form of illness or health care system are consequences of a particular form of political economy: capitalism. Global (macro) politico-economic systems govern health, influencing meso-level structures and driving actor and individual-level outcomes.

The studies by Engels, Navarro, and Doyal-Pennell represent actual, historical IPE scholarship examining health as a core issue to the field, albeit through the lens of alternative theoretical perspectives (i.e., communism and socialism). Perhaps because of their affiliation with alternative theories, as compared to neoliberal perspectives, these examples are “rare exceptions,” demonstrating a continued preference within IPE to view health as an economic and individual

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growth and development. For a discussion of theories and issues in IPE in addition to the Palgrave Handbook (2019), see Thomas Oatley, *International Political Economy*, 6th ed. (New York, NY: Routledge, 2018); and John Ravenhill, ed., *Global Political Economy*, 6th ed. (New York: Oxford University Press, 2020).

<sup>268</sup> Bambra, Smith, and Pearce, “Scaling up: The Politics of Health and Place.”

<sup>269</sup> Navarro, *Medicine Under Capitalism*.

<sup>270</sup> Ibid.

<sup>271</sup> Doyal and Pennell, *The Political Economy of Health*.

matter and an unwillingness to politicize and globalize health.<sup>272</sup>

The continued assumption that health is an apolitical issue reserved to the markets to distribute does not hold. Even if health were neither a public good nor a GPG, it clearly retains political, economic, and social dimensions, and operates on a global scale, well in line with what David N. Balaam and Bradford Dillman (2011) call the “central elements of the antecedent fields of study that contribute to IPE”<sup>273</sup> (page 248). Today, a market is not just a place where people go to buy or exchange something face-to-face with the product’s maker or the service provider; much commerce occurs through electronic commerce versus traditional brick-and-mortar storefronts.

As Balaam and Dillman note (2011), these and other concepts of what a market is and is not, and what it does and does not, have evolved meaningfully, with implications for global society and the international political economy. A notable conclusion they arrive at, based on these three central elements, is that the market is a “driving force that *shapes* human behavior” (emphasis added):

First, IPE includes a political dimension that accounts for the use of power by a variety of actors... All these actors make decisions about the distribution of tangible things such as money and products or intangible things such as security and innovation...

Second, IPE involves an economic dimension that deals with how scarce resources are distributed among individuals, groups, and nation-states. A variety of public and private institutions allocate resources on a day-to-day basis in local markets where we shop...

Third, the works of such notables as Charles Lindblom and economists Robert Heilbroner and Lester Thurow help us realize that IPE does not reflect enough the societal dimension of different international problems. A growing number of IPE scholars argue that states and markets do not exist in a social vacuum.<sup>274</sup>

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<sup>272</sup> Eckhardt and Lee confirm this exclusion on the basis that the research was not affiliated with liberal economics and capitalism modalities: “The study of political economy, notably the interaction between actors and structures across the political and economic domains, was largely associated with neo-Marxist perspectives (Navarro 1976) and thus falling outside mainstream analysis of health policy in Anglo-American scholarship.” See Eckhardt and Lee, Page 667 in *Shaw et al., The Palgrave Handbook of Contemporary International Political Economy*.

<sup>273</sup> Op. cit., Balaam and Dillman, *Introduction to International Political Economy*.

<sup>274</sup> Ibid.

When consumers buy things, when investors purchase stocks, when banks lend money, when patients ask their doctor for a certain medicine, when a family makes educational or childcare decisions, these and many other individualized decisions become depersonalized transactions that constitute a vast, interdependence, complex, and increasingly sophisticated web of relationships, data, and norms that coordinate economic activities all over the world—and also heavily shape political priorities and preferences. That, too, goes for health.

### 5.5.2 Health as an “Emerging Issue” in Contemporary IPE

If these effects have been observed in global politico-economic processes governing such topics as war and peace, international regulatory cooperation, and trade, as the case of the TRIPS Agreement well demonstrates, they have been similarly present in areas of “low politics,” like health, for far longer than the recent two decades.<sup>275</sup> As Bruce Bueno de Mesquita and Alastair Smith (2012) explore, both the neighborhood effect, whether locally or globally, and fragmentation boil down to something O’Neill would well recognize: “we must look within states to understand interactions between states,” and the role of power and politics over issues of import to states.<sup>276</sup>

The respected IPE journal RIPE describes itself as the “leading international journal dedicated to the systematic exploration of the international political economy from a plurality of perspectives,” and yet it defines the topics core to the journal (and to the field of IPE) as “international trade and finance, production and consumption, and global governance and regulation.”<sup>277</sup> If RIPE were a proxy for the discipline’s treatment of health as an area of scholarly

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<sup>275</sup> Op. cit, Youde (May 2016).

<sup>276</sup> Ibid., page 162.

<sup>277</sup> RIPE is described as having “successfully established itself as a leading international journal dedicated to the systematic exploration of the international political economy from a plurality of perspectives. The journal encourages a global and interdisciplinary approach across issues and fields of inquiry. It seeks to act as a point of convergence for political economists, international relations scholars, geographers, and sociologists, and is committed to the publication of work that explores such issues as international trade and finance, production and consumption, and global governance and regulation, in conjunction with issues of culture, identity, gender, and ecology.” See <https://www.jstor.org/journal/reviintepoliecon>.

focus, it is possible to practically appreciate this topical area's marginalization. Despite the centrality of health to the moment – when has health not been a central tenant of politico-economic relations – RIPE has published two issues focused on health over two decades. In 2000, RIPE published “Medicine, Conflict and Survival,” which included a cross-published British Medical Journal article calling for collaboration on global economic disparities alongside articles on the intersection of public health and decommissioning nuclear reprocessing plants, nuclear weapons, food safety, conflict and survival, refugee support, globalization, and the WTO. Of these articles, only one, Michael Rowson’s “Globalization and health – some issues,” articulates the need for “rigorous analysis of the health and other social impacts of economic policies.”<sup>278</sup> It would be two decades before RIPE would answer the call with 2020’s “Special Edition: Political Economies of Global Health,” which was published in the midst of at least the sixth global pandemic (and fourth current) of the 21st century (return to Table 5.2-A).<sup>279</sup>

The 2019 update to the *Palgrave Handbook of Contemporary International Political Economy* included a new second to last chapter – discussing how “health has become one of the key emerging issues in the study of contemporary IPE,” describing “pandemics as a new security issue” and health as a “trans-border issue” emerging since “the early 2000s.”<sup>280</sup> Public Health, Social Epidemiology, and Medical Sociology scholars may regard this finding with good humor or, at worst, dismay. From the bubonic plague of the 14th century to the H1N1 influenza, cholera, and HIV/AIDS pandemics of the 20th century, pandemics have long been a global health and security issue, though their

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<sup>278</sup> Rowson, “Globalization and Health - Some Issues.”

<sup>279</sup> Sell and Williams, “Special Issue on Political Economies of Global Health.” Special articles within the Special Issue include: Sell and Williams, “Health under Capitalism: A Global Political Economy of Structural Pathogenesis”; Elbe and Long, “The Political Economy of Molecules: Vital Epistemics, Desiring Machines and Assemblage Thinking”; Gill and Benatar, “Reflections on the Political Economy of Planetary Health”; Sparke, “Neoliberal Regime Change and the Remaking of Global Health: From Rollback Disinvestment to Rollout Reinvestment and Reterritorialization”; Hester and Williams, “The Somatic-Security Industrial Complex: Theorizing the Political Economy of Informationalized Biology,” 27; Nunes, “The Everyday Political Economy of Health: Community Health Workers and the Response to the 2015 Zika Outbreak in Brazil,” 27.

<sup>280</sup> Op. cit., Eckhardt and Lee, Chapter 41 in Shaw et. al. (2019).



frequency and severity have increased since the turn of the century.<sup>281</sup>

Eckhardt and Lee, the authors of this new chapter, describe the contemporary IPE of health agenda in terms of the marketization (i.e., “the changing role of the state and market in health care,” including “the health implications of emerging powers in the global economy”), internationalization (“the health impacts of a restructured global economy”), privatization (“the IPE of corporate actors in global health”), and globalization of health (“the IPE of global health governance”). In these ways, health is considered an “emerging issue” because of its proximity to core issues of the global economy — not because health is a core issue of IPE. When health directly complicates or implicates one of the core issues of the global economy, then and only then is it relevant. Health’s value as an area of research is rooted in its relationship to dominant IPE structures and paradigms, like trade, finance, and development—not because, alike these “core issue areas” of IPE, health is a *problematique* proper to the field.

By employing *RIPE* and *Palgrave’s Handbook* as proxies, imperfect though they may be, the IPE of health agenda is nascent and, at worst, structured for positivist modeling and further marginalization—described as ‘only as needed.’ While the fields of Public Health, Social Science, and Medical Sociology make quick moves to deepen their research and understanding of the normative issues of this new century, including by applying IR and IPE theories and frameworks,<sup>282</sup> IPE

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<sup>281</sup> The opening two decades of the 21st century has witnessed two pandemics (i.e., H1N1 influenza and Covid-19) and 11 epidemics, and these counts do not include the ongoing “seventh” cholera and HIV/AIDS pandemics that onset in 1961 and 1981, respectively. See World Health Organization, “Timeline of Major Infectious Threats in the 21st Century and Collaboration Mechanisms to Fight Against Them,” (May 4, 2020); and Council on Foreign Relations, “Major Epidemics of the Modern Era,” (March 2020).

<sup>282</sup> Muntaner et al. (2011) refer to this scholarship as “politically-oriented, empirical studies in the population health literature.” For a comprehensive discussion of this scholarship, see Carles Muntaner, Carme Borrell, Edwin Ng, Haejoo Chung, Albert Espelt, Maica Rodriguez-Sanz, Joan Benach, and Patricia O’Campo, “Politics, Welfare Regimes, and Population Health: Controversies and Evidence,” *Sociology of Health & Illness* 33, no. 6 (2011): 946–64. For particularly notable examples relevant to this research, and otherwise noted, see Clare Bambra, Debbie Fox, and Alex Scott-Samuel, “Towards a Politics of Health,” *Health Promotion International* 20, no. 2 (June 2005): 187–93; Bambra, Katherine E. Smith, and Jamie Pearce, “Scaling up: The Politics of Health and Place,” *Social Science & Medicine* 232 (July 2019): 36–42; and Suerie Moon, “Power in Global Governance: An Expanded Typology from Global Health,” *Globalization and Health* 15, no. 1 (November 28, 2019): 74.

continues to view health in cursory terms. As Eckhardt and Lee rightly note, “[t]here has been limited analysis by IPE scholars to date on how these trends, while played out at the national level, are shaped by powerful political and economic forces on an increasingly global scale.”<sup>283</sup>

And yet, as this chapter and its predecessors have examined, the present moment reflects a world reliant on health for economic, political, and social gains as much as for individual wellness. The extant literature on public goods, political economies, globalization, and health reflect a significant body of evidence of the *political determinants of health* and the *health determinants of society*, including political and economic relations spanning the level of analysis (i.e., system, national, individual). The evidence from the literature can be summarized by illustrating the collection of externalities, political linkages, and adjacent decision points generated by states’ political decisions to provide universal health coverage (UHC), defined as either the direct or indirect financing and reimbursement of health care and innovation.<sup>284</sup>

How (and how much) states pay for health care influences not only the proportion of public and private resources devoted to health but also how health care is organized, delivered, and paid for; the politico-economic relevance of health as a market influencer; the policies advanced and preferences of powerful actors; and, last but not least, the just distribution of individual health (equity).

In an era of global markets, the scale and slope of health care financing, especially global

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<sup>283</sup> Op. cit., Eckhardt and Lee, Chapter 41 in Shaw et. al. (2019).

<sup>284</sup> This refers to the WHO definition of UHC, which is “UHC means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course. . . . UHC emphasizes not only what services are covered, but also how they are funded, managed, and delivered. A fundamental shift in service delivery is needed such that services are integrated and focused on the needs of people and communities. This includes reorienting health services to ensure that care is provided in the most appropriate setting, with the right balance between out- and in-patient care and strengthening the coordination of care. Health services, including traditional and complementary medicine services, organized around the comprehensive needs and expectations of people and communities will help empower them to take a more active role in their health and health system.” See WHO, “Fact Sheet: Universal health coverage (UHC).”

medicine spending, can have magnanimous effects on developed and developing economies and their domestic preferences and role in international politics primarily driven by their economic impact. The overreliance by states on the pharmaceutical market for economic development, growth, or recovery flows down to the individual level—resulting in the practice of medicine fast becoming the prescribing of medicines. Global medicine spending and excess use and cost growth informs and is informed by the allocation of limited fiscal resources on health versus other domestic and international priorities; domestic policymaking; aggregate economic indicators and performance; a state’s relative competitiveness within the global economy; and global health policy and governance.

These examples of externalities and linkages, however, are neither independent nor isolated to states that primarily finance health care through private means or in public-private partnership (e.g., U.S., Switzerland). The relationship between advanced economies who publicly finance health care and the pharmaceutical market is just as significant; the size and scope of the pharmaceutical markets of Germany, Ireland, and Belgium, and the U.K., are striking examples. For example, three of the top five pharmaceutical exporters fund approximately three-quarters of total health expenditure (THE) through public sources ([Table 5.5](#)). Regardless the share of total health expenditures from public sources, the underlying norms and their consequences are visible in the outcomes. Public financing *on its own* cannot curb these influences *because they are systemic consequences – dependent variables* – of democratic capitalism gone global—of “globalization and its *new* discontents,” per Joseph E. Stiglitz (2003, 2016).<sup>285</sup>

Whether countertendencies, such as national security concerns, state sovereignty over public health, or public support for social models of health care provision can balance globalization’s

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<sup>285</sup> Stiglitz, *Globalization and Its Discontents*.

powerful commodification of health and liberalization of health services and sectors is “a function of the adjustment costs”<sup>286</sup> that primarily state actors face in altering their alignment with neoliberalism. Will state actors – competitive as they are – and market-motivated actors willingly temper or forego (some or all of) the implicit economic gains associated with the current model, to sustain globalization’s broader structures amidst growing opposition by domestic constituencies.<sup>287</sup> So far, the evidence suggests that public financing cannot counter the negative externalities generated by health-amidst-globalization.

### 5.5.3 Summary Findings of Critical Review of the Literature

The marginalization of health in IPE scholarship is deeply unfortunate. Reserving health to the margins of IPE creates a significant gap in the literature that cannot be remedied by further health-adjacent research on global value chains, regime complexity, conflict and governance, and wealth distribution (though the IPE discipline continues to try). From a normative perspective, if IPE intends to advance social forces that would, to paraphrase Cox, “bargain for a better deal within the world economy,” there is no greater bargain to be struck than that of good (global) health.<sup>288</sup> This research is premised on the belief that IPE should regard health as a central research concern and articulate clear and present examples of social distribution questions that must be prioritized in IPE, including pricing and access of pharmaceuticals. Distributing health (in terms of outcomes) and health care is *distinctively* political in cause and consequence and sufficiently different from global poverty, inequality, development, and security studies as to constitute a unique object of inquiry.

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<sup>286</sup> Op. cit, Drezner (2007), page 5.

<sup>287</sup> As Stiglitz previewed in 2003, the “unhappiness with globalization on display in so many countries in the developing world” has spilled over and into “those in the middle and lower classes of the advanced industrial countries.” See Stiglitz, “Globalization and Its New Discontents”; Stiglitz, Globalization and Its Discontents Revisited; Roosevelt Institute, “Taking on Trade, Unions and Banks in 2016.”

<sup>288</sup> Op. cit, Cox (1981), Page 151.

**Table 5.5. Comparison of total health expenditure from public sources and pharmaceutical exports, by Country**

<u>Country, Ranked by Share of Gross Pharmaceutical Exports</u>	<u>Health Expenditure from Public Sources, Share of Total Health Expenditures (2018)</u>	<u>Gross Pharmaceutical Exports, Share (2018)</u>
Germany	77.7%	16.5%
Switzerland	31.22%	11.4%
Ireland	73.9%	9.7%
U.S.	50.4%	8.3%
Belgium	75.8%	6.8%
Netherlands	64.9%	5.8%
France	73.4%	5.7%
U.K.	78.6%	5.1%
Italy	73.9%	4.9%
India	27.0%	2.5%
Denmark	83.9%	2.3%
Singapore	50.4%	2.1%
Spain	70.4%	2.1%
Austria	73.1%	1.7%
China	56.4%	1.5%

The World Bank, “Domestic general government health expenditure (% of current health expenditure),” 2018 or latest available (<https://data.worldbank.org/indicator/SH.XPD.GHED.CH.ZS>); and Harvard Atlas of Economic Complexity for “Pharmaceutical products (20 HS2),” 2018 or latest available.

How (and how much) states pay for health care influences not only the proportion of public and private resources devoted to health but also how health care is organized, delivered, and paid for, and individual access to and the quality of such care (equity). In an era of global markets, the scale and slope of health care financing, especially global medicine spending, can have magnanimous effects on developed and developing economies and their domestic politics. As Chapter 2 explored, global medicine spending and excess cost growth informs, and is informed by the allocation of limited fiscal resources on health versus other domestic and international priorities; domestic

policymaking; aggregate economic indicators and performance; a state's relative competitiveness within the global economy; and global health policy and governance.

This first analysis, the critical literature review, finds that globalization liberalizes and commodifies health, meaning that it turns health and the production of health into a commodity and service subject to economic rationalism and free trade rules. This liberalization and commodification – collectively called marketization of health – drives a global governance for health that sustains and embeds zero-sum dynamics and imbalances across levels of analysis. For example, for individuals in terms of health equity, hegemonic ideas about health contrary to health. Whether countertendencies, such as national security concerns, state sovereignty over public health, or public support for social models of health care provision, can balance globalization's powerful individualization of health and marketization of health services and sectors relies on whether powerful actors, states in particular, are willing and able to pay the adjustment costs<sup>289</sup> associated with altering their alignment to neoliberalism and neoliberal ideas about health.

The adjustment costs of rebuilding legitimacy in government and its processes of political representation could be far greater than renegotiating states' relationship with neoliberalism. Either way, such an argument accepts both a causal relationship between globalization and health and explicitly roots health within the global political economy—a placement whose acceptance has accelerated in recent years by IPE scholars, mostly of the British school. This influence warrants a greater focus on health within IPE unburdened of the bounds of health 'securitization.' The second part of the analysis, a qualitative analysis and descriptive accounts of the ideas, explored herein, in practice, examines these themes practically through an examination of power asymmetries across the

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<sup>289</sup> *Op. cit.*, Drezner (2008), page 5.

pharmaceutical lifecycle: that globalization<sup>290</sup> deepens power asymmetries and embeds market-oriented norms relating to health across political processes and even within personal ideas about health.

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<sup>290</sup> Globalization is defined as the consistent and inconsistent globalizing of the processes of modernity and rationality, which are simultaneously constructed and applied through political means that magnify asymmetries in power and resource enhance thereby both enhancing and lessening the costs, benefits, and trust-risk dynamics of complex interdependence and global consciousness.

## CHAPTER 6

### EXAMINING POWER ACROSS THE MEDICINES LIFECYCLE: FROM THERAPEUTIC TARGETS TO PRICING & ACCESS— DESCRIPTIVE ACCOUNTS OF THE ROLE OF POWER, ACTORS, AND IDEAS ACROSS THE MEDICINES LIFECYCLE

“Medicine-as-commerce is at the heart of each of these stories, just as it is at the heart of some of the good trends and most of the bad ones. It is clear enough that biotech and pharmaceutical firms can work miracles. But it is also true that they lean heavily on public funding and end up making a great deal of private profit.”

—Paul Farmer (2020)<sup>1</sup>

The pace of biopharmaceutical innovation has been unprecedented over the past decade, and the prior year in particular—crafting complete treatments (‘cures’) and close to real-time preventative vaccines for diseases. The speed, efficacy, and global health impact of the bioeconomy’s first-to-market messenger ribonucleic acid (mRNA) vaccines to prevent SARS-CoV2, the virus that causes Covid-19, is just one example is nothing short of remarkable.<sup>2</sup> GlaxoSmithKline’s Cabenuva may represent a new standard of care for the complete treatment of human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS) and comes 25 years after the first antiretroviral (ART), which are maintenance treatments.<sup>3</sup> over 500 new medications were brought to market globally between 2000 and 2017 alone, and the future outlook is no different.<sup>4</sup>

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<sup>1</sup> Farmer, “A Critique of Market-Based Medicine.”

<sup>2</sup> Norbert Pardi, Michael J. Hogan, Frederick W. Porter, and Drew Weissman. “mRNA Vaccines — a New Era in Vaccinology.” *Nature Reviews Drug Discovery* 17, no. 4 (April 2018): 261-279.

<sup>3</sup> Office of the Commissioner, U.S. Food & Drug Administration (FDA). “FDA Approves First Extended-Release, Injectable Drug Regimen for Adults Living with HIV,” (January 21, 2021).

<sup>4</sup> Angelika Batta, Bhupinder Singh Kalra, and Raj Khirasaria. “Trends in FDA Drug Approvals over Last 2 Decades.” *Journal of Family Medicine and Primary Care* 9, no. 1 (January 28, 2020): 105–14.



According to the IQVIA<sup>TM</sup> Institute for Human Data Sciences, 54 new active substance (NAS)<sup>5</sup> launches per year are projected over the next five years, up from 46 in the prior five-year period.<sup>6</sup> This pace of drug development and market launch has been acute over the recent period, with new treatments and preventatives for ebolavirus (Ebola), advanced prostate cancer, aggressive forms of breast cancer (HER2+, triple-negative), cardiovascular disorders, and multiple sclerosis—and this short list reflects 14-months of product approvals (i.e., U.S. market approvals through December 2020).<sup>7</sup> It does not include, for example, a new treatment for Alzheimer’s disease (AD), the approval of which (for the U.S. market) on June 7, 2021<sup>8</sup> was heralded as simultaneously “historic”<sup>9</sup> and “probably the worst drug approval decision in recent [] history.”<sup>10</sup>

The characterizations of pharmaceutical product approvals and the ‘drug pipeline’ employ descriptives of speed, efficacy, impact, and scientific advancement to contextualize a ‘Bio-Century’ of “long-term societal advancement,”<sup>11</sup> of “improving human lives,”<sup>12</sup> of human technological achievement and betterment—made possible by private industry. The bioeconomy narrative is premised on a particular form of hope—the ‘hope’ to ‘cure’ disease and illness, to grow the global economy, to reverse national and local job losses (by stabilizing or converting declining sectors of the economy), to achieve “a world free of poverty.”<sup>13</sup> Reflecting Antonio Gramsci’s theory of

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<sup>5</sup> “New active substances” (European Medicines Agency) or “new active ingredients” (FDA) generally refer to a chemical active substance that has not been previously authorized (whether approved, licensed, authorized) for human use in the political authority that the pharmaceutical manufacturer is seeking authorization. Political jurisdictions have criteria to define the scope of NAS products. See Committee for Medicinal Products for Human Use, European Medicines Agency. “Reflection Paper on the Chemical Structure and Properties Criteria to Be Considered for the Evaluation of NAS Status of Chemical Substances,” January 19, 2016.

<sup>6</sup> IQVIA Institute. “The Global Use of Medicine in 2019 and Outlook to 2023,” January 29, 2019. Page 17.

<sup>7</sup> Food and Drug Administration (U.S.), “Novel Drug Approvals for 2021”; Center for Drug Evaluation and Research, “Advancing Health through Innovation: New Drug Therapy Approvals, 2020.”

<sup>8</sup> Food and Drug Administration (U.S.), “FDA Grants Accelerated Approval for Alzheimer’s Drug”

<sup>9</sup> Feuerstein and Garde, “FDA Grants Historic Approval to Alzheimer’s Drug from Biogen.”

<sup>10</sup> Bill Chappell, “3 Experts Have Resigned from an FDA Committee over Alzheimer’s Drug Approval.” See also Mullard, “Landmark Alzheimer’s Drug Approval Confounds Research Community?”

<sup>11</sup> Stansberry, Anderson, and Rainie, “Experts Optimistic About the Next 50 Years of Digital Life.”

<sup>12</sup> Roco and Sims, “Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology, and Cognitive Science.”

<sup>13</sup> Granzow, “Our Dream: A World Free of Poverty.”

cultural hegemony,<sup>14</sup> this hope is a *form of discursive power* and a *rationale for power* but is not a *source of power*. It is a tool and defense of power employed for the preservation of power. Understanding and examining its use may help to explain the why-and-how of the global politics of health.

As this collection of case studies descriptively explores, the narrative of the Bio-Century reflects *and* imparts a rationale for the global pharmaceutical market to *exist* (as a private, capital-generating entity) and to *do well*. This market's success, framed as its ability to innovate the "nature of medicine... to take care of and solve the unsolvable,"<sup>15</sup> discursively and practically "legitimize[s] and protect[s] the system," referring to the global neoliberalism (capitalism) embedded in globalization, "and its power relations."<sup>16</sup> state and global policies that double-down on the innovation-oriented rationale of the Bio-Century discursively preserve the pharmaceutical market as a solution to the negative externalities generated by globalization, which itself reflects broader systems of power. While expressions of power in the international political economy of medicine have the practical effect of furthering pharmaceuticals' relevance and primacy in the politics of medicine, is this a cause-and-effect or a 'symptom' of broader systems of power relations?

This chapter, or *Part II* of the analysis, comprises descriptive accounts of the role of power, actors, and ideas as hypothesized political influence points across the pharmaceutical lifecycle. Instead of specific policy outcomes and an exclusive focus on state actors as leading agents in any preceding policy negotiation process, the pharmaceutical lifecycle is employed as a practical testing ground for applying the Four Factors model and exploring the findings of Part I's narrative synthesis for three reasons. *First*, the pharmaceutical lifecycle itself is a meso *political system* – a sub-

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<sup>14</sup> For discussions of Gramsci's theory of cultural hegemony, which describes how states and the Capitalist Class use cultural institutions to maintain power in capitalist societies, see Lears, "The Concept of Cultural Hegemony: Problems and Possibilities;" Bates, "Gramsci and the Theory of Hegemony;" and Maglaras, "Consent and Submission: Aspects of Gramsci's Theory of the Political and Civil Society." For the underlying text, see Gramsci, *Prison Notebooks (Quaderni del Carcere)*.

<sup>15</sup> Navarro, *Medicine Under Capitalism*, 218–19.

<sup>16</sup> Navarro, 119.

system of the global political economy – that shapes and is shaped by global norms and governance, spans levels of analysis, and features power relations between actors. *Second*, the pharmaceutical lifecycle exists in near-identical forms around the world because of political processes of regulatory convergence<sup>17</sup> and the corporate decision-making of the global pharmaceutical industry vis-à-vis multinational pharmaceutical corporations (MNPCs).<sup>18</sup> And, *third*, the lifecycle itself is diverse enough to afford varied market conditions, actor types, sub-system regulatory infrastructure, and state-to-state differences.

These three characteristics of the pharmaceutical lifecycle are helpful as they allow for the examination of whether the determinants hypothesized in Part I are distinct, interacting mechanisms that operate to similar effect at different levels of political action and types of actor interaction. The hypothesized determinants may operate only in specific or idealized scenarios. Specifically, the descriptive accounts are organized in four sections, which align with the major components of the pharmaceutical lifecycle: therapeutic targeting and discovery; research investment and financing, clinical trial research and pre-market approval, and commercialization strategy (Figure 1.2-B).

First, the early processes of determining which therapeutic areas (disease categories), modalities (delivery mechanism for the pharmaceutical), and geographies (states as markets) that pharmaceutical research and development (R&D) should prioritize are examined. Specifically, trends in the therapeutic class priorities that underpin R&D decision-making and strategy are examined, with particular attention to the consequence of global governance of orphan drug designations,

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<sup>17</sup> Kumar Reddy and Kumar Reddy, “Significance of Pharmaceutical Regulatory Bodies: A Review.”

<sup>18</sup> Specifically, the research and development pipelines and associated processes, pre-approval engagement of regulatory authorities whom shared common regulatory approaches, and similar commercialization practices of pricing, market determination, access strategies, and post-market lifecycle management strategies. For example, CMS Plus Corporation provides pharmaceutical regulatory affairs consulting services in Japan and has defined the “life cycle and task at each step” as comprising basic research, development, approval application, manufacturing, and post-marketing ([https://cm-plus.co.jp/en/service/gmp\\_consulting/regulatory\\_affairs/](https://cm-plus.co.jp/en/service/gmp_consulting/regulatory_affairs/)). Similarly, Emergo prepares Regulatory Affairs Management Suites (RAMS) to explain the regulatory processes for selling medical devices and pharmaceuticals in Japan (<https://www.emergobyul.com/resources/japan-process-chart>).

expedited regulatory approval, and collaborative research consortia (Chapter 6.2).

Second, the rise and role of non-manufacturer funding (‘capital investment’) in pharmaceutical research and pre-discovery is evaluated against respective actor goals for health, particularly, the state funding and venture philanthropy (VP)—a spin on venture capital (VC) financing (Chapter 6.3).

Third, the systems and processes of power relations post-discovery and pre-market approval that influence the approval of pharmaceuticals are considered, as are the systemic and structuring influences of power on the stages of the medicines lifecycle that come before and after this midpoint (Chapter 6.4). This third collection of case studies does not address the inputs and outcomes of regulatory approval for a pharmaceutical to enter a market, as this area is well explored through existing health policy analysis. Reminiscent of Walt and Gilson’s critique, the endpoint of this midpoint in the lifecycle reflects the standard questions of ‘what is the policy’ (i.e., the standards for pharmaceutical approval or licensure in a particular market) and ‘what are the policy’s outcomes’ (e.g., how many drugs were approved). Rather, “distant proximities”<sup>19</sup> inform the processes of actor interaction, the ideas informing available policy choices (content), and the market context preferencing the design of regulatory oversight of the states’ domestic pharmaceutical approval and licensure policies are explored. Specifically, the somewhat-obscure international regulatory coordination that underpins many states’ contemporary pharmaceutical regulation is examined, along with the geopolitical and historical legacy of the emerging contract research industry.

Fourth, the case studies turn to what happens after clinical research trials and pharmaceutical approval or licensure: commercialization, pricing, and market access strategies. This closing section examines one potential endpoint to the pharmaceutical lifecycle – patient access to the Covid-19

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<sup>19</sup> Rosenau, *Distant Proximities: Dynamics Beyond Globalization*.

vaccine – as a consequence of pre-purchasing and purchasing power parity (Chapter 6.5).

Of the descriptive accounts, the majority could be considered deviant or semi-deviant, meaning ill-suited to the research’s premise, analytical framework, or paradigm. The research seeks to examine the politics of health which, one could presume, are limited to the confines of *explicit* requirements under particular modes of regulatory governance, versus the independent decision-making of private actors, including firms. Contrary to this presumption, several cases focus directly or indirectly on industry- or firm-level decision-making processes and considerations, which is presumed to be outside the bounds of politics. These accounts’ inclusion is intended to test the hypothesis’ application to actors, ideas, processes, and outcomes that may be considered ‘apolitical,’ including those wholly within the purview of private firms.<sup>20</sup>

To begin this second analysis, Chapter 6.1 presents an example a narrative of the Bio-Century that is compelling in its message but deeply problematic in practice: the development, pricing, and limited accessibility of the complete treatment for the hepatitis C virus (HCV or hepC). The influence of power in the example of hepC treatment extends across the fullness of its pharmaceutical lifecycle, which this descriptive account and others in this chapter explore. But it begins as most things do with a single decision to move forward—or not—with investment in a potential pharmaceutical.

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<sup>20</sup> We hypothesize that these cases will demonstrate the interrelation and complex interdependence of firm- and state-level decision-making, or how state and global policy contextualizes the ideas, preferences, and available choices of market actors even in areas absent direct regulation.

## 6.1 The Case of the “Uncurable” Virus: A Short Story of the Political Determinants of Pharmaceutical R&D, Marketing, Pricing, and Access

Hepatitis C is a liver disease that can develop into cirrhosis or even cancer. It remains a major public health burden, with estimated global prevalence of between 2.5% and 3.0%.<sup>21</sup> For contextual purposes, there were approximately 111 million cases of Covid-19 in early 2021<sup>22</sup> but over 177.5 million cases of hepatitis C at year-end 2016, which reflects an improvement over prior single-year estimates of 185 million.<sup>23</sup> Before 2014, the standard of care for hepatitis C was regular injections and long durations of therapy, often with toxic side effects, that, ultimately, were ineffective for many patients.<sup>24</sup> Pharmaceutical manufacturer Gilead introduced sofosbuvir, a once-daily pill for the complete treatment of hepatitis C, in early 2014.<sup>25</sup> Better known by its brand name, Sovaldi™, the market approval of sofosbuvir recast hepatitis C from a difficult-to-treat, incurable disease into one often completely treatable in a matter of months. As a combination treatment, DAAs drive sustained virological responses (‘virological cure’) for more than 95% of patients with hepatitis C.<sup>26</sup>

Malaria, tuberculosis, and HIV are similarly illustrative, where biopharmaceutical innovation for each have advanced meaningfully in terms of treatment and prevention. They also are reflections, per Singh (2010),<sup>27</sup> of modern society’s – modern medicine’s – penchant for efficiency

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<sup>21</sup> Arnolfo Petruzzello, Samantha Marigliano, Giovanna Loquercio, Anna Cozzolino, and Carmela Cacciapuoti. “Global Epidemiology of Hepatitis C Virus Infection: An Update of the Distribution and Circulation of Hepatitis C Virus Genotypes” *World Journal of Gastroenterology* 22, no. 34 (September 2016): 7824–7840.

<sup>22</sup> Henrik Pettersson, Byron Manley, and Sergio Hernandez. “Tracking Coronavirus’ Global Spread.” CNN, February 21, 2021.

<sup>23</sup> Seyed Moayed Alavian. “Sofosbuvir Has Come Out of the Magic Box.” *Hepatitis Monthly* 13, no. 12 (December 2013): e16916.

<sup>24</sup> Alexandra Alexopoulou and Peter Karayiannis. “Interferon-based combination treatment for chronic hepatitis C in the era of direct acting antivirals” *Annals of Gastroenterology* 28, no. 1 (January/March 2015): 55-65.

<sup>25</sup> In 2014, Gilead Sciences introduced Sovaldi, a complete, curative treatment for hepatitis C. At launch, Sovaldi cost \$1,000 a pill, or \$84,000 for a typical 12-week course of treatment.

<sup>26</sup> Michael J. Zoratti, Ayesha Siddiqua, Rita E. Morassut, Dena Zeraatkar, Roger Chou, Judith van Holten, Feng Xie, and Eric Druyts. “Pangenotypic Direct Acting Antivirals for the Treatment of Chronic Hepatitis C Virus Infection.” *EClinicalMedicine* 18, no. 100237 (January 2020).

<sup>27</sup> Singh, “Modern Medicine: Towards Prevention, Cure, Well-Being and Longevity.”

and crisis response, which have resulted in “great strides... when it comes to the prevention and cure”<sup>28</sup> of select communicable diseases (CDs), both access to the innovation and which diseases deserve to be treated, prevented, or cured pharmacologically are *politically determined*. At what point are the size of the *disease market* and degree of *political incentive and urgency* adequate for triggering the pharmaceutical research and development (R&D) process?

In the cases of malaria, tuberculosis, and HIV, the answer may be less influenced by market size – as expected under macroeconomics theory of the law of supply and demand (see Chapter 3) – and more by political incentive,<sup>29</sup> which ideologically, structurally, and financially underpin the risk-oriented conditions for innovation and its investment and commercialization.<sup>30</sup> Despite declines since 2000, these three CDs continue to be globally significant, with global average incidence rates of 55, 128, and 0.21 per 1,000 people (Figure 6.1), respectively, and remain significant despite the collective scientific understanding and associated tragedy of vast human experience. The results of a phase 1 clinical trial announced in April 2021 confirmed a novel approval to vaccination “could, in principle, work against HIV,” and the same approach may aid development of a vaccine for malaria.<sup>31</sup> Between 1990 and 2013, the tuberculosis mortality rate fell by 45% and another 20% between 2019 and 2020,<sup>32</sup> just as “recent advances in improving Bacille Calmette-Guerin immunization along with other new [anti- tuberculosis] vaccines in clinical trials are promising candidates for the future.”<sup>33</sup>

Returning to the example of hepatitis C, access to curative treatment has improved significantly since sofosbuvir and similar direct-acting antiretrovirals (DAAs) came to market in 2014

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<sup>28</sup> Holmes, “Profile | Ole Petter Ottersen.”

<sup>29</sup> For example, refer to *Chapter 2.2*’s discussion of “productive intervention policies” and other Selection Mechanisms per Vicente Navarro (1976) and Michael E. Porter’s (1990) Diamond of National Advantage.

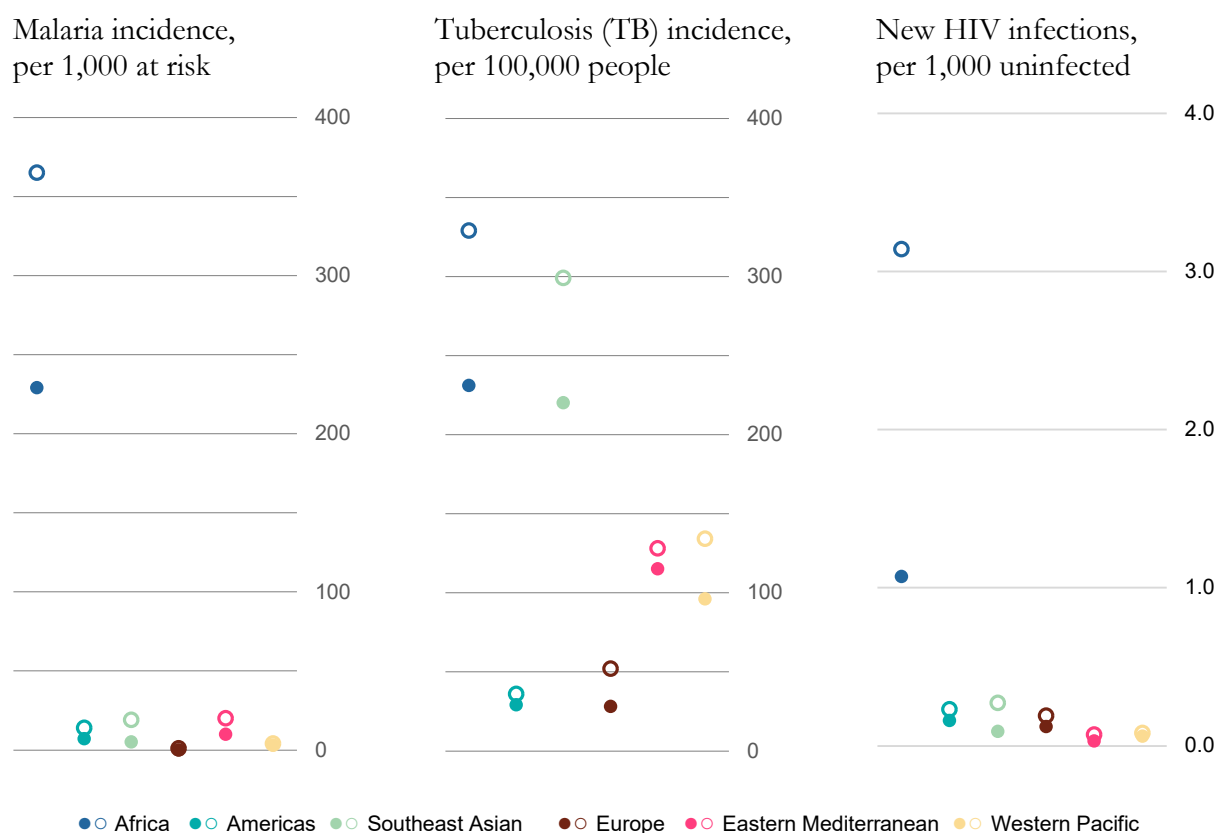
<sup>30</sup> Navarro, *Medicine Under Capitalism*, 213–14.

<sup>31</sup> Kingsland, “HIV: Clinical Trial Brings Vaccine One Step Closer.”

<sup>32</sup> Deutsch-Feldman et al., “Tuberculosis — United states, 2020.”

<sup>33</sup> Fatima et al., “Tuberculosis Vaccine: A Journey from BCG to Present.”

**Figure 6.1. Malaria, Tuberculosis, and HIV incidence rates on the decline since 2000**



Author-generated image based on data from Adhanom Ghebreyesus, “World Health Statistics 2020: Monitoring Health for the SDGs, Sustainable Development Goals.” See also World Health Statistics 2020: Monitoring Health for the SDGs, Sustainable Development Goals.

but it remains limited. While 71 million individuals worldwide had been diagnosed with chronic hepatitis C (of 177.5 million cases), only 7% had received treatment with DAAs by late 2017.<sup>34</sup> This minority that has received DAA treatment is concentrated in the Americas and south-east Asia where prevalence is lowest, and the Mediterranean where prevalence is highest (Table 6.1).<sup>35</sup> Though

<sup>34</sup> World Health Organization, “Hepatitis C.”

<sup>35</sup> World Health Organization, “Accelerating Access to Hepatitis C Diagnostics and Treatment: Overcoming Barriers in Low and Middle-Income Countries. Global Progress Report 2020.” Page 6, Table 1.



**Table 6.1. Global hepatitis C pandemic and response, by WHO region, 2015**

WHO Region	Prevalence of Infection (%)	Incidence (per 100,000)	Proportion with Diagnosis (%)	Proportion with Treatment (%)
Africa	1.0	31.0	5.7	2.2
Americas	0.7	6.4	36.3	11.1
South-east Asia	0.5	14.8	8.7	7.1
Europe	1.5	61.8	31.2	4.9
Eastern Mediterranean	2.3	62.5	17.7	12.1
Western Pacific	0.7	6.0	21.5	4.8

Author-generated table using data from World Health Organization, “Hepatitis C.”

good news for the Americas, south-east Asian, and the eastern Mediterranean regions, the concentration of access, on net, in regions with far lower prevalence bodes less well for global health broadly and for lower-income patients with chronic hepatitis C in Europe and Africa. This promise of the bioeconomy – sofosbuvir and similar DAAs – is a market product, politico-economically constructed to be scarce and distributed globally not based on equity, but on who can negotiate pricing and access as compared to those who cannot.

The WHO estimates that approximately 2 billion individuals the world over are without access to essential medicines, “effectively shutting them off from the benefits of advances in modern science and medicine,” despite the promises of the bioeconomy.<sup>36</sup> The cases of malaria, tuberculosis, hepatitis C, HIV/AIDS, and Covid-19 are hopeful, but they reveal a deeper truth. The high valuation and investment in the bioeconomy of the prior two-plus decades turned its attention to preventatives against and cures for infectious disease only once the consequences of these diseases moved beyond the boundaries of the global poor, and within the context of risk to global economic

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<sup>36</sup> Chan, “Access to Medicines: Making Market Forces Serve the Poor.”

growth, international trade, and labor productivity. Once constructed not as a problem of the global poor, but for the globally wealthy, the stars (financial incentives) aligned, and vaccines and cures have come to market.

This alignment, however, is precarious. Striking the just-right balance between biopharmaceutical innovation, patient access, treatment affordability, and politico-economic incentives to maximize the pharmaceutical market is more than tricky. Absent a significant financial motivator (e.g., loss of economic gains, state intervention to create a highly profitable short-term market), there is extraordinarily little long-term incentive for industry to eliminate the market's demand (disease) for its product (medicines). It is worth exploring whether, reminiscent of this research's earlier discussion of public goods, absent state intervention of any style or substance, there are organic market influences or forces that would dictate the efficient and equitable allocation of pharmaceutical investments and innovations. And the global patient is ill-equipped to act collectively to demand political action to create such incentives or else remove counterincentives. There is, however, significant and near-constant incentive for industry to insulate itself from the market. The twin narratives of economic crisis and unsurpassed growth are deeply compelling.

## **6.2 Targeting Innovation and Discovery: Examining Pharmaceutical Development Portfolio Management and Political Influences on Firm Decision-making**

In *Security and Global Health*, Stefan Elbe (2010) considers global health governance and political security, or the 'medicalization of security.' While this research adopts a different approach to the global governance of health and rejects securitization approaches as too narrow, Elbe correctly alludes to the fundamental power disparities inherent in contemporary global politics of health and disease—a base inequity hidden within the promise of the bioeconomy:

Every era, it is said, has its defining malady. What will be ours? Will it be a new human pandemic caused by an animal-borne infectious disease, such as swine flu? Will it be a lethal microbe like anthrax deliberately released by terrorists bent on

causing mass civilian casualties? Or will it be one of our new ‘lifestyle’ diseases – the epidemics of smoking, obesity and excessive alcohol consumption that threaten to engulf modern societies? Perhaps our era will even be remembered for its tragic neglect of certain health issues – endemic diseases such as malaria, tuberculosis and HIV/AIDS that continue to ravage millions in developing countries.<sup>37</sup>

Writing more than a decade before a global pandemic that will define the global political economy and state-to-state relations for this century, Elbe’s concern captures the casual tragedy of modern health. It is a tragedy observable in the discussed cases of hepC, malaria, tuberculosis, and HIV/AIDS. What has been socially constructed, embedded, and sustained is a global system-in-society that preserves mass ill health despite the long-standing existence of preventatives and curative treatments (in the non-pharmacological sense), *and* promoted narratives to the contrary—all the while placing the health of our collective selves in the care of a marketplace ill-suited to balance needs for which there are not always pure economic gains.

To borrow once more from Elbe (2012), health marketization thus takes the provision and production of health from the most intimate spaces, where we care for ourselves and for one another, often in community, and brings the distant market, the Invisible Hand, “to bear directly on—and indeed inside—the individual body, as the inner biological processes of our bodies become” new goods, products, and resources for the global bioeconomy.<sup>38</sup>

What the hepC case and associated narrative tells us about power in the earliest stages of the pharmaceutical lifecycle is compelling and will be explored in this first pair of descriptive accounts. Briefly, the component steps captured in these earliest stages are described. Referring to the drug development pipeline and associated R&D, the earliest stages of the pharmaceutical lifecycle primarily reflect decision-making and strategy by the pharmaceutical sponsor – whether an MNPC, academic medical center (AMC), global public-private partnership (PPP), or patient advocacy group

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<sup>37</sup> Elbe, *Security and Global Health*; Elbe, “Bodies as Battlefields: Toward the Medicalization of Insecurity.”

<sup>38</sup> Page 321 in Elbe, “Bodies as Battlefields: Toward the Medicalization of Insecurity.”

– to target a particular disease and associated biomarker for pharmacological intervention, secure capital investment to fund the R&D, and – if successful – make a novel discovery or improvement to existing treatment modalities. Practically, these earliest stages reflect which *potential* pharmaceutical innovation are prioritized and funded for R&D over others.

Recent evidence by Gaessler and Wagner (2018) suggests a “causal effect of the duration of market exclusivity,” which is a form of positive selection mechanisms of state intervention (allocative) that extends public benefits – in protection from market competition (i.e., longer duration of monopoly pricing) – to certain types of pharmaceutical innovation over others.<sup>39</sup> Gaessler and Wagner find that “a reduction in the expected duration of market exclusivity upon drug approval significantly reduces the likelihood of successful drug commercialization,” meaning the product sponsor – most often “medium/large originators,” including MNPCs – elects *against* investing in specific treatment and modality R&D or introducing the otherwise researched, developed, and approved product to the market *at all*.<sup>40</sup>

Under the Four Factors model, power can be expressed through ideas, context, processes, and policy content that indirectly or directly generate a response by certain actors complementary to the interests and preferences of powerful actors. This section explores the role of public-private partnerships (PPPs), and state actors’ use of power to influence the earliest phase of the pharmaceutical lifecycle directly and indirectly: ‘drug targeting,’ or the decision by a pharmaceutical product sponsor to research the identification of a particular disease and its biomarkers. Specifically, through two multifaceted descriptive accounts, examples of Navarro’s (1976) negative and positive selection mechanisms and M. E. Porter’s (1990) determinants of National Advantage are examined

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<sup>39</sup> Gaessler and Wagner, “Patents, Data Exclusivity, and the Development of New Drugs.” This paper also was presented to the 11th Annual Searle Center / U.S. Patent and Trade Office Conference on Innovation Economies (June 3, 2018), which suggests regulatory interest in understanding the relative success of such policies *within the context of advancing on-patent (i.e., protected) pharmaceutical innovation*.

<sup>40</sup> Op. cit., Gaessler and Wagner.

relating to biomarker identification and R&D investment for priority diseases and cross-industry collaboration to promote efficiency in target identification (e.g., public resource allocation, favorable regulatory treatment).

### 6.2.1 Incentives for Biomarker Identification and Pharmaceutical Industry Collaboration

The earliest stage of the pharmaceutical lifecycle is commonly described as R&D: a scientist and their assistant in a lab researching a biomarker, testing samples one after another, and stumbling on “something truly miraculous.”<sup>41</sup> Historical accounts of the “wonderful thing we call insulin”<sup>42</sup> and the “birth of the first” blockbuster medicine,<sup>43</sup> injectable insulin, are framed in such terms. Michael Bliss’ (2007 [1984]) *The Discovery of Insulin* traces the history of this seminal medical innovation. Though scientific investigation of diabetes’ biomarkers – objective, measurable “indications of medical state observed from outside the patient” indicative of some phenomenon, whether a disease, infection, or exposure to environmental factors, “which can be measured accurately and reproducibly”<sup>44</sup> – has been traced by Ignazio Vecchio et al. (2018) back to 1552 B.C.E., the discovery of insulin as a *treatment* for diabetes is validated in the 20th century.<sup>45</sup> Specifically, the summer of 1921 at which time an orthopedic surgeon, Sir Frederick G. Banting, and his student assistant, Charles H. Best, remove the organic chemical insulin (from the Latin word *insula*, meaning island) from a dog’s pancreas, and then inject it into another dog with diabetes.<sup>46</sup> The dog is kept alive for 70 days, or until Banting and Best run out of the extracted insulin. Joined by J. J. R. Macleod and James B. Collip, who purifies the extract for human experimentation, the purified extract is then injected into a Canadian teenager dying from diabetes—*et voilà!*

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<sup>41</sup> American Diabetes Association. “The History of a Wonderful Thing We Call Insulin.”

<sup>42</sup> Op. cit., American Diabetes Association.

<sup>43</sup> Sullivan, “The Miracle of Insulin.”

<sup>44</sup> Strimbu and Tavel, “What Are Biomarkers?” 464.

<sup>45</sup> Vecchio et al., “The Discovery of Insulin: An Important Milestone in the History of Medicine.”

<sup>46</sup> Bliss, *The Discovery of Insulin*, 45–60.

Modern biomarker identification and drug discovery is similar: the process of discovery begins with the *identification of a biomarker target* (e.g., absence of insulin production) for a prioritized disease (diabetes) and then *testing known interactive chemicals, or discovery of new interactions*. If successful, the discovery is advanced through to *validation and evidence generation*, or clinical research, beginning with effective cell cultures and animal modeling before moving to human trials phased to first test for toxicity and, only if safe, efficacy and scaled replicability. The differences between modern drug discovery and the processes of Banting et al. are in the micro steps between these sub-stages.

Specifically, modern drug discovery reflects two significant differences. *First*, using omics techniques, which refers to using large data sets to identify biological patterns at the molecular level, specifically, one of the four groups of molecules, including deoxyribonucleic acid (DNA, or ‘genomics’), RNA (‘transcriptomics’), proteins (‘proteomics’), and metabolites (‘metabolomics’), often using genomics as a starting point. *Second*, using automated testing of biomarker targets against extensive datasets of known chemical interactions, including robotics processes (e.g., high throughput screening) or virtual screening (i.e., chemical compound library screening and interaction generation). Multi-omics techniques and machine-learning, or artificial intelligence (AI) “has been increasing in various sectors of society, particularly, the pharmaceutical industry” to efficiently screen for drug-protein interaction, physicochemical properties, and bioactivity and toxicity prediction.<sup>47</sup> These processes also are favored for their ability to yield the highest possible output: “the best bet to find a treatment for an UHD [unknown human disease] isn’t to create one optimized potential drug but 10 to 20.”<sup>48</sup>

The increasing use of multi-omics and AI in drug discovery suggest the influence of power through two of the Four Factors: ideas and process. First, these techniques align with hegemonic

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<sup>47</sup> Paul et al., “Artificial Intelligence in Drug Discovery and Development.”

<sup>48</sup> Rowe, “Modern Drug Discovery: Why Is the Drug Development Pipeline Full of Expensive Failures?”

ideas of Flexnerianism, the individualist-mechanistic ideology of medicine, and Rationalism (see Chapter 5.2), and neoliberalism's marketization of health (Chapter 5.1), which globalization has embedded in macro, meso, and micro political systems. These reflect what Navarro (1976) described as Negative Selection Mechanisms (return to Table 2.2),<sup>49</sup> specifically ideological incentives (e.g., proliferation of medical and other scientific research examining individual causation of disease and responsive treatment<sup>50</sup>).

*Second*, these techniques are reinforced and facilitated through political processes that reflect M. E. Porter's (1990) Diamond of National Advantage: the advantage of close working relationships between related and supporting industries, and the ability to mutually benefit from downstream efficiencies; and the convergence of firm strategy, structure, and practices with the modes favored by the state because of their alliance with the state's sources of competitive advantage.<sup>51</sup> Specifically, state-established, convened, and funded collaborative forums for disease target and biomarker identification. A leading example of the practical global governance of pharmacological targeting and decision-making – meaning, the actors engaged represent the majority of the pharmaceutical market – is the Foundation for the National Institutes of Health (FNIH, U.S.). This U.S.-established, funded, and managed Foundation oversees several health innovation collaboratives, including the Accelerating Medicines Partnership (AMP), which is a PPP between the National Institutes of Health (NIH, U.S.), the Food & Drug Administration (FDA, U.S.), the European Medicines Agency (EMA, EU), and a host of MNPCs and patient advocacy groups, including AbbVie, the Alzheimer's Association®, American Diabetes Association, Biogen, Eisai, Inc. (Japan), Eli Lilly and Co., Merck, the Michael J. Fox Foundation for Parkinson's Research, National Alliance on Mental Illness, Pfizer,

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<sup>49</sup> Navarro, *Medicine Under Capitalism*.

<sup>50</sup> For example, 'precision medicine,' diet, exercise, genetic inheritance), including through public funding (e.g., market exclusivity for pharmaceutical products that treat 'rare' or 'orphan diseases.'

<sup>51</sup> Porter, "The Competitive Advantage of Nations."

Pharmaceutical Research Manufacturers of America (PhRMA, U.S.), and others.<sup>52</sup>

The AMP was convened to streamline “the process for identifying and validating clinically relevant disease targets for drug design” to “make drug development a more attractive investment.”<sup>53</sup> The Partnership’s web site refers to the high costs (“more than 1 billion” USD) and failure rates (i.e., 59% of Phase II and 52% of Phase III trials<sup>54</sup>) as challenges that, if not solved, “can result in failures late in the drug development process, costing time, money, and ultimately, lives.”<sup>55</sup> Inclusive of initiatives addressing AD, autoimmune disorders like rheumatoid arthritis, Parkinson’s disease, schizophrenia, and type 2 diabetes, the Partnership collaborates by “rigorously validating” available “human data” to “better understand[] biological targets” to advance only “the most promising compounds quickly into the [R&D] pipeline” and only for the diseases most likely to respond to *new pharmacological treatments*.

Besides these U.S.-convened consortia, other advanced economies have been and are increasingly collaborating through state-funded or convened forums of state, industry, researcher, and even patient advocacy collaboration on target identification. Kym M. Boycott et al. (2019) identify a range of similar “collaborative and novel funding models,” including the E-Rare 3 initiative, which was co-founded by the European Commission (EC) and 26 partners spanning 18 states from the EU, Canada, Israel, and Japan.<sup>56</sup> Daria Julkowska et al. (2017) notes that, through the E-Rare 3 initiative, transnational research collaboration is collectively financed across states, some of which may lack specifically dedicated national programs, to “enhance cooperation among scientists, thus reducing fragmentation”<sup>57</sup> and also creating “vital infrastructures including biobanks and

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<sup>52</sup> National Institutes of Health (NIH) (US), “Accelerating Medicines Partnership (AMP).”

<sup>53</sup> Op. cit., NIH.

<sup>54</sup> Arrowsmith and Miller, “Trial Watch: Phase II and Phase III Attrition Rates, 2011-12.”

<sup>55</sup> Op. cit., NIH.

<sup>56</sup> Boycott et al., “Commentary: International Collaborative Actions and Transparency to Understand, Diagnose, and Develop Therapies for Rare Diseases,” e10486.

<sup>57</sup> Julkowska et al., “The Importance of International Collaboration for Rare Diseases Research: A European Perspective,” 566.



registries.”<sup>58</sup> Also state-facilitated international data sharing consortia, knowledge organization and ontologies platforms and databases, networking patient registries, and therapeutic development guidelines and platforms include Orphanet, a French-founded central knowledge database of rare diseases now inclusive of over 40 states,<sup>59</sup> and the guidelines for Standard Pre-clinical Experiments,<sup>60</sup> a set of globally accepted guidelines by the TREAT-NMD Advisory Committee for Therapeutics, which was established and originally funded by the EU in 2009.<sup>61</sup>

Kathryn R. Wagner et al. (202) describe state facilitation of industry collaboration, particularly, those “de-coupled from funding considerations,” as models of “multidisciplinary, unbiased expert opinion provided in a supportive environment” that can serve as an example for “de-risk[ing] drug developing and facilitate[ing] the approval of novel therapeutics for rare diseases.”<sup>62</sup> However, as Ariel Dora Stern (2019) has noted, biomarkers are essential to successful pharmaceutical innovation but they “must be validated — a complex and costly endeavor,” which the FNIH, AMP, E-Rare 3, Orphanet, and similar state-facilitated R&D consortia illustrate and intend to streamline. However, these forums and programs are “meaningfully shaped by economic and policy-driven incentives,”<sup>63</sup> whether or not they are ‘coupled’ with state funding or not. This section has briefly described many state-funded and facilitated consortia operating around the world.<sup>64</sup> Whether mechanisms of access to state research grants or not, they *create efficiencies* and streamline R&D, which, if successful, decrease the costs of drug discovery. Each mechanism features a particular area of focus, often pharmaceuticals for rare diseases (‘orphan drugs’), signaling

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<sup>58</sup> Op. cit., Boycott et al., e10487.

<sup>59</sup> Ibid., Boycott et al.

<sup>60</sup> Willmann et al., “Enhancing Translation: Guidelines for Standard Pre-Clinical Experiments in Mdx Mice.”

<sup>61</sup> Wagner et al., “A Decade of Optimizing Drug Development for Rare Neuromuscular Disorders through TACT.”

<sup>62</sup> Op. cit., Wagner et al.

<sup>63</sup> Stern, “Managing the Use and Dissemination of Information about Biomarkers: The Importance of Incentive Structures.”

<sup>64</sup> Julkowska et al. (2017) features a more robust accounting of such models with a primary focus on European-facilitated or participatory forums.

to the market and its actors state interest in particular types of innovation over others.

Recall Navarro's conceptual point that every *positive* incentive – such as a collaborative research forum – creates a dichotomy: what is *not* being valued? What is being discouraged? As a product of these political mechanisms of 'research collaboration,' an MNPC may strategically decide to forego certain commercial or capital investment so as to invest in alignment with a particular state's or several states' priorities. For example, an MNPC may alter *decision-making* about their respective R&D 'product portfolio' and 'pipeline' *not to include* a particular target or biomarker. What this leads to is a *lack of R&D* for a particular therapeutic area (disease class or strain), delivery mechanism or modality, or geography (i.e., region of the world and/or their local health care needs in terms of disease burden). The alignment of nonstate actor decision-making in the target identification phase of the lifecycle with state and global policy priorities, as codified in these consortia and similar forums, may have important implications for what diseases are prioritized for treatment, prevention, or cure.

This initial descriptive account finds that ideas and processes but also how ideas and processes are contextualized as actor understandings about the priorities of the global pharmaceutical market, influence the earliest stage of the pharmaceutical lifecycle. This finding may afford critical insights into the point that Elbe made at the outset of this section: *cui bono* from the opportunity for pharmaceutical innovation? However, the examples presented here are simple one set of ideas, processes, and context informing pharmaceutical R&D. Another are those state-sponsored targeting incentives with direct financial corollaries: direct research funding, IP protections, patents, exclusivities, and criterion for expedited regulatory approvals that can prolong monopolistic pricing and speed time-to-market.

### 6.2.2 Incentives for Targeting Certain Health Priorities over Others

To further explore the potential influence of power expressed through ideas, context,

process, and policy content for ‘drug targeting’ decision-making, this section examines *indirect* incentives for targeting certain health priorities, whether disease states or ease of treatment modality, over others. A leading example of such incentives is the range of IP protections, patents, and exclusivity policies embedded not only in national law but also as a global norm through international agreements. Their significance is best exemplified by consultancy recommendations for corporate strategy. For example, consultants to pharmaceutical manufacturers often produce reports on exclusivity and patent strategies in particular markets. One such report, by Washington, D.C.-based firm Latham & Watkins (May/June 2009), recommends manufacturers directly incorporate the suite of indirect incentives into their “long term exclusivity” and R&D strategies:

It is essential that a pharmaceutical company evaluate its exclusivity options and develop its competitive strategy early in the drug development process...

This article is intended to provide an overview of the nonpatent exclusivity provisions in the U.S. and EU that pharmaceutical companies should consider when forming a global exclusivity strategy for their products. In some instances, government authorities have established a common application for a specific form of exclusivity, reflecting the recent trend toward harmonizing and simplifying the process by which a drug manufacturer can attain exclusivity in the U.S. and EU...

Taking advantage of the multiple forms of market exclusivity available in both the [U.S.] and EU is critical for securing the optimum financial return on a new or updated drug. A pharmaceutical manufacturer can capitalize on these opportunities by considering the following recommendations: develop a comprehensive long-term exclusivity strategy that incorporates the various testing and development activities required. Plan your exclusivity strategy early and take advantage of U.S./EU simplification procedures.<sup>65</sup>

Latham & Watkins discuss the 2010 announcement of a common annual report for affirming continuing eligibility under the designation,<sup>66</sup> specifically differentiating whether the manufacturer is originating their market application in the U.S. or the European Union (EU).

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<sup>65</sup> Hathaway, Mantheir, and Scherer, “Exclusivity Strategies in the United states and European Union.”

<sup>66</sup> European Medicines Agency, “*FDA and EMA Agree to Accept a Single Orphan Drug Designation Annual Report*.”

## IP Protections, Patents, and Exclusivities

Another consideration for firms is whether similar incentives are available in other leading markets. A 2015 legislative review by Todd Gammie et al. suggest orphan drug designations may be a fast-emerging area of regulatory coordination approximating harmonization. Of the 35 states reviewed, only nine were found to lack any financial or non-financial Selection Mechanism to incentivize ‘orphan drug’ R&D; marketing exclusivity akin to the EU and U.S. approach is used in 26 of 35 countries and ranges from five to 10+ years on average.<sup>67</sup>

Aaron Kesselheim (2011) examined U.S. laws affecting pharmaceutical development, including the Bayh-Dole Act of 1980, the Orphan Drug Act of 1983, the Hatch-Waxman Act of 1984, and the pediatric exclusivity provisions of the Food & Drug Modernization Act of 1997.<sup>68</sup> Kesselheim, without reference to Navarro, is channeling him, describing market and data exclusivity incentives as “tool[s] to promote drug development allows the government to subsidize a certain goal without directly allocating its resources, with the costs borne by patients and third-party payers.”<sup>69</sup> One notable finding is in relation to the positive structural effects of the pediatric exclusivity, which Kesselheim notes has had the practical effect of extending exclusivity for already-approved pharmaceuticals with meaningful market shares and the proliferation of approved pharmaceuticals for the ages 6-12 population—and in a manner disproportionate to other advanced markets “(where no similar incentive provisions exist).”<sup>70</sup>

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<sup>67</sup> Gammie, Lu, and Babar, “Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries.”

<sup>68</sup> Kesselheim, “An Empirical Review of Major Legislation Affecting Drug Development: Past Experiences, Effects, and Unintended Consequences.”

<sup>69</sup> We would not that, while exclusivities do not incur a direct fiscal or budgetary cost, per se, certainly the government does bear some costs if it is presumed monopolistic prices are charged during the period of exclusivity, and the government pays those higher costs through the public health coverage programs it funds. Op. cit., Kesselheim, 453.

<sup>70</sup> Op. cit., Kesselheim, 455.

## Orphan and Rare Drug Designations

Though, as Kesselheim himself explains, the existing literature examining the effectiveness of such selection mechanisms leaves much to be desired (i.e., drug class-to-class analysis of the policy's *outcomes*), the strategy recommended by Latham & Watkins – of focusing R&D on disease categories, drug classes, and market geographies where there is not only streamlined filing processes for the majority of the global pharmaceutical import market, but a concentration of guaranteed public support – provides anecdotal evidence these mechanisms, political influence the strategic decisions of private firms. Aarti Sharma et al. (2010) come to a similar conclusion in their analysis of various *national* policies and orphan drug incentives within the context of a shift in pharmaceutical industry focus away “from the *essential medicines* to the *new business model* — niche busters, also called orphan drugs.”<sup>71</sup>

Sharma et al. evaluate various national policies to stimulate ‘orphan drug’ development, including those of the U.S. (originating in 1983), Japan (1993), Australia (1998), the EU (2000, 2007), and Taiwan. As part of their analysis, they review respective national policies and rationale for supporting essential medicines versus orphan drugs, noting that the “primary focus” of essential medicines is “public health: bringing effective medicines to as many patients as possible,” whereas the focus of “orphan drugs” is “individual patient: even a single patient warrants all possible treatment.” Similarly, the mechanisms of state intervention, returning to Navarro, are different: for essential medicines (EMLs); the policies aim to “provide established medicines to patients,” which generally are off-patent and therefore generating low levels of capital returns.

Conversely, orphan drugs, which are intended to capture innovation that “provide[s] new medicines to as yet untreatable conditions,” and therefore qualify for IP, patent, and exclusivity

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<sup>71</sup> Sharma et al., “Orphan Drug: Development Trends and Strategies,” 290–91.

protections and, often, expedited regulatory approvals (‘accelerated approvals’), have “relatively high prices per individual patient.” As demonstrated by Figure 6.2, the number of orphan drug designations increased 96% between 2019 and 2020 alone, but the overall trend reflects literally hundreds of pharmaceuticals annually receiving these benefits. As Boycott et al. illustrate in a similar compilation for the 2001-17 period, orphan designations granted in the EU and the U.S. increased from fewer than 100 in 2001 to over 450 in the U.S. (2017) and a peak of over 200 in the EU (2016).<sup>72</sup> The opportunity for mid-range monopolistic pricing is an intentional albeit indirect incentive for MNPCs and other pharmaceutical product sponsors to self-select certain disease categories, biomarkers, and treatment modalities for innovation over others.<sup>73</sup> And with the average exclusivity period now exceeding 13 years,<sup>74</sup> the potential for new capital generation associated with orphan drugs is strikingly higher, which may explain the significant increase in orphan drug designations granted in the EU and the U.S.

Sharma et al. note the orphan drug incentives implicitly *reduce* incentives for “new drugs and vaccines for the neglected diseases such as malaria and tuberculosis that affect poor countries”<sup>75</sup>—although the underlying markets for these neglected tropical diseases (NTDs) are significant—though the less powerful states where NTDs are most acute have a differential capacity to pay, let alone to develop, cost-based market incentives. The study authors note the tension between values and ideas is a natural result of these policies—not solely because of manufacturer choices:

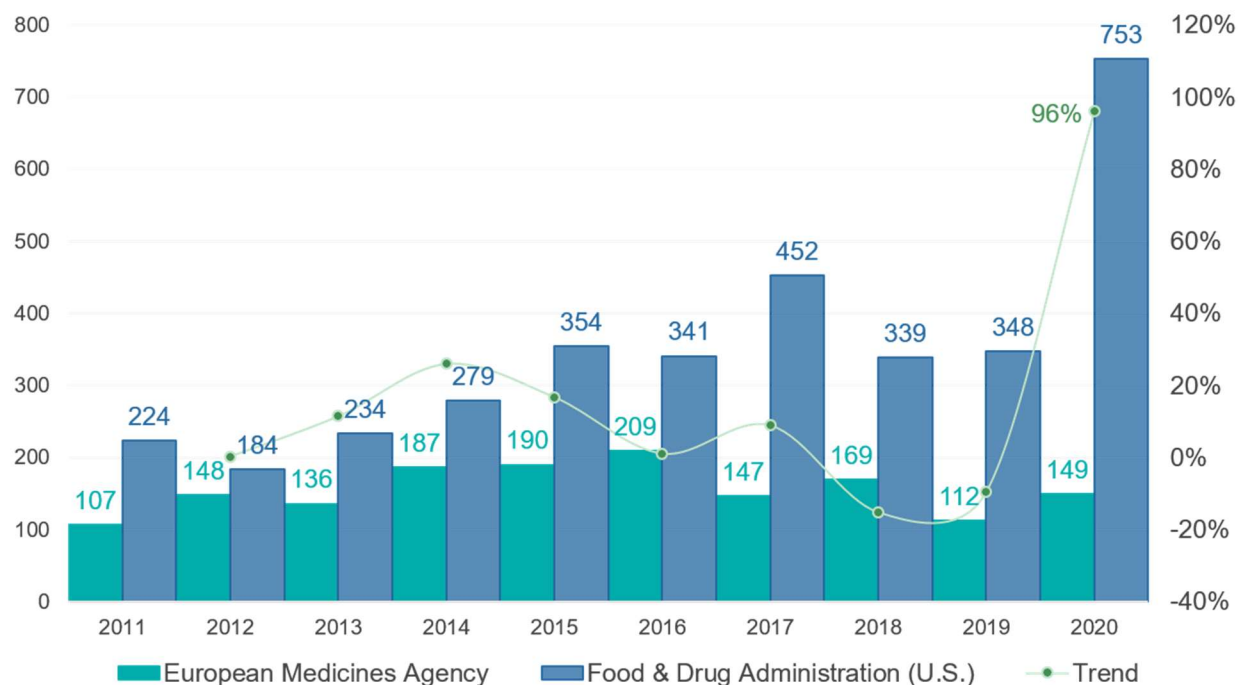
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<sup>72</sup> Op. cit., Boycott et al., Figure 2.

<sup>73</sup> Op. cit., Sharma et al., Table 8.

<sup>74</sup> Grabowski et al., “Evolving Brand-Name And Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act.”

<sup>75</sup> Op. cit., Sharma et al., 299.

**Figure 6.2. Pharmaceuticals approved or licensed and granted an orphan designation**

Author aggregated analysis reflecting data from the EMA and FDA for calendar years 2011-20 (EMA) and federal fiscal years 2011-20 (U.S.). European Medicines Agency, “Annual report on the use of the special contribution for orphan medicinal products: Year 2020” (February 15, 2021); and, Food & Drug Administration (U.S.), “Total number of orphan drug designation decisions that resulted in orphan designation in the month, by Federal Fiscal Year” (September 30, 2020). See also trends between 2001 and 2017 as captured by Boycott et al. (2019).

Developments in policies affecting the model of essential medicines (EML) may result in these fields becoming more and more distinct in the future. The primary focus in the orphan drug arena is the individual patient, irrespective of the demands of society at large. This contrasts with the more ‘utilitarian’ public health approach of the current EML definitions. Moreover, the two systems also differ in their drug/disease orientation...

The domain of the EML is dominated by public health concerns (i.e., priority diseases) and proven effectiveness of medicines through the methods of ‘evidence-based medicine.’ The 2002 revisions of the EML entry criteria show an increased move toward the upper right quadrant. Therefore, if current EML definitions are

applied strictly, both fields may ‘lose touch.’ This is an unwanted situation in the future developments in the pharmaceutical field.<sup>76</sup>

Besides the IP protections and exclusivities afforded to pharmaceutical product sponsors, which themselves reflect particular health care priorities, states also incentivize targeting particular disease states for biopharmaceutical innovation through expedited regulatory approval processes and direct funding of prioritized R&D. For example, the European Union appropriated 100 billion EUR (113 billion USD) for the seven-year fiscal period that runs 2021 to 2027—1 billion EUR of which is reserved to brain science and quantum technologies.<sup>77</sup> As reporters Alison Abbott and Quirin Schiermeier (2019) explain, this multi-billion research program, known as Horizon 2020, “set[s] the agenda for science across the bloc,” particularly focusing on the collaborative research projects of “older EU countries” like France, Germany, the Netherlands, and (at the time) the U.K.—states also leading pharmaceutical exporters (return to Figure 2.2-D).<sup>78</sup>

Horizon 2020 is not the EU’s first regional research program. Pan-European research funding and collaboration, and the scientific agendas they inform, originated in 1984 as a way “to achieve political objectives such as spurring the economy or improving the health and well-being of citizens.”<sup>79</sup> What is new, however, is a “mission” specific approach to funding; for example, Horizon 2020 includes “heavily financed collaborations” that concentrate on, among other notable priorities, “cancer.”<sup>80</sup> Other developments of significance include, *first*, the *sheer size* of research funding, which has grown from under 5 billion EUR for the 1984-87 period to over 100 billion EUR proposed for 2021-28. *Second*, within-region disparities of resource allocation have grown to practically favor select states over others in EU support of the domestic innovation to be the competition state of the 21st

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<sup>76</sup> Op. cit., Sharma et al., 299.

<sup>77</sup> Abbott and Schiermeier, “How European Scientists Will Spend 100 Billion EUR.”

<sup>78</sup> Op. cit., Abbott and Schiermeier, figure “Core Club.”

<sup>79</sup> Ibid., Abbott and Schiermeier.

<sup>80</sup> Ibid.



century á la M. E. Porter,<sup>81</sup> as explained by Alison Abbott and Quirin Schiermeier (May 22, 2019):

For scientists from countries that spend little on research, the EU's centralized research programs represent hope. 'EU research money is absolutely vital for us,' says Igor Papič, an electrical engineer at the University of Ljubljana in Slovenia who is involved in a Horizon 2020 project aimed at integrating renewable-energy sources into the European electricity grid. 'We just wouldn't be able to participate in this kind of research if we relied solely on local funding sources.'

The majority of these nations with smaller research budgets are former communist countries in central and eastern Europe, which — together with the small states of Cyprus and Malta — joined the EU after 2004 and are known collectively as the EU13. As a group, they have won just 5% of the money from Horizon 2020 so far, even though they contribute 9% to its total budget.<sup>82</sup>

### Accelerated Approval and Expedited Review Programs

The final targeting incentive to be briefly examined in this section, expedited regulatory approvals (e.g., accelerated review, accelerated assessment (EMA, EU), accelerated approval (FDA, U.S.), breakthrough therapy (FDA), conditional marketing authorization (EMA), orphan (FDA), priority review (FDA)), refers to state regulatory policies “intended to prioritize the most important medicines for faster access by patients”<sup>83</sup> by reducing the timeframe or required for a state's pharmaceutical RA to review a sponsored product for market approval or licensure. A 2015 analysis of expedited review programs in the U.S. by Aaron Kesselheim et al. found significant increases in the proportion of overall drug products being approved through these programs. The analysis found “a significant increase” in share of new drug products approved or licensed by the Food & Drug Administration (FDA, U.S.) through expedited review edited, increasing from 34% of approvals and licensures in 2000<sup>84</sup> to, as Thomas J. Hwang et al. (2020) find, 60% in 2019.<sup>85</sup> By comparison, 15%

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<sup>81</sup> Op. cit., M. E. Porter.

<sup>82</sup> Op. cit., Abbott and Schiermeier.

<sup>83</sup> Hwang et al., “Association between FDA and EMA Expedited Approval Programs and Therapeutic Value of New Medicines: Retrospective Cohort Study,” m3434.

<sup>84</sup> Aaron Kesselheim et al., “Trends in utilization of FDA expedited drug development and approval programs, 1987-2014: cohort study.”

<sup>85</sup> Op. cit., Hwang et al.

of the 268 new drugs approved by the EMA from 2007 through 2017 (that also were approved by the FDA) qualified for expedited review.

Other advanced and pharmerging economies, including post-Brexit U.K., China, and Japan, have expedited review programs,<sup>86</sup> though other observers, including Takashi Nagasawa and Atsushi Aruga (2020) note ongoing “drug lag” between Japan and the U.S. despite these pathways.<sup>87</sup> Alike orphan drug designations, expedited review policies increasingly represent a quasi-global governance of pharmaceuticals: similar regulatory frameworks are present in states that, collectively, represent most of the global pharmaceutical market.<sup>88</sup> As Kesselheim et al. (2015) note, however, such policies may not actually result in the incentivizing of innovative and high-value pharmaceutical R&D: “Though some drugs associated with an expedited program may indeed provide noticeable clinical advances, this trend is being driven by drugs that are not first in class and thus potentially less innovative.”<sup>89</sup>

Hwang et al. (2020) echo this sentiment:

We found that less than a third of all new drugs approved by the FDA and EMA were rated by any of five independent organizations as having high therapeutic value—that is, providing moderate or better improvement in clinical outcomes for patients. Most of the increase in the number of new drug approvals over the past decade was driven by drugs rated as having low therapeutic value, which calls into question the common practice of using simple counts of new drug approvals as a measure of innovation...

[I]n absolute terms, most drugs in the FDA’s expedited programs were rated as having low therapeutic value—even for breakthrough designated therapies and those that qualified for priority review, which is intended for drugs that provide ‘significant improvement.’ By contrast, few drugs qualified for the EMA’s accelerated assessment, but most of them were rated highly...

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<sup>86</sup> Aman Khera, “Expediting Drug Development Regulatory Pathways Globally.”

<sup>87</sup> Nagasawa and Aruga, “Potential Impact of Accelerated Approval on the Drug Lags for Anticancer Drugs between the United States and Japan.”

<sup>88</sup> The top 15 pharmaceutical exporters, which include many EU member states, the U.K., the U.S., and China, and the addition of Japan, expedited review policies are present in the regulatory frameworks of at least 86% of the global pharmaceutical market.

<sup>89</sup> Op. cit., Kesselheim et al.

The study findings... suggest a widening gap between regulatory approval and the clinical and public health priorities of health systems, payers, and patients after approval.<sup>90</sup>

### 6.2.3 Summary of Findings

The descriptive accounts discussed in this section – from collaborative research forums to patent protections to expedite review programs – highlight the importance of the Four Factors in examining the influence and expression of power in global governance for health, and how and why certain outcomes may be generating. Specifically, state power is being expressed through *context* (i.e., the geopolitical importance of competition states and their interventions to secure national advantage), *content* (policies to directly invest in specific diseases), *processes* (to streamline innovation and lower R&D investment costs through cross-industry collaboration), and *ideas* (about the value of biopharmaceutical innovation, the value of scientific solutioning, the role of the market to generate research efficiencies) to influence the investment decisions of nonstate actors.

Specifically, these factors influence – they *set* – practical, industry priorities early in the pharmaceutical lifecycle, including favoring R&D that meets the criteria for long-term monopolistic pricing opportunities instead of R&D that serves significant global health needs. For example, political incentives favoring R&D for rare conditions and highly specialized biomedical technologies (biopharmaceuticals) may also discourage *competition*, which is necessary for price deflation and overall innovation (i.e., novel value added). For example, collaborative forums seek efficiency in biomarker identification and, discursively, favor R&D and investment priorities that target R&D in a particular opportunity area. It would be inefficient for R&D in that *particular* line of pharmacological research to be pursued by multiple product sponsors. Rather, adjacent biomarkers and targets can be advanced, which is promoted by industry collaboration on their identification and collective

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<sup>90</sup> Op. cit., Hwang et al.

awareness of respective R&D pipelines.

The tensions observed by Sharma et al. in R&D decision-making is reminiscent of the same inherent conflicts explored in Chapter 5.2: the globalization of certain ideas about health, including the conflict between the hegemonic ideas of Flexnerianism (i.e., concepts of health as individual responsibility, determined by genetic factors and individual behaviors) and western medical practice on the one hand, and holistic, public health approaches that recognize the political origins of health inequities and social factors comprising most diseases. If most diseases, under Flexnerianism, are individually controllable, then the role of states in advancing industry innovation should be for diseases rare, purely genetically originating, and where the market is so small as to be unable to invest in itself. Practically, however, this account suggests the opposite: markets large enough that, based on size alone, they should warrant industry prioritization and investment (e.g., neglected tropical diseases) are not politically prioritized and therefore under-invested by the pharmaceutical market.

### **6.3 Financing Innovation: Public Investment and Venture Philanthropy in Biopharmaceutical Research**

One rational for state intervention in the pharmaceutical market is to alleviate the costs inherent to this stage of the pharmaceutical lifecycle. For example, a recent analysis of Alzheimer's disease (AD) pharmaceutical development found that “costs associated with drug development programs are high and serve as a significant deterrent to AD therapeutic investigations.”<sup>91</sup> The Congressional Budget Office (U.S.) (2021) comes to a similar conclusion, asserting a positive relationship (directionality) between states' allocative intervention policies, the R&D strategies of pharmaceutical manufacturers, and, conversely, the lack of biopharmaceutical innovation or

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<sup>91</sup> Cummings, Bauzon, and Lee, “Who Funds Alzheimer's Disease Drug Development?” e12185.

commercial products resultant from the *absence* of such interventions:

If expected profitability of new drugs declined—because of a change in federal policy, a shift in demand or supply, a revision in the balance of power between drug companies and drug buyers, or for any other reason—the expected returns on drug R&D would decline as well. Lower expected returns would probably mean fewer new drugs, because there would be less incentive for companies to spend on R&D. (If expected profitability were to rise, the opposite effects would occur.) Expectations about returns on R&D partly depend on expectations of prices that future drugs could command—which, in turn, partly depend on current drug prices and influences on those prices...

CBO estimated that under the bill, approximately eight fewer drugs would be introduced to the U.S. market over the 2020–2029 period and about 30 fewer drugs over the subsequent 10 years.<sup>92</sup>

Similarly reflective of significant risk aversion, this same CBO report notes that, at least regarding the U.S., a top five pharmaceutical exporter, the “federal (U.S.) government is the main funding source for basic research related to biomedical sciences,” with the majority of disease target research being funded by the National Institutes of Health (NIH, U.S.) before it was applied by private firms to develop new pharmaceuticals.

Of two descriptive accounts on non-manufacturer funding (‘capital investment’) in pharmaceutical research and pre-discovery, the first considers public funding, through research grants as well as direct investment. The second considers venture philanthropy (VP) by patient advocacy groups as a means of co-financing pharmaceutical R&D for underinvested diseases and treatments, which is evaluated against respective actor goals for health. Through these descriptive accounts, this section examines what ideas, context, content, and processes have power and what are the influence points on actors that generate not only what disease targets and biomarkers are identified but whether such research prospects are financed for R&D investment.

### 6.3.1 Public Investment in Biopharmaceutical Innovation

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<sup>92</sup> Op. cit, Congressional Budget Office (U.S.).

Over the past two decades, NIH funding exceeded 700 billion USD. (For context, North American economies, which include the U.S., Canada, and Mexico (but the U.S. is dominant) exported 58 billion USD worth of pharmaceuticals in 2018.<sup>93</sup>) From the standpoint of innovation and new therapeutic options, such taxpayer funding is essential. Ekaterina Galkina Cleary et al. (2018) found that NIH funding of biomedical research between 2010 and 2016 was associated with each of the 210 new drugs approved by the FDA that same year.

Besides direct financing of biomedical research and pharmaceutical innovation (e.g., through public funding of research grants), states may establish another allocative intervention: favorable tax treatment of R&D spending, including credits for developing pharmaceuticals to treat “uncommon diseases”<sup>94</sup> (orphan), which generally accompany a market or data exclusivity.<sup>95</sup> But these are two of several funding models for pharmaceutical R&D; other models include involvement of “a not-for-profit pharmaceutical company, a foundation that operates a virtual company linking investors with biopharmaceutical companies, a for-profit company with a vested interest in rare diseases, and a global private-equity fund dedicated to advancing drug discovery.”<sup>96</sup>

Considering the pharmaceutical industry’s ‘innovation crisis’ against the range of innovative products that came to market during the 2010s, it is possible to conclude that the prior decade’s R&D pipeline advanced select innovations in mechanisms of treatment, including RNA-based therapeutics (e.g., some Covid-19 vaccines are made by mRNA technology, as is the new AD treatment approved in June 2021) and calcitonin gene-related peptide (CGRP) receptor antagonists for migraine treatment. At least nine of the remaining products and vaccines relate to the SARS-

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<sup>93</sup> Op. cit., Harvard Growth Lab.

<sup>94</sup> Galkina Cleary et al., “Contribution of NIH Funding to New Drug Approvals 2010–2016.”

<sup>95</sup> Op. cit., Congressional Budget Office (U.S.).

<sup>96</sup> National Academies of Sciences, Engineering, and Medicine, *Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies*, 99.

CoV-2 virus and Covid-19 pandemic, were the beneficiaries of significant state intervention and global public-private partnership financing (e.g., GAVI Alliance).

Excluding new neurological treatments to treat pain, mental health conditions, and migraines, the balance of 2013's new products comprised DAAs for hepC and neglected tropical diseases (NTDs) like malaria, tuberculosis, and Ebolavirus, which were funded in partnership with “global philanthropy,” referring to the venture philanthropy of the Bill and Melinda Gates Foundation; the Chan-Zuckerberg Initiative; and other global public-private partnerships (PPPs) or national collaborations between patient advocacy groups and pharmaceutical manufacturers, including the FNIH.

### 6.3.2 Patient Groups as Venture Philanthropists: Alternative Investment in Pharmaceutical R&D

Jeffrey Cummings, Justin Bauzon, and Garam Lee (2021) examine the funding of AD pharmaceutical R&D, finding that the number of AD clinical trials sponsored solely by pharmaceutical manufacturers is on the decline, and the proportion funded by public-private partnerships (PPPs), including manufacturer-philanthropic and manufacturer-state partnerships, is on the rise.<sup>97</sup> Through the Alzheimer's Clinical Trials Consortium (ACTC), which is managed by the National Institute on Aging of the National Institutes of Health (U.S.) and allocates publicly-funded grants to support “270 active clinical trials on Alzheimer's disease and related dementias.”<sup>98</sup>

Boston-based Biogen, Inc. and Tokyo-based Haruo Naito (“Eisai, Co., Ltd.”) jointly developed Aduhelm™ (aducanumab-avwa) (BIIB037), an amyloid beta-directed antibody treatment for AD. Though Lecanemab received market approval in the United States in June 2021, a Phase III clinical trial is ongoing, with primary results expected in September 2022.<sup>99</sup> This trial is being

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<sup>97</sup> Cummings, Bauzon, and Lee, “Who Funds Alzheimer's Disease Drug Development?”

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conducted in partnership with the Alzheimer's Clinical Trials Consortium (ACTC), Biogen recently said it has completed submitting a Biologics License Application (BLA) for aducanumab to the FDA, hoping to sell the world's first Alzheimer's drug. Biogen's corporate value is rising as another candidate, BAN2401, is to be tested in the phase-3 trial under the public-private partnership. Roche's gantenerumab and Lilly's solanezumab, anti-amyloid beta antibodies, are in phase-3 trials.

Let us consider the cystic fibrosis (CF) treatment Kalydeco® (ivacaftor), which was co-funded by the Cystic Fibrosis Foundation (CFF) and resulted in the charity profiting 3.3 billion USD after the sale of its share of the pharmaceutical's IP rights.<sup>100</sup> It is possible to imagine the role of venture capital (VC) or even global philanthropic organizations, styled as venture philanthropy (VP), in the financing of pharmaceutical investment. These are market actors, and so the extension of market norms of behavior to biomedical research makes sense. Is a patient advocacy group similarly primed to adopt the ideas of health as a commodity, as a form of capital?

Esther S. Kim and Andrew W. Lo (2017) of the MIT Laboratory for Financial Engineering examined the case of Kalydeco® in a 2017 assessment of 'new' venture philanthropy—the new bit being its application to biopharmaceutical research *by patient-advocacy groups*.<sup>101</sup> Akin to the efforts of the Juvenile Diabetes Research Foundation, Michael J. Fox Foundation for Parkinson's Research, and other patient-advocacy (or disease-focused) foundations, CFF has practiced VP for decades. For example, Foundation-funded research supported the discovery of the gene responsible for cystic fibrosis in 1989. In 2010 and subsequent years, CFF invested donations and other sources of revenue into pharmaceutical therapeutics development; the scale of the Foundations' investment is estimated at 425 million USD for the 2010-16 period.<sup>102</sup> Similar to the research grant-making

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<sup>100</sup> Tozzi, "This Medical Charity Made \$3.3 Billion From a Single Pill," Bloomberg (July 7, 2015).

<sup>101</sup> Kim and Lo, "The 'New' Venture Philanthropy: A Case Study of the Cystic Fibrosis Foundation."

<sup>102</sup> Op. cit., Kim and Lo.



activities of select states' public health research authorities, CFF has awarded over 1,100 laboratory and research grants for a range of scientific endeavors, including gene editing and gene therapy. One such research partnership, with Aurora Biosciences in 2000, ultimately, led to the successful market launch of a new treatment for CF.

Less than one year into the partnership, however, Aurora Biosciences was acquired by Vertex Pharmaceuticals.<sup>103</sup> Lacking experience both with clinical research into CF and VP arrangements, Kim and Lo (2019) suggest that Vertex was hesitant to continue the partnership. Ultimately, the decision to proceed rested on the likelihood that any such resultant treatment would be profitable because of the underlying political context and related ideas about the value of pharmaceutical innovation:

Despite CF's small patient population, Vertex saw commercial potential in sales domestically and abroad. As treatments for a rare disease, CF therapies under development also qualify for market incentives under the Orphan Drug Act, including support for clinical trial costs, tax breaks for certain expenses, Prescription Drug User Fee Act waivers, and favorable EU Orphan Drug policies...

The development of Kalydeco® benefited not only from incentives of the Orphan Drug Act, but also from the Food & Drug Administration Safety and Innovation Act (FDASIA), which gave Kalydeco® a 'breakthrough' designation and priority review within the FDA approval process. Kalydeco® was approved in 2012 for individuals of ages 6 years and older who had the G551D mutation.<sup>104</sup>

The assurances of a pricing monopoly fast-tracked and simplified approval pathway, potential growth in the patient population,<sup>105</sup> and use of a common market approval framework that would

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<sup>103</sup> Earlier this year, U.S. Representative Katie Porter released the results of an investigation into the role of pharmaceutical manufacturer mergers and acquisitions as a mechanism for 'padding' a firm's pharmaceutical R&D pipeline, particularly, when early pipelines thin out as late-stage trials approach. Porter's 2021 report discusses the Amgen acquisition of Immune, which had been developing a rheumatoid arthritis treatment, Enbrel®. The acquisition transferred ownership of the known-commodity (Enbrel) but resulted in the "shutting down" of all other research lines. This research does not detail this or other such examples, but the dynamics are worth further exploration for their ideational and discursive components. See Porter, *"Killer Profits: How Big Pharma Takeovers Destroy Innovation and Harm Patients"* (January 2021).

<sup>104</sup> Ibid., 8.

<sup>105</sup> Kim and Lo note that the initial FDA approval of Kalydeco® took only 100 days (in 2012). The product, subsequently received two

enable simplified access to the leading U.S. and European were compelling for the firm to continue the collaboration with CFF. The rest, as they say, is history: Kalydeco® (ivacaftor) was approved for the U.S. and EU markets in 2012.<sup>106</sup>

Less than two years following market approval, the Foundation pursued negotiations with Royalty Pharma to monetize its royalties in Kalydeco® and other future CF-related royalties from Vertex (i.e., if combination treatments occurs leveraging the original Kalydeco® investment). The sale of the royalties represented 80% of the Foundation's total assets, greatly shifting the Foundation's financial capabilities for similar VP investments or other patient-support efforts. Kim and Lo note that a priority for the Foundation, in terms of a fast sale of the royalties, was to “remove the potential for a conflict of interest for the nonprofit resulting from an ongoing interest in the sales of a commercial product,” as the Foundation had been receiving royalties from Kalydeco® sales up to that point.<sup>107</sup>

The success of the CFF-Vertex partnership was broadly commended, including by former U.S. President Barack Obama (in the 2013 state of the Union address), other patient groups seeking to build out their own VP initiatives (referring to the “Kalydeco” case study), and the broader business community, particularly, pharmaceutical manufacturers, who viewed similar partnerships as a smoothed pathway for identifying “profitable therapies for *rare diseases*” pre-discovery—a shift away from former R&D strategies oriented to mass-market ‘blockbuster’ pharmaceuticals. And the patients living with CF, for whom Kalydeco® and its sister products (Orkambi®, Trikafta®, and Symdeko®) represent improved symptom management and wellness. This example highlights the

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expanded indications in 2017, which expanded the available market and revenue potential of this product—without having to innovate or generate new pharmaceutical value. Kalydeco® is now approved to treat 38 different mutations of the CFTR gene among people living with CF

<sup>106</sup> Ibid., and European Medicines Agency, “Authorization details: Kalydeco” (July 23, 2012).

<sup>107</sup> Ibid., Kim and Lo, 10-11.

important role financing innovation can play early in the pharmaceutical lifecycle, though it clearly has immediate and long-range costs not necessarily recognized at this early stage, including the *opportunity costs* of foregone investments in products meeting greater global health needs, the *global health costs* of underinvestment in the systemic changes that address the actual political origins of the leading global burdens of disease, and the *fiscal costs* of favoring markets *primed to product ever-more expensive drugs* for ever-longer spans of use.

### 6.3.3 Summary of Findings

The Kim and Lo study analyze many details of the Vertex-CFF partnership and, later, the CFF-Royal Pharma sale, stating that they “consider[ed] the role and incentives of all the major stakeholders, highlighting the keys to the CF Foundation’s success and implication for best practices in VP.”<sup>108</sup> What they do not consider, however, are the role and incentives associated with the market-oriented norms underpinning this immediate partnership and how this partnership may influence the Foundation’s health promotion agenda moving forward. The authors proactively respond to the lack of analysis of the dynamics surrounding the unit price of Kalydeco® (300,000 USD per patient/per year at launch), which informed the 3.3 billion USD royalties pay-out that the Foundation received from Royal Pharma. Instead, Kim and Lo note that CFF is “motivated solely by its mission to reduce the burden of disease on people with CF—and not on financial return,” and so their effort to analyze “how for-profit financing techniques can be used effectively to achieve [the] mission-driven goals” of other patient-advocacy groups is concordant and appropriate.

A 2015 piece by Bloomberg reporter John Tozzi (2019) captures the expressly difficult underlying tensions inherent in the Kalydeco® case and others like it—the incorporation of market-oriented goals, particularly, of capital accumulation, into patient advocacy:

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<sup>108</sup> Ibid., 2.

The CF Foundation's exclusive goal used to be the search for a cure. But now that it has helped fund two promising drugs, the group needs to make sure patients can actually access them—which is tougher than it sounds. Both medications are accompanied by staggering price tags: Kalydeco's list price, before the discounts [that] insurers negotiate, is about \$300,000 a year. Orkambi will cost \$259,000 a year. "The worst thing we could ever do is throw these patients a great lifeline out there, and have it been frayed by the issue of access," [Former CFF President and CEO Robert] Beall said.<sup>109</sup>

The Kalydeco® case is a powerful example of the role of ideas, particularly, hegemonic ideas of market-based solutions, in influencing the interests and behaviors of actors. Here, a patient-advocacy group whose mission was to cure a disease financially benefited from the marketization of the disease and the bodies of its patient members—not only in terms of the R&D processes, but subsequently in the valuation of their royalties, which reflects *the value of a life with treatment*.

The Foundation monetized not only its Kalydeco® assets, but also its scientific expertise, "strong relationships with patients," and "insights from individuals living with a disease," as an in-kind resource to pharmaceutical manufacturers. It also is a practical example of the co-production of marketized health: whereby the patients needing treatment have a role, financially and physically, in developing that treatment, and then bear financial responsibility for the treatment they co-produced. Rather than "a commercial product they [CFF] funded and their patient community will use," it is a pharmaceutical that patients and CFF co-produced, but only the patients will pay for.

How can we make sense of patient co-production of their own health care treatments, which then are *priced at the expense of their bodies*?<sup>110</sup> This is a complex dynamic that is neither free of "real and perceived conflicts of interest," nor of the stark consequence of ideas and power in making global health—, at the sub-system or meso level of analysis. This and similar trends towards the heightened marketization of so many facets of health deserve continued attention.

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<sup>109</sup> Tozzi, "This Medical Charity Made \$3.3 Billion From a Single Pill."

<sup>110</sup> See, for example, the pricing and clinical evidence dynamics of the new-to-market AD pharmaceutical: Mullard, "Landmark Alzheimer's Drug Approval Confounds Research Community."

The case of Kalydeco®, an orphan-designated pharmaceutical co-produced by patients, and the explicit influence of 20th century Flexnerianism on 21st century pharmaceutical incentives demonstrate how simple ideas can shift actor choices and preferences in ways that appear counter to their own interests. The mission of the Cystic Fibrosis Foundation had been to find a cure; in two decades of dabbling in venture philanthropy, the Foundation became a successful, though small in volume, VC for developing pharmaceutical *treatments*. Similarly, an organization founded by patients for patients to provide support and promote awareness of a disease, with time, *commodified* its relationships with patients, credibility as a trusted and conflict-free voice, and privileged access to expert knowledge about disease for gain—at a cost of 300,000+ USD per year for its own patient members.

What is compelling about the Kalydeco® case is the complementary idea of benefit to the patient, versus benefit to capital holders at the expense (and potential gain) of the patient. Similarly, the broad adoption by states, particularly, advanced economies, of orphan designations and similar incentives practically shifts an entire market from a focus on accessible, affordable, and mass-producible pharmaceuticals—to *one of precision medicine, of personalized health care innovation*—even if such innovation, now insulated from market forces for even longer, is immediately unaffordable and inaccessible, driving the adoption of further governance approaches to rebalance the power imbalance incurred by the prior policy. The implications of these dynamics, however, are not contained within this first stage of the pharmaceutical lifecycle.

#### **6.4 Clinical Trial Research and Market Approval: Examining the Harmonization of Pharmaceutical Pre-Approval Rules and the Outsourcing of Trial Research**

As the prior series of descriptive accounts touched on, power can shape and influence not only policy but, both directly and indirectly, the *capital-seeking behaviors* of nonstate actors through the four factors of ideas, context, processes, and content. The visible implications of such influence

often are like an iceberg: far smaller than the broader implications, often invisible, with consequences for individuals and actors that participate neither in the policy's design nor in the industry decision-making that such policy informs. This certainly is the case for the global pharmaceutical market, a significance tied to the growth of advanced economies as noted by Kean Birch and David Tyfield (2013):

In the policy discourses of the OECD and EC, modern biotechnology and the life sciences are represented as an emerging 'bioeconomy,' in which the latent value underpinning biological materials and products offer the opportunity for sustainable economic growth.<sup>111</sup>

In the next stage of the pharmaceutical lifecycle – clinical trial research and pre-marketing approval – the contextual lens returns to the international system of analysis, specifically, global coordination between states' regulatory authorities (RAs) – and the resultant capture of actors and interests through the power of ideas and context.

This third collection of descriptive accounts does not address fullness of *inputs and outcomes* of pre-market regulatory approval for a pharmaceutical, as this area is well explored through existing analysis. Reminiscent of Walt and Gilson's critique, the endpoint of this midpoint in the lifecycle reflects the standard "what is the policy?" (i.e., the standards for pharmaceutical approval or licensure in a particular market) and "what are the policy's outcomes?" (e.g., how many drugs were approved). Rather, the "distant proximities"<sup>112</sup> that inform the *processes* of actor interaction, the *ideas* informing *policy choices*, and the (market) *context* preferencing the design of global governance of states' domestic pharmaceutical approval and licensure policies are explored. For this pair of descriptive accounts, *first*, the somewhat-obscure international regulatory coordination that underpins the global governance of pharmaceutical pre-market approval and evidence review

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<sup>111</sup> Birch and Tyfield, "Theorizing the Bioeconomy: Biovalue, Biocapital, Bioeconomics or . . . What?"

<sup>112</sup> Rosenau, *Distant Proximities: Dynamics Beyond Globalization*.

processes are examined. *Second*, the implications of such convergence for determining the regulatory (meaning, *process*) expectations for and conduct of clinical trial research are considered against the compromised historical legacy (*context*) of clinical trials and the contemporary *context* of a new global market sector: contract research organizations (CROs).

#### 6.4.1 International Regulatory Coordination as Policy Harmonization: Global Governance of Pharmaceutical Clinical Practice, Trial Conduct, and Pre-market Approval Guidelines

Recall the prior discussion in Chapter 5.3.2 of forms of global regulation. The scholarship of James N. Rosenau (1990), Susan Strange (1996), Virginia Haufler (2001), and Daniel W. Drezner (2007), among others, was reviewed, who have sought to explain the processes of global regulation – collectively, governance – as mechanisms for power sharing. Recall also that Critical Theory asserts forms of institutional power, whether of the regulatory or governance variety, may do less to level the playing field for weaker actors, than to embed more deeply the power of the already strong. Efforts at international regulatory coordination reflect this similar dichotomy between intent and practice, between mechanisms for power sharing and embedding existing power sharing arrangements. These regulatory constructs are power-sharing mechanisms. However, under processes of globalization, global regulatory coordination often advances to a common governance or policy endpoint, which might reflect idealized power-sharing dynamics but a preferred power division.

The concepts of international *regulatory coordination* versus *policy convergence* or *policy harmonization*, need to again be examined and why they matter to better understand these power sharing arrangement. Beginning with *international regulatory coordination*, this form of global regulation refers to the codified adjustment of states' individual national standards, policies, and rules to recognize or accommodate *other* states' regulatory frameworks. *Policy convergence* reflects a heightened standard, policy, or rule coordination *across* states, or “the narrowing of national policy

differentiations or gaps in national standards over time.”<sup>113</sup> Rather than the accommodation of other states’ policies by a state’s existing domestic processes, policy convergence assumes the policies of individual states are approaching alignment. Policy convergence makes possible additional forms of international cooperation and collaboration, particularly, in areas where differential standards are helpful politically or otherwise.

When coordination and convergence result in the adoption of the “the same harmonized technical guidance documents, standards, and scientific principles,” and “similar regulatory practices and procedures are introduced,” including policies and rules, state-to-state dialogue, collaboration, and regulatory accommodation has aligned to the point of policy harmonization, creating *de facto* or actual global rules (“regulatory standards”) for those harmonized policy issue areas.

The interrelation between these forms of governance is striking, as coordination in one policy area may quickly lead to alignment or, conversely, the perceived success by one state in a policy arena may drive mimicking—a policy neighborhood effect. The adoption by 29 states of orphan designation is such an example of global regulation through policy convergence (return to Table 5.3-A). The changing dynamics of the global political economy may make securing buy-in for large, multilateral trade agreements difficult. Simultaneously, however, the complexity of the international system encourages regulator-to-regulator interaction to enable the allowance or cross-adoption of local regulatory mechanisms that also account for common or internationally recognized standards. Though a fine line, achieving regulatory coordination so it balances local preferences and common principles can achieve a flexible system of global governance for health.

International Generic Drug Regulators Program, 2011

One such example of these dynamics is the International Generic Drug Regulators Program

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<sup>113</sup> *Op. cit.*, Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*, 11.



(IGDRP), which started as an information sharing pilot and, over time, has grown to represent a leading but little-known area of global pharmaceutical governance. The evolution of the IGDRP Pilot and establishment of its sister forums, including the International Pharmaceutical Regulators Forum and the International Pharmaceutical Regulators Program, reflects a qualifier inherent to international regulatory coordination: the mutual recognition of other national standards cannot result in practical policy convergence but *does* presume greater coordination and *may generate* convergence or even harmonization.

In the late aughts and the early 2010s, select states' pharmaceutical regulatory authorities (RAs) were collectively facing a pace of generics introduction, which the RAs felt that their domestic institutions were increasingly under resourced to aptly respond to. According to Mike Ward (2014) of the World Health Organization (WHO) Drug Information Bulletin, the pressures were a double-edged sword for states' pharmaceutical RAs:

The availability of quality generic drugs, also known as multi-source medicines or pharmaceuticals, plays an increasingly important role in helping to address rising health care costs and in promoting access to essential medicines worldwide. This, however, has led to significant pressures on medicines [regulatory authorities] RAs charged with the review and approval of these products. In addition to an increased workload associated with the growing number of generic drug applications, RAs must now also contend with more sophisticated generic drug products and complex global production and distribution chains.<sup>114</sup>

To address increasing generic drug review pressures,<sup>115</sup> the pharmaceutical regulatory authorities (RAs) from Australia, Brazil, Canada, the EU, the Republic of Korea, Singapore, Switzerland, and the U.S., and representatives from the WHO, met in Ottawa in October 2011 to evaluate potential regulatory “collaboration and convergence”<sup>116</sup> around a “collaborative drug review model.”<sup>117</sup> The

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<sup>114</sup> Ward, “Regulatory Harmonization: The International Generic Drug Regulators Pilot.”

<sup>115</sup> See Ward, 3.

<sup>116</sup> European Medicines Agency, “Reflection Paper on the Chemical Structure and Properties Criteria to Be Considered for the Evaluation of New Active Substance (NAS) Status of Chemical Substances.”

<sup>117</sup> Ward, “Regulatory Harmonization: The International Generic Drug Regulators Pilot,” 3.

resultant pilot included the Ottawa meeting attendees. Following a successful three-year pilot (2012-14), the IGDRP was made permanent in 2015, with the intent of “work[ing] towards regulatory convergence and cooperation” in pre-market review of generic medicines.

In 2018, the IGDRP Pilot and International Pharmaceutical Regulators Forum (IPRF), a broader forum of information sharing on medicines of all types, was consolidated with the International Pharmaceutical Regulators Program (IPRP). The new IPRP facilitates an ongoing exchange of information, explores opportunities for regulatory cooperation, and promotes convergence of regulatory approaches among its RA members. The IPRP’s membership now reflects over 30 national and regional RAs from every region of the world. The membership includes the original members plus Argentina, Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Columbia, Cuba, East African Community (EAC), Gulf Health Council (GHC), Indonesia, Iran, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Pan American Health Organization (PAHO), Russia, South Africa, Southern African Development Community (SADC), Saudi Arabia, Taipei, and Turkey. See International Pharmaceutical Regulators Program, “Members & Observers.”<sup>118</sup>

Practically, the IPRP has encouraged extensive dialogue across pharmaceutical RAs that, often, have facilitated interstate regulatory coordination, including the common application for orphan designation discussed, and common principles for the pre-market review (i.e., approval) of generic and other pharmaceuticals. From the standpoint of global efficiency and safety, such regulator coordinating mechanisms is welcome and helpful: a way to ensure everyone is on the same page—a minimum bar that all must meet to ensure the safety of the global ‘drug supply.’ Conversely, membership-driven requirements to meet coordinated standards before a state is able or

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<sup>118</sup> See International Pharmaceutical Regulators Program, “Members & Observers.”

ready could be counterproductive and result in poor quality and safety. There also is the role of ideas, which may drive coordination from neither a safety nor quality basis, but to eliminate barriers to trade posed by individual states' regulatory priorities.

#### International Conference On Harmonization Of Technical Requirements For Registration Of Pharmaceuticals For Human Use, 1990

Akin to the pre-market approval and safety review efforts of the IPRP, the World Health Organization's (WHO's) International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1990, is a complementary forum for coordination of pharmaceutical safety, manufacturing, and clinical practice (i.e., evidence generation and trials) regulation. Similar to the IPRP in its earliest days, select member states came together to devise common guidelines for the conduct of pharmaceutical clinical trials and their evaluation for drug product pre-market approval.

The founders included pharmaceutical RAs from the U.S., EU, and Japan, and industry representatives, namely the European Federation of Pharmaceutical Industries and Associations (EFPIA), Japan Pharmaceuticals Manufacturer's Association (JPMA), and Pharmaceutical Research and Manufacturers of America (PhRMA). Canada and Switzerland serve as Standing Regulatory Members. The original founder states and trade associations continue to lead the ICH Steering Committee, on which the WHO and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) service as non-voting members. Other regulatory member states include Brazil, China, Republic of Korea, Singapore, Taipei, and Turkey, and the Biotechnology Innovation Organization (BIO), Global Self-Care Federation, and the International Generic and Biosimilar Medicines Association (IGBA) are industry members. Many other states are observers to the ICH, including Argentina, Armenia, Australia, Colombia, Cuba, Jordan, Iran, India, Israel, Kazakhstan, Lebanon, Malaysia, Mexico, Moldova, Russia, Saudi Arabia, and South Africa.

Since its formation, the ICH has been a forum for significant regulatory coordination. It has established the Common Technical Document (M4), Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Q7), and Good Clinical Practice (E6 [R2]), besides many others, which member states must have implemented before membership. These documents, for example, address the standards of clinical practice necessary when conducting clinical research trial for evidence-generation for pre-market approvals. They also include the minimum technical standards for safe manufacturing.

Besides agreeing to and accepting the above guidelines as components of their own domestic regulatory frameworks for pharmaceutical governance, ICH members also must agree to the ICH Articles of Association, which were revised in 2020, and, among other provisions, requires members to “implement all ICH Guidelines in accordance with the applicable Rules of Procedures,” thus ensuring policy harmonization across the membership. Recent reports suggest, however, that states eager to join the ICH and similar global regulatory coordinating bodies may have committed to too much, too quickly, creating a practical gap in on-the-ground compliance. While such gaps are normal when operationalizing new policies, if the speed of adoption, implementation, and lack of resolution are compounded by economic pressures, regulatory coordination in *context and process* may wind up being a representation of inequities and imbalances.

#### 6.4.2 Global Context, Historical Legacy, and Modern Expression of Clinical Trial Research

The historical legacy of clinical trials is mixed, inclusive of unethical and unimaginable approaches to human subject experimentation. For example, beginning during the wartime period (World War II) of the 1940s through the late 1960s, human subject experimentation in the U.S., was dominated by prison-based clinical trials, including clinical trial laboratories being on prison grounds and prisoners being trained “as clinicians, capable of carrying out tests at a fraction of the cost

outside prison walls.”<sup>119</sup>

After the 1960s, clinical trial practice evolved again, taking root in academic medical centers (AMCs) through the late 20th century. (Such centers conducted 80% or more of trials in the late 1970s; that figure dropped to less than half by 1998 and has continued falling, now representing a minority of conducted clinical trials.) Beginning in the 1980s and accelerating significantly in the decades since, the research and development of pharmaceuticals, and the running of clinical trials, has become highly privatized, shifting from AMCs to manufacturer-designed and sponsored trials.

The evolution of clinical research trials from World War II to the 1990s – from military research to the gross mistreatment of incarcerated individuals, and from academia to the private sector – is very recent and an ethically compromised history, but a movement all the same to the privatization and, eventually, outsourcing of clinical trials. In this way, also, private and non-academic clinical trial research is a relatively new construct requiring a clear set of guidelines to guard against the ethical harms of yesterday.

The adoption of the WHO ICH Good Clinical Practice guidelines in 1996 has helped to improve clinical trial practices in the U.S. and elsewhere, but the legacy of experimentation is stark and approximate. As regulatory requirements impose new costs, R&D costs increase, firms face other margin pressures, and states seek to compete for new markets, there is a reasonable and realistic concern that historically rooted ideas about human value, the commodification of bodies, and the relatively brief global experience with modern clinical practice standards may unwind contemporary progress on human subject experimentation – and outsourcing the troublesome historical legacy of clinical research trials to other parts of the globe, including the pharmerging and low-income economies outside the ‘great power’ circle often called the ‘global South.’ Turning to the

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<sup>119</sup> Cooper, “Experimental Labour–Offshoring Clinical Trials to China,” 79–81. See also Hornblum, *Acres of Skin: Human Experiments at Holmesburg Prison*.

fast-growing clinical trial industry in pharmerging economies like China and India, it is possible to practically examine the conceptual narrative in terms of ‘bio-economic value’ and the modern expression of historical notions of ‘human value’ in making global health.

#### Poverty and Policy Harmonization: Contract Research In India

Anthropologist Kaushik Sunder Rajan (2017) examines the relationships between the pharmaceutical industry, the market, and the political economy through a field-based study of clinical trials and patent litigation in India. Introducing the concept of ‘pharmocracy,’ Sunder Rajan applies to the multinational pharmaceutical industry IR concepts of the structuring qualities of global concentrations of power, or global hegemony. Using case studies of a controversial clinical study of a human papilloma virus (HPV) vaccine, Gardasil, in 2010 and the Indian Patent Office’s denial of a patent on minor variations for anticancer drug, Gleevec, in 2006, Sunder Rajan (2017) argues that conceptions of ‘what health is’ are normatively and practically reconstituted in terms of health’s biological value to the global pharmaceutical market:

The notion of health itself as it gets constituted in relation to emergent forms of experimentation and therapy comes to be at stake. Health is no longer just an embodied, subjective, experiential state of well-being or disease; it can be abstracted and grown, made valuable to capitalist interests.<sup>120</sup>

While both case studies explore the reconstitution of health to serve market ends (i.e., the bioeconomy’s articulation of health in terms of value to capital generation<sup>121</sup>), it is Sunder Rajan’s consideration of the “new sector devoted to the management and administration of clinical trials,”<sup>122</sup> referring to the rapid and significant proliferation of domestic and foreign CROs mediating between multinational pharmaceutical companies, clinical trial centers, national pharmaceutical RAs, and the

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<sup>120</sup> Ibid., 7.

<sup>121</sup> Ibid., Figure 1.1, 19.

<sup>122</sup> Ibid., 9.

local community of trial participants themselves, that is most poignant.

In *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine* (2017), Sunder Rajan introduces readers to the ICH, which – like the IPRP – is a somewhat obscure global regulatory coordinating body established by the U.S., EU, and Japan in 1990 to drive harmonization on national pharmaceutical clinical trial policy, standards, and guidelines. Unlike the IPRP, however, it includes industry representation and, due to its size, lacks the Observer Status and other checks-and-balances to ensure member state readiness for adoption of the common standards.

In his discussion of the ICH, CROs, and the movement of clinical trials to non-U.S. locations, Sunder Rajan joins Melinda Cooper (2008), Vinh-Kim Nguyen (2010),<sup>123</sup> Jill A. Fisher (2006, 2012),<sup>124</sup> and others in examining the consequences of globalization and the burgeoning pharmaceutical market on the health and opportunity of individuals. Sunder Rajan explains that the boom in CRO-led clinical testing has become a means for states, like China and India, with lesser shares of pharmaceutical exports to gain a foothold in the market and join the global ranks of “Innovation states.”<sup>125</sup> Some states are enthusiastic, amending national pharmaceutical regulations and “active[ly] encouraging foreign companies to conduct clinical trials.”<sup>126</sup>

The cost of entry, however, is adoption of other states’ pharmaceutical regulations, those of the ICH sometimes in a quick and streamlined fashion, and more often than not within political communities and economic circumstances absent the mature regulatory oversight and administrative means to properly govern them. This market-driven adoption also can be viewed as a politico-

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<sup>123</sup> Nguyen, *The Republic of Therapy: Triage and Sovereignty in West Africa’s Time of AIDS*.

<sup>124</sup> Fisher and Kalbaugh, “United States Private-Sector Physicians and Pharmaceutical Contract Research: A Qualitative Study.”

<sup>125</sup> *Op. cit.*, Cooper, 75.

<sup>126</sup> According to Bailey et al. (2007), China placed first in a Country Attractiveness Index for clinical trials released by the business consulting company A. T. Kearney. As Cooper explains, this index was calculated on the basis of data relating to patient pool, cost efficiency, regulatory conditions, relevant expertise, and infrastructure. See *Ibid.*, 82. For the Country Attractiveness Index, which recently has been renamed the Global Services Location Index (GSLI), see Bailey, Cruickshank, and Sharma, “Make Your Move: Taking Clinical Trials to the Best Location.”

economic means of coercing participation in policy harmonization, in the adoption of a one-size-fits-all global pharmaceutical regulation that a state may not otherwise have pursued.

The result, in India, has been “a proliferation of poorly regulated clinical trials” since the mid-2000s, when the state undertook efforts “to make India a global experimental hub.”<sup>127</sup> The emerging clinical trial industry in India has been mired in controversy and public scandal as “cases of possibly unethical clinical studies have come to light” since the death of seven teenage girls in an “observational study” of the HPV vaccine conducted by the Program for Appropriate Technology in Health (PATH), Bill and Melinda Gates Foundation, and Indian Council of Medical Research (ICMR).<sup>128</sup> Other such examples noted by Sunder Rajan involve victims of the 1984 Bhopal gas-leak disaster, clinical trials conducted in an Indore hospital, and trials in Ahmedabad involving volunteers with far limited economic means:

One resident of the slums told me that he does not go to the hospital anymore, because ‘they do trials there, and we come out dead.’ Satinath Sarangi, who runs a free clinic in the slums for gas victims, subsequently described this to me as a continuation of the ‘circle of poison’ that started with chemical companies and continues to be propagated by pharmaceutical companies.<sup>129</sup>

### The Clinical Trial Industry In China

The context and reality in China are not dissimilar. Research by Cooper (2008),<sup>130</sup> reflecting the concept of experimental (clinical) labor<sup>131</sup> per Catherine Waldby and Cooper (2008),<sup>132</sup> finds that the negative externalities of globalization—the rising incidence of extreme poverty, rates of internal

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<sup>127</sup> Op. cit., Sunder Rajan, 35.

<sup>128</sup> Ibid., 13 and 68.

<sup>129</sup> Op. cit., Sunder Rajan, 3.

<sup>130</sup> Op. cit., Cooper, 75.

<sup>131</sup> Cooper explains that the process of participating in a clinical trial is “self-transformation—commodified,” where risk is transferred from the firm to the individual for the development of the pharmaceutical, with the individual’s contribution “to the production of bioeconomic value” resulting in a “surplus of biological potentiality... that can then be transformed into the surplus value accruing from bio-innovation.” Op. cit., Cooper, 76. See also Blumenthal and Hsiao, “Privatization and Its Discontents — The Evolving Chinese Health Care System,” 1166–67.

<sup>132</sup> Waldby and Cooper, “The Biopolitics of Reproduction: Post-Fordist Biotechnology and Women’s Clinical Labour.”



migration from rural to urban communities, and rates of the “working uninsured”<sup>133</sup>—have oriented Chinese transient workers and local hospitals to either participate in, or facilitate, CRO-conducted clinical trials. Offshoring clinical trials to China, as the name of Cooper’s study suggests, follows “in the path of manufacturing, software, and ITCs [information technology support centers], relocating its R&D to environments where the costs and conditions of clinical research labor and human subject recruitment are less onerous,” and where the national economy, local markets, local health care systems, and individuals all have been primed to participate in clinical trials.<sup>134</sup>

The emergence and rooting of the CRO-conducted clinical trial industry in China and India illustrates particular political consequences of the bioeconomy for making global health; the literal, actual production of health as a good (in trial data to support pharmaceutical development) and as a construct of economic value (in market inputs that generate market outputs downstream). So, too, do these cases demonstrate that the bioeconomy generates other political conditions, similarly rooted in power differentials and the Nation-state as the Competition state: the power-informed engagement in processes of global health governance, particularly, national pharmaceutical clinical trial, pre-market approval, and manufacturing policy harmonization.

These cases demonstrate the precarious situation in which Sunder Rajan’s ‘pharmocracy’ places state actors and their constituencies as the former increasingly seek to accommodate a global pharmaceutical market by adopting not only a global pharmaceutical regulatory framework, but all

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<sup>133</sup> Cooper notes this is the result of market-oriented reforms to the then-centralized Chinese health care system in 1978, which resulted in the decentralization of public health insurance to provincial and local authorities, including funding, as a means to cut overall public expenditures on health. As industrialized, coastal and urban regional economies were able to generate more revenue for their local health authorities than rural communities, health care disparities quickly emerged, resulting in a de facto privatization of the Chinese health care system, where local hospitals were, first, “forced to generate their own sources of private income” as public health funding fell; second, permitted to earn extra profits following introduction of a system of uniform price regulation; and, third, Chinese physicians were incentivized to prescribe medicines and deliver care based on a new, standardized salary system, which was supplemented by a bonus system tied to physicians’ “revenue-raising activities.” See Cooper, 83-84; and Blumenthal and Hsiao, “,” 1166-1167.

<sup>134</sup> Approximately 30% of Chinese lack access to health insurance, which is necessary given the high and rising costs of health care. Cooper notes that out-of-pocket costs accounted for 58% of total health expenditures in China in 2002, as compared to 20% in 1978. Such dynamics combine to produce meaningful incentives to participate in clinical trials to either pay for health care costs or else have access to some for health care service. See op. cit., Cooper 83-84.

components of the pharmaceutical life cycle: privatized R&D, clinical trials, production and manufacturing, marketing, and pricing. So, too, are states adopting other norms associated with the marketization of health, including deregulation (‘decentralization’) and commodification. Particular to pharmerging economies, the international political economy of medicine suggests a hegemony of norms, ideas, regulatory structures, and actors’ roles that are reinforcing and manifesting.

The extant literature defines the bioeconomy as the “articulation of capitalism and biotechnology,”<sup>135</sup> which derives market value from the human form: our bodies and body parts, molecules and cellular tissues, biological processes and genomics, and relative state of health, wellness, and sickness. Applying market-based notions of production, commodification, assetization, and marketization to the most intimate of intimates – our bodies, ourselves – the bioeconomy is neoliberalism realized. As the cases of China and India help illustrate, the bioeconomy embeds capitalism and the market in all aspects of human life: turning our own bodies into markets and profit centers.

#### 6.4.3 Summary of Findings

In their discussion of the commodification and privatization of care services, like personal and child care, Tina Vaittinen, Hanna-Kaiser Hoppania, and Olli Karsio (2018) apply a branch of Constructivism called Feminist Theory to explain the narrative construction of the perception that the “private sector... [is] better capable of providing autonomous (masculine) individuals the possibility to choose the kind of care they like.”<sup>136</sup> This constructed perception, Vaittinen, Hoppania, and Karsio suggest, reflects the belief that public services or goods (being dependent [feminine]) have less value than privatized services or goods and are devalued and devalorized within “the neoliberal discourse of globalization.” The state “is typically ‘feminized’ in relation to the more

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<sup>135</sup> Birch, “Rethinking Value in the Bioeconomy.”

<sup>136</sup> Vaittinen, Hoppania, and Karsio, “Chapter 27: Marketization, Commodification and Privatization of Care Services.”

robust market by being represented as a drag on the global economy that must be subordinated and minimized.”<sup>137</sup>

As with pharmaceuticals and health overall, biopharmaceutical innovation takes place under conditions of neoliberal globalization, or global capitalism, generating political economies and power-oriented absolute gains and losses. These embedded political economies drive economic and political relationships (and requirements) that advance the system’s constructing beliefs, ideas, and norms. Here, biopharmaceutical innovation and investment are instruments to achieve western-style industrialization and Keynesian economic growth. Applying the Vaittinen, Hoppania, and Karsio construct, the political economies of medicines promote the valuation and valorization of private biopharmaceutical investment, innovation, and production, which are created in contrast to the devaluation and devalorization of individuals and their health, collectively, public health, which only attains value and valor in production or consumption (e.g., as an unwilling clinical trial subject, a patient barely able to afford an essential medicine, a day laborer seeking care for an illness caused by poor living and working conditions).

For global decision-makers and power brokers, bio-innovation becomes a narrative component of global health gains and what is “necessary to help the rural poor.”<sup>138</sup> As the descriptive case accounts of the CRO industry and global governance of pharmaceutical safety, manufacturing, clinical guidelines, and approval illustrate, and the scholarship of Sunder Rajan, Cooper, Seiter, Vaittinen et al., Nguyen, and others, within contemporary globalization, national health sectors have become the clients meant “to ensure the prosperity of” these efforts, with their citizens the thankful patients.<sup>139</sup> The marketization of bodies – for clinical trial experimentation,

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<sup>137</sup> Vaittinen, Hoppania, and Karsio; Marchand and Runyan, *Gender and Global Restructuring: Sightings, Sites and Resistances*.

<sup>138</sup> Sunder Rajan, *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine*.

<sup>139</sup> Seiter, *A Practical Approach to Pharmaceutical Policy*.

biological data generation, location of disease for R&D prioritization – that the bioeconomy requires cannot differentiate between a body meant as a consumer and a body meant for the production of value. In the same way that the bioeconomy frames the global poor as patient and beneficiary, so, too, can it frame them as means to a production end, which has the potential, as the literature suggests, of creating global pharmaceutical governance that restricts access to the very innovation their bodies produced.

### **6.5 Marketing, Pricing, and Access: Examining Medicines without a Market, Convergence in Pharmaceutical Pricing Regulation, and the Political Determinants of Access**

As the prior three descriptive accounts have illustrated, the power of ideas to shift state actors toward paths they otherwise may not choose or that may not be in their immediate or long-term interests is a profound form of coercion that often is invisible and indirect. The global health, equity, and fiscal costs of the observed influences of power are made consequential because of their occurrence *early* in the pharmaceutical lifecycle. As this final series of accounts demonstrates, industry decisions to commercialize their innovation and determine a pricing and marketing access (P&MA) strategy are, ‘pre-baked’: the market and pricing considerations were decisional factors based on the politicized health and pharmaceutical environment *prior to* disease and biomarker targeting.

In other ways, however, the expression and consequences of ideas-as-power can be both visible and directly harmful. This final collection of descriptive accounts turns the focus to the endpoint: what happens after clinical research trials and pharmaceutical approval or licensure, or the processes of determining whether and how to bring a pharmaceutical to market (‘commercialization’), pricing, and market access. Can we observe the influences of power and ideas in the earlier stages of the lifecycle here, too, at the proverbial end of the line? This closing series of accounts also examines the primary endpoint of any pharmaceutical lifecycle: patient access to a

medicine—, the Covid-19 vaccine. This final case specifically examines mass purchasing and patient access as determined by power structures.

#### 6.5.1 Animal Research and the Unexpected Cure without a Market

River blindness, or onchocerciasis, caused by a parasitic (roundworm) infection, and Mectizan (ivermectin) – another miraculous cure – similarly demonstrate the impact of the bioeconomy narrative, exacerbated by one’s relative proximity to power and influence. In the late 1980s, river blindness affected over 20 million people around the world, causing irreversible blindness and making it difficult, if not impossible, for many stricken with the disease in lower-income countries (and absent accessibility commitments) to work, care for their families, attain an education, and otherwise lead their lives. In 2017, about 21 million people had river blindness; 70% (or 14.6 million) were infected with the associated skin disease, while 1.2 million (or 18%) were found to have irreversible vision loss.<sup>140</sup> The disease is concentrated in the African continent: over 99% of infected people live in 31 countries of sub-Saharan Africa.

Discovered in 1978 by Merck & Co. scientists William C. Campbell and Satoshi Ōmura, who would win the Nobel Prize in Medicine in 2015, ivermectin is a powerful curative treatment for river blindness.<sup>141</sup> With a single dose taken annually, patients are rid of the disease and, if treated early enough, progression toward blindness can be halted. Mectizan also is inexpensive to manufacture and easily synthesized, greatly simplifying the production and coordination for global distribution. Twelve years after company scientists’ discovery of ivermectin and seven years following successful human clinical trials in Dakar, Senegal, Merck announced, on October 21, 1987, its commitment to immediately begin distribution of ivermectin without cost to any country that requested it “for as

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<sup>140</sup> World Health Organization, “Onchocerciasis (River Blindness).”

<sup>141</sup> Tambo et al., “Nobel Prize for the Artemisinin and Ivermectin Discoveries: A Great Boost towards Elimination of the Global Infectious Diseases of Poverty.”

long as needed.”<sup>142</sup>

The Merck Mectizan Donation Program (MDP) “has since become the largest ongoing donation program of its kind,” per Jeffrey L. Sturchio, executive director of public affairs and human health for Merck (2001). Sturchio’s case study estimates that more than half a billion Mectizan tablets were donated in the 15 years’ following the MDP initiative’s launch, with about 25 million individuals being treated annually.<sup>143</sup> (Other estimates suggest slightly lower figures of 292 million as of 2002.<sup>144</sup>) In the Americas, a biannual large-scale community-directed treatment effort, inclusive of Mectizan, the MDP initiative, and the World Health Organization, has largely eradicated the disease in South America, particularly, in Colombia, Ecuador, Mexico, Guatemala, and Venezuela. Similar efforts in Sudan and Uganda have also led to the disease’s elimination. There are active treatment programs in 33 of 35 countries in sub-Saharan Africa, Latin America, and Yemen, where onchocerciasis remains prevalent at endemic levels.

What prompted the development of the MDP and Merck’s multi-decade philanthropic commitment? According to Kimberly Layne Collins (2004), it was an “unpredicted outcome.”<sup>145</sup> In 1955, Merck established an anthelmintics program as part of its animal health research division, intended to develop a “profitable” antiparasitic for veterinary settings.<sup>146</sup> The resultant product, brand name Ivomec, was first marketed for cattle in 1981. By 1987, Merck had introduced variations for pigs, sheep, horses, dogs, and cats, with ivermectin quickly becoming “the Company’s second largest selling product, a first for an animal health product.”<sup>147</sup> Campbell, the veterinary research

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<sup>142</sup> (Staff), “Merck Offers Free Distribution of New River Blindness Drug - The New York Times.”

<sup>143</sup> Sturchio, “The Case of Ivermectin: Lessons and Implications for Improving Access to Care and Treatment in Developing Countries.”

<sup>144</sup> Burnham and Mebrahtu, “Review: The Delivery of Ivermectin (Mectizan).”

<sup>145</sup> Collins, “Profitable Gifts: A History of the Merck Mectizan Donation Program and Its Implications for International Health,” 102.

<sup>146</sup> For fellow dog owners, ivermectin may be familiar for precisely this reason: it is a common treatment for canine mites, intestinal parasites like roundworms, and capillaria, and marketed under such names as Heartgard™. In cats, it is used to treat ear mites and scabies. Six chewable tablets of ivermectin commonly sell for 50 USD or more, depending on the size of your canine or feline friend.

<sup>147</sup> The quote is from Merck’s 1987 Annual Report. See Collins, “Profitable Gifts: A History of the Merck Mectizan Donation Program and Its Implications for International Health,” 103.

scientist that co-discovered ivermectin, also was interested in antiparasitic treatments for humans, and had successfully applied a veterinary drug, thiabendazole, to humans in 1964 as Mintezol, to treat trichinosis. This interest and experience led to successful WHO-supported human clinical trials in Dakar, and a quick hand-off to Merck's marketing department to develop strategies for sales and distribution. According to Collins and based on interviews with former Merck marketing executives, "when marketing laid out the figures, they realized there was no way the Company could make money on the drug:" one executive, Charles Fettig, recollected that they "couldn't find a way to price it" because "there's no way [patients] can afford it."<sup>148</sup>

Collins' interviews and analysis suggest Merck first turned to state actors and international organizations, including the U.S. Agency for International Development, U.S. Congress, and WHO, for funding of ivermectin's distribution. After reviewing the potential costs of production and distribution of Mectizan on a donation basis compared to the limited profitability of a commercial distribution strategy, Merck concluded the annual profits on its animal version of ivermectin, Ivomec, would more than exceed the costs of any such donation. And thus, the MDP program was born. The program, which has been tremendous, has not been profit-free for Merck: Collins notes that "Merck has received extensive recognition as a publicly responsible company," including from its stockholders and potential employees, which she notes reflects that "they might be more likely to invest [or work] in a socially conscious company."<sup>149</sup>

#### 6.5.2 External Reference Pricing: Policy Convergence at the End of the Line

In the U.S., state attorneys general – responding to an "insulin crisis," where diabetics have died because of the high cost of insulin – have called on regulatory authorities to limit U.S. intellectual property protections to engender competition in the global insulin market. Yet insulin is

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<sup>148</sup> Op. cit., Collins, 104.

<sup>149</sup> Ibid, 108.

sold for 500 USD although it was discovered more than a century ago and the patent sold for 1 USD to the University of Toronto in 1922. In the United Kingdom, the National Institute for Health and Care Excellence (NICE), an advisory body to the National Health Service, approved funding for a 15.2 million USD treatment for a rare blood disorder. In the Netherlands, the government stopped paying for an immuno-oncology drug, pembrolizumab (Keytruda™), it had helped develop because it was too expensive. The list price of Keytruda is approximately 13,000 USD per month (for as long as treatment continues). The examples of insulin, the NICE-approved multi-million-dollar treatment, and Keytruda make for front-page news and real-world pain for countless patients in high- and low-income countries. The countless patient experiences and deep-rooted challenges to *affordable access* to treatment drive calls globally and within states' domestic constituencies for greater control of pharmaceutical expenditures to address pricing and access challenges.

Though once rarities reserved for break-through innovations and curative therapies for rare diseases, such as insulin and Keytruda, the frequency of these pricing-and-access conundrums have forced the unaffordability of medications to the top of the global health agenda and most countries' domestic health agendas, even though poorer countries have complained about it for decades. As pharmaceutical manufacturers shift their R&D strategies away from generics and essential medicines and towards break-through treatments for 'orphan' and 'rare' diseases, such conundrums may be a long-lasting symptom of political choices early in the pharmaceutical lifecycle, plus those that have had property protections for years. In advanced and pharmerging economies, the high and rising cost of pharmaceuticals, matched with high rates of use have placed questions of cost control front and center. From the leading pharmaceutical exporters of Europe to China and other countries of the Asia-Pacific region and also the U.S., rapidly rising pharmaceutical expenditures create tension points with other state investment priorities. A particular approach to pharmaceutical expenditure



containment, known as Reference Pricing, pertains to the global political economy in multiple ways, but stylistically it mirrors the concepts of interdependence in practice and design.

Reference Pricing, as it is commonly referred to in policy circles, establishes a maximum allowable cost (MAC), ceiling price, or reimbursement level for a particular pharmaceutical or class of pharmaceuticals referring to other prices paid, whether those prices are ‘internal’ (i.e., other prices paid for the same pharmaceutical by that state, firm, or other actor, prices paid for more cost-effective pharmaceuticals in that ‘drug class’), or ‘external’ (i.e., other prices paid for the same pharmaceutical by other states, firms, or other actors). Of the two approaches, External Reference Pricing (ERP) is most common, and usually take the following form: a state identifies a list of pharmaceuticals, usually those without competition that are still protected by patent or exclusivity; a price list for the same basket of pharmaceuticals is constructed, often based on the prices paid for the same drugs in similarly-situated peer economies; an average or benchmark price is derived for each pharmaceutical under the intervention; and, often, the benchmark is privately negotiated down between the state and the manufacturer.

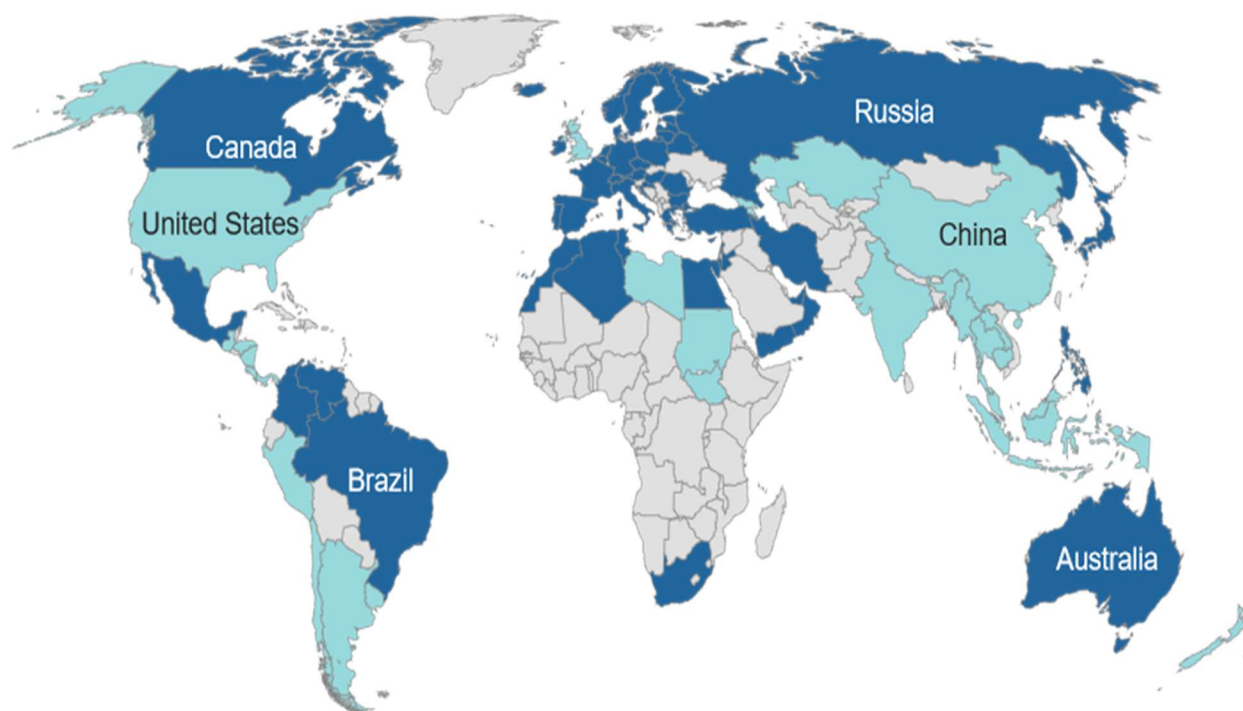
This policy is increasingly popular among states: it is used in over 50 states and incorporated directly or indirectly in the prices paid by over 90 states (Figure 6.5-A). A 2012 analysis by Sabine Vogler estimated that 26 out of 27 European Union (EU) member states used external reference pricing, including Germany, which incorporated ERP into its broader value assessment-based P&A policy framework in 2011.<sup>150</sup> Beyond the European continent, Australia, Brazil, Canada, Jordan, Lebanon, and South Africa employ ERP to varying degrees and often draw on one another’s prices, especially those of the U.K.<sup>151</sup>

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<sup>150</sup> The only exception being Sweden. Figure includes the U.K., which is departing from select EU member state commitments at the time of writing. See Vogler, “The Impact of Pharmaceutical Pricing and Reimbursement Policies on Generics Uptake: Implementation of Policy Options on Generics in 29 European Countries.”

<sup>151</sup> Author’s own findings, as supplemented by Espin, Rovira, and Olry de Labry, “External Reference Pricing”

**Figure 6.5-A. External reference pricing is used in more than 50 countries and incorporates directly or indirectly pharmaceutical prices from more than 90 countries**



Author compiled and generated based on data in Minhas and Moon, “The Office of Fair-Trading Report: A Prescription for Value-Based Drug Pricing.”

In their evaluation of European ERP frameworks, Christine Leopold et al. (2012) noted that the U.K. was the top referenced country, meaning that other countries that employed ERP either directly or indirectly referenced U.K. prices (by referencing prices of a country that references U.K. prices).<sup>152</sup> According to the Office of Fair Trading, the fiscal projection arm of the U.K.’s central government, 15 countries directly or indirectly reference U.K. prices, including Belgium, Canada,

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<sup>152</sup> Leopold et al., “Differences in External Price Referencing in Europe: A Descriptive Overview.”

Denmark, Finland, France, Hungary, Ireland, Italy, Japan, Mexico, the Netherlands, Norway, Poland, Spain, and Switzerland.<sup>153</sup> Using 2007 estimates, these countries accounted for at least 25% of global pharmaceutical sales, while the U.K. market itself accounts for 3.5%.<sup>154</sup> Other commonly referenced countries include Germany, Spain, and France.<sup>155</sup> The price of medicine in London (or Berlin, Barcelona, or Paris) is more practically relevant than a manufacturer's own list price for more than a quarter of the world.

In their attempt to govern pharmaceutical pricing within their own borders, to shape the pricing of a good in a global market they otherwise have consistently deferred to that same market to self-regulate – the use of ERP, and its embedded comparison-meets-price control features, appears to be an odd choice. At the surface level, particularly, for advanced economies, the choice reads as a departure from the market oriented and Flexnerian policy choices: a final effort to balance the relationship through the state's overt use of size and scale. Through the lens of the Four Factors model, however, the ideas and context are visible: a series power-oriented relationship with mutual losses and gains at stake. Rather than a policy that imposes on one part a take-it-or-leave-it price, all ERP models incorporate a private negotiation feature, which is not open to the public or other actors *to preserve* the secured 'deal,' so to speak. In this way, rather than ERP reflecting a departure from the ideational norms otherwise expressed – including globally aligned regulatory frameworks, layers of incentives for domestic drug development, and health coverage policies to engender use domestically abroad – it is a policy itself embedded in the same neoliberal and market-oriented ideas: competition and negotiation can make for fairer prices. It is, practically, a supplemental forum for conducting the same negotiations that occur between any buyers and sellers in a market.

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<sup>153</sup> Op. cit., Minhas and Moon, "The Office of Fair Trading Report: A Prescription for Value-Based Drug Pricing" Page 216.

<sup>154</sup> Ibid.

<sup>155</sup> Op. cit., Leopold et al., "Differences in External Price Referencing in Europe: A Descriptive Overview."

ERP provides a framework for reinforcing the influence and purchasing power of powerful actors within the system, rather than creating competition among states or opportunities for less powerful actors to benefit from efficiencies of scale. The extensive use of ERP does not necessarily create dynamics of states *competing* against one another for the ‘best price.’ Like other coordinating frameworks and because of the secrecy of negotiations (required in many of these frameworks by participating MNPCs), allows powerful actors to drive negotiations and prevent less powerful actors from driving a similarly hard bargain. With MNPCs on the other side of the table of these negotiations, it seems unlikely that the firms themselves would negotiate absent that contextual, holistic perspective. MNPCs are negotiating within a system that designed based on national advantage, to favor the larger, pricier markets with greater rates of immediate and politically constructed returns. Alike the Clinical Practice Guidelines, Generic Pre-approval Framework, and orphan designation, powerful actors continue to advance hegemonic ideas related to health and the markets and, though first-mover advantage, embed those ideas as policies for coordination, convergence, and harmonization—which globalizes these power-oriented ideas about global health in a holistic, system-wide manner.

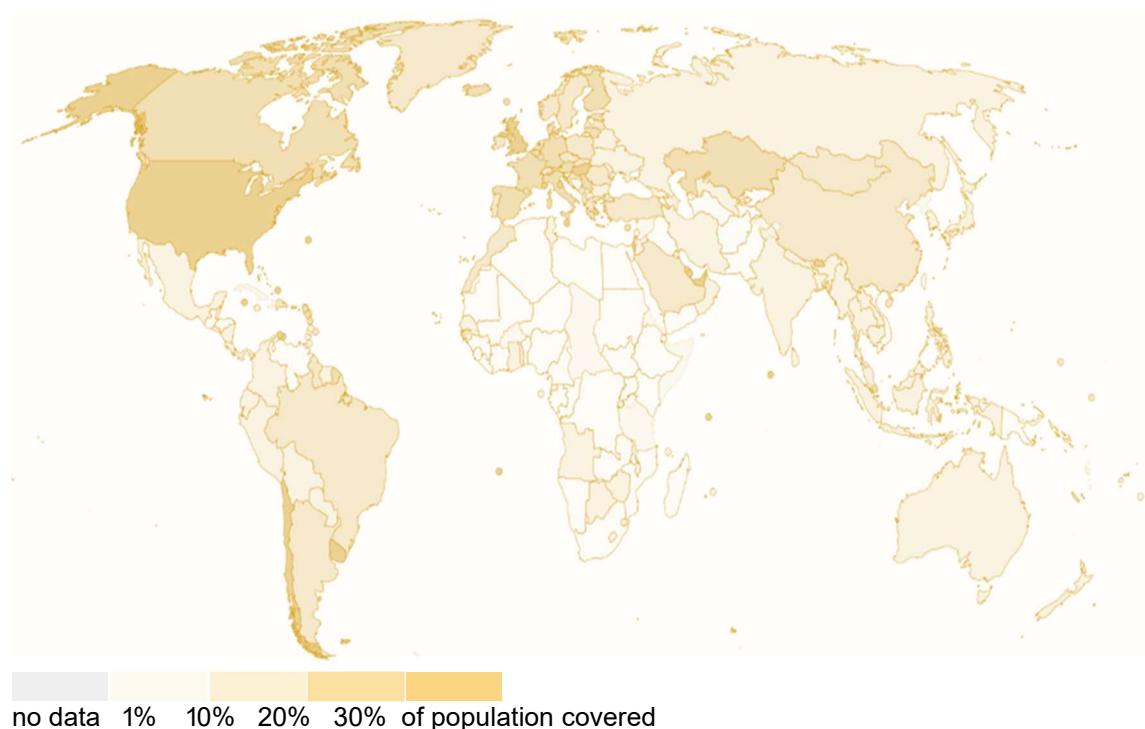
#### 6.5.3 Market Access and Pre-Purchasing Commitments: Power as an Access Determinant

Defined in terms of administered doses per 100 people, access to Covid-19 vaccine illustrates similar global externalities, which are considered broadly negative externalities given the highly infectious nature of this viral pandemic. As the global pandemic entered its second year of transmission in January-February 2021, vaccine doses remained relatively scarce globally, with approximately 200 million vaccine doses administered worldwide (2.6 doses per 100 people).<sup>156</sup> For many countries, May 2021 marked the fifth-straight month of their respective national vaccination

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<sup>156</sup> Holder, “Tracking Coronavirus Vaccinations Around the World.”

**Figure 6.5-B. Covid-19 vaccination rates, by Country (May 2021)**



“Population covered” divides the doses administered for each vaccine type by the number of doses required for full vaccination. Author-generated figure based on data gathered from government websites, press conferences, public statements and Bloomberg interviews. Op. cit., (Staff), “More Than 1.38 Billion Shots Given: Covid-19 Tracker.”

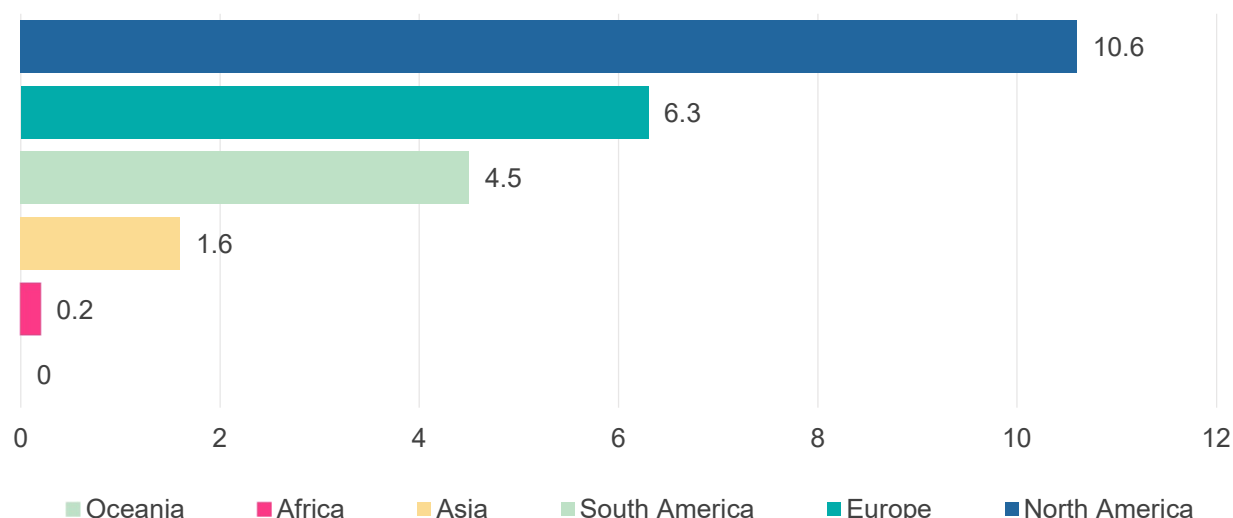
programs, with global doses administered per day surging to 22.5 million and over 1.38 billion doses administered—enough to vaccinate 9.1% of the global populations.<sup>157</sup> Such gains, however, are globally uneven (Figure 6.5-B).

According to *The New York Times*, “83% of shots that have gone into arms worldwide have been administered in [higher- and upper-middle-income economies]. Only 0.3% of doses have been administered in [low and lower-middle income economies].”<sup>158</sup> As the U.S. announced reduction in

<sup>157</sup> (Staff), “More Than 1.38 Billion Shots Given: Covid-19 Tracker.”

<sup>158</sup> The New York Times has collected and sorted data that is compiled from government sources by the Our World in Data project at the University of Oxford. A ‘vaccinated person’ refers to someone who has received at least one dose of a vaccine, and a fully vaccinated person has received all required doses of a vaccine. For example, the Pfizer-BioNTech vaccine, which currently is in use in at least 97 countries, requires two doses before a person is ‘fully vaccinated.’ Op. cit., Holder, “Tracking Coronavirus Vaccinations Around the World.”

**Figure 6.5-C. Covid-19 vaccination doses administered per 100 people, by Continent (May 2021)**



Author-generated figure based on data from Rauhala, “As Rich Countries Hoard Potential Coronavirus Vaccine Doses, Rest of World Could Go Without.”

public health measures like mask wearing on May 13, 2021, having administered over 267 million doses – 80 doses administered per 100, or 46% of its adult population – much of the world continued to navigate vaccine supply and coordination issues, further surges in the disease itself, and, sometimes, not yet reporting a single administered dose (Figure 6.5-C).<sup>159</sup> At 1.6 doses administered per 100, Africa has the slowest vaccination rate, with some states “yet to start mass vaccination campaigns.”<sup>160</sup> The ability to make pre-market purchase commitments for Covid-19 vaccine candidates, and thus ensure first access once those vaccines came to market, was essential to timely rollouts of national vaccination programs.

Access to pre-market purchasing between May and November 2020 was reserved largely to

<sup>159</sup> Op. cit., Holder.

<sup>160</sup> Ibid.

powerful state actors representing advanced economies, notably the U.S., Japan, Australia, and Canada, which negotiated favorable purchasing terms with multinational vaccine manufacturers.<sup>161</sup> An analysis of pre-market purchase commitments as of November 2020 found that more than half (51%) of the approximately 7.5 billion committed doses had been purchased by advanced economies representing 14% of the world's population.<sup>162</sup> Advance purchasing can be considered a proxy for access. By May 2021, the wealthiest 27 countries representing approximately 10% of the global population had reserved access to, and administered, slightly over 34% of Covid-19 vaccine supply.

The size of this disparity is reflected well in reports that the U.S., flush with vaccine – a “glut of vaccine,”<sup>163</sup> is now encouraging so-called “vaccine tourists,” including direct invitations and proposals by half of all U.S. state government leaders to offer tourists the Johnson & Johnson Covid-19 vaccine at popular tourist sites.<sup>164</sup> It's a win-win for the U.S. and other wealthy countries: protection for their citizens against the harms of the Covid-19 pandemic, and a proverbial shot-in-the-arm to their economic recovery efforts, as Eileen Guo's interview of U.S. Virgin Islands Tourism Commissioner Joseph B. Boschulte notes:

“This checks a lot of boxes for us,” tourism commissioner Joseph Boschulte told *Travel Weekly* in April [2021]. “Our economy benefits from those who stay several weeks, eat in our restaurants, stay at hotels, charter boats for day trips, and shop while waiting for the second shot. The airlines get the passengers who return a second time, and our visitor numbers increase. Our airlift right now is ahead of both the pre-pandemic lift and the pre-2017 hurricane flight operations.”<sup>165</sup>

Differential access to available vaccine stocks align not only with the historical geopolitical binary of North and South, but also within-region concentrations of purchasing power. The United Arab

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<sup>161</sup> Ibid.

<sup>162</sup> So and Woo, “Special Paper: Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross Sectional Analysis.”

<sup>163</sup> LaFraniere and Weiland, “For Biden, a New Virus Dilemma: How to Handle a Looming Glut of Vaccine.”

<sup>164</sup> Guo, “The US Worried about Vaccine Tourists. Now It's Encouraging Them.”

<sup>165</sup> Guo.

Emirates (U.A.E.) and Bahrain, with doses administered per 100 people of 56.8 and 17.1, respectively, are cases to the contrary due to their wealth.<sup>166</sup> The U.A.E. also has reframed their vaccine supply in terms of economic opportunity, reportedly offering “luxury vaccine vacations” to U.K. residents able to pay 56,000 USD for the shot.<sup>167</sup>

In comparison, a recent estimate by *The Economist* suggests the 85 poorest countries will not have access to vaccine supplies able to achieve herd immunity against Covid-19 – or vaccine doses to immunize 60 to 70% of their adult populations – until 2023. To help address these disparities, the World Health Organization has partnered with a variety of global actors to purchase and distribute vaccine to lower income countries. The Covid-19 Vaccines Global Access (COVAX) Facility, which is the global Covid-19 vaccine initiative directed by GAVI, the Vaccine Alliance (formerly, the Global Alliance for Vaccines and Immunization); the Coalition for Epidemic Preparedness Initiative; and the WHO, reserved about 700 million doses.

Despite the backing of the only global governance body for health (WHO) and several leading state and nonstate actors, COVAX secured less than 14% of the estimated 9.6 billion Covid-19 vaccine doses reserved.<sup>168</sup> Rather than contribute to COVAX, leading state actors dominated the available vaccine market: “a global arms race for a coronavirus vaccine is underway,”<sup>169</sup> and only once their own constituencies have been vaccinated are they considering reallocation of excess vaccine supply to COVAX. The challenges faced by COVAX in securing the support and engagement of state actors to finance global Covid-19 vaccination are a clear example of the negative externalities that global public goods, including for health, can generate absent equitable

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<sup>166</sup> Op. cit., Holder, “Tracking Coronavirus Vaccinations Around the World.”

<sup>167</sup> Op. cit., Guo.

<sup>168</sup> Op. cit., (Staff), “More Than 1.38 Billion Shots Given: Covid-19 Tracker.”

<sup>169</sup> Sanger et al., “Search for Coronavirus Vaccine Becomes a Global Competition.” See also Marshall and Knight, “The Covid-19 Technology Access Pool: Sharing Is Caring?”



distribution mechanisms. The dramatic differences in vaccine supply alone demonstrate select states that have three-times the purchasing power parity than normal market allocation would otherwise anticipate. Assuming the market allocated scarce global vaccine stocks under population size, let alone equitable considerations (e.g., prevalence, availability of Covid-19 treatments, mortality rates)—if not for differential power and geo-politics.

#### 6.5.4 Summary of Findings

What each case has in common is not good will or socially conscious investment, despite the narrative of the Bio-Century. Rather, these cases demonstrate that pharmaceutical innovation, investment, and production rely on market viability or, if it lacked market viability, an opportunity to generate that good will. The global pharmaceutical market remains a market, and those purchasers that lack the economic means (to afford these medicines) or the political influence (to negotiate favorable pricing and access terms, to budget for public R&D in or distribution of treatments) lack access to life-saving pharmaceutical innovation. Countries that lack national incomes and mechanisms for participating meaningfully or in the pharmaceutical market are left in the difficult place of relying on the philanthropy of multinational firms or the good will of more powerful states, such as the example of the Merck Mectizan Donation Program (MDP) cited in this section. Or the June 2021 announcement that the U.S. would donate Covid-19 vaccines to COVAX.

Meanwhile, countries that have become ‘pharmerging’ markets – growing pharmaceutical producers, importers, and/or exports – or grown otherwise in global economic power and influence specific to the health and pharmaceuticals industry may have opportunity to inform the market so it achieves the twin goals of economic and health gains. Much of the world suffered (and still does) from tuberculosis, malaria, river blindness, and other so-called neglected tropical diseases (NTDs) that affect over 1 billion people each year. For several of the more prevalent NTDs, the bioeconomy sometimes has an answer and yet the promise of cure or prevention, in terms of access, rarely

matches up with reality. What the bioeconomy has meant for less powerful actors, however, is not innovation styled as access to cures or prevention but testing grounds for the cure and treatment of others.<sup>170</sup>

The continued exploration of pharmaceutical regulation, and the unabated twin rise in pharmaceutical use and spending, are forcing a reexamination of health's place within and between the global and the domestic. State actors are increasingly relying on the domestic policies of their peers to correct the imbalance of power they feel with MNPCs. Simultaneously, such policy efforts are constrained or at least carefully constructed to preserve the competition state (return to Figure 2.2-C). It is a tricky business growing a burgeoning economic sector that relies on price as much as volume, while agonizing over how to pay for the sector's pricey goods.

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<sup>170</sup> Sunder Rajan, *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine*, Sunder Rajan's (2017) case study of the pharmaceutical industry in India well captures the on-the-ground "benefits" of the bioeconomy for particularly disempowered actors: the subjects of clinical testing and the many unable to afford needed medicines. See.

## CHAPTER 7

### DISCUSSION AND CONCLUSIONS: POWER, ACTORS, AND IDEAS IN THE MAKING OF GLOBAL HEALTH

“A substantial proportion of the world economy today revolves around the commercialization of biological products and processes.”

—Stefan Elbe and Chris Long (2020)<sup>1</sup>

“I have often argued in my career for more attention to the political economy in public health—for more attention to the political dimensions of health policy.”

—Michael Reich (2019)<sup>2</sup>

This dissertation proposed that power asymmetries sustain and embed market-oriented global norms, which shape the political salience of actors and ideas, and have corresponding impacts on what is considered global health and the practical application of health equity. To examine power as a constructive and discursive force on health, the dissertation synthesized the International Political Economy (IPE), International Relations (IR), BMC: Globalization & Health journal, Public Health, Macroeconomics, Medical Sociology, and Microeconomics literature and the theoretical approaches behind them. Chapter 7.1 discusses the findings from this analysis in Part I of this research.

To examine power as a practical and coercive force in global governance for health, the dissertation also proposed a simple, multi-factor analytical model (i.e., the Four Factors Model of Power Expression in Governance and Policymaking), which incorporated the primary factors of the elements of power relations: content, context, ideas, and processes. The model was applied to descriptive case accounts exploring the influence of power, ideas, and actors at points along the

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<sup>1</sup> Elbe and Long, “The Political Economy of Molecules: Vital Epistemics, Desiring Machines and Assemblage Thinking”

<sup>2</sup> Reich, “Political Economy of Non-communicable Diseases: From Unconventional to Essential.”

pharmaceutical lifecycle. Chapter 7.2 also discusses the findings from Part II and offers comments on power as a discursive force through the influences of the modeled four factors in global governance. The dissertation's inherent limitations are refreshed in Chapter 7.3, before closing with concluding remarks (Chapter 7.4), a review of contributions to the literature, and recommendations for future research (Chapter 7.5).

## **7.1 Findings of the Critical Literature Review: No Greater Bargain than that of Good (Global) Health**

This dissertation employed a mixed-methods approach yielding a two-part analysis. The first, Part I (Chapters 3-5), analyzed the extant literature on health, ideas, and power within the heightened economic interdependence (globalization) that marked the field's emergence in the mid-20th century. Following the oil embargo and other global fiscal and monetary crises of the 1970s IPE has emerged as a dedicated scholarly discipline to explore the economic relations between states intentionally shaped by globalization and the neoliberal discourse. Health as a primary arena of global social, political, and economic life and its shifting politico-economic context has been relatively unexamined within IPE.

Its dynamic forces of the global and local ("centralization and localization"), positive and negative externalities, and integration and fragmentation generate such complex political economies from which health and other issues of 'low' politics, or politics primarily observed to be within a domestic framework and not relevant to IPE's 'high' politics of trade and development, are not immune. Pharmaceuticals are no exception, no deviant to these global forces

The extant literature on public goods, political economies, globalization, governance, and global health reflect a world reliant on health – and pharmaceuticals, in particular – for economic, political, and social gains. Health is informed by, and informs, every facet of social interaction, including politics and economics, whether local or global. And like all other facets of health,

globalization and governance drives health equity. As *The Lancet*-University of Oslo Commission found, health inequities are political creation and ‘cure.’ The reasons for these global political interdependencies of health are multiple and, as these pages articulates, are rooted not only in the dynamics of globalization themselves but the hegemonic ideas about health, economics, and markets that underpin contemporary global capitalism. The findings and their interdependencies can be organized by validation of the original premises of this research.

#### 7.1.1 Premise No. 1: “Health is Political Because Power is Exercised over It”<sup>3</sup>

*First, health is political because power is exercised over it.* Determining who gets what, when, and how (*cui bono*) inevitably involves power and politics. U.S. policymakers politically decided to structurally favor access to affordable pharmaceuticals by older and lower-income Americans. As the extant literature demonstrated, from constructing ideas about what health is to the influence on health outcomes of globalization, the politics of medicine – of global health broadly and medical practice from the individual or patient perspective – are dynamic and interactive. These are two-level games, with actors across levels of analysis evolving their strategy and approach. The descriptive case accounts of *Part II* reinforced this finding, demonstrating how influential political action and priorities are to the corporate investment and allocation of capital by multinational pharmaceutical corporations (MNPCs).

The validation of this premise has three immediate implications. *First, power and its political expression within health generate imbalances in distributing health gains and risks* between and within countries, and between and within centers of global power and of weakness—and also beyond states in terms of the potential for collective action on health or equitable global governance for health.

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<sup>3</sup> Bambra, Fox, and Scott-Samuel, “Towards a Politics of Health.”

*Second, but these distribution imbalances depend on political action and, amenable to political intervention* if the sources of power and the ideas, relevant processes, and context behind such power and/or its expression (in terms of content or policy outcomes) either act to remediate the risks associated or, as a product of adjustment costs adopt power-sharing agreements or alter the foundational four factors that sustain power imbalances.<sup>4</sup>

*And third, global collective inaction on health is illogical in terms of global health goals and values*, but expressly rational in terms of the privileging of certain actors and these actors' interests.

#### 7.1.2 Premise No. 2: Health is Public Good but Politically Constructed to be a Scarce Private Good Produced and Allocated by the Market

*Second*, health is a public good. Through the reexamination of public goods theory by Angela Kallhoff (2011), Maxime Desmarais-Tremblay (2017), and others, including this research, the perspectives of the theory's own originators, Paul Samuelson and Richard A. Musgrave, on the normative potential of economics, including and especially related to questions of social conditions and public goods, are clarified. Even at their most optimal, Samuelson and Musgrave believed that markets are ill suited to address political questions – of which health is one – just as markets are constrained in their ability to sort through the thorny ethics of providing goods, the market also under-resources and must be made to invest in certain goods. This latter point is well emphasized in Part II's descriptive accounts of state interventionism, but *Chapter 4.3's* extensive review of how markets are expected to behave, and how health care markets actually behave, affords similar validation.

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<sup>4</sup> Myriad examples, including at the meso or sub-system level (i.e., a particular state example) and at the macro or international system level (i.e., the World Health Organization (WHO)) demonstrates that balances of power (or, in this case, imbalances) are sustained or renegotiated through political intervention. Recalling the proposal by Giulia Grillo concerning access to medicines and the engagement of global civil society organizations in the amendment to the TRIPS Agreement, power can be used also to push back against established imbalances and related ideas, context, and processes, though success may be constrained by these same factors.

The validation of this premise has at least five immediate implications, and possibly others. *First*, the Microeconomics literature on public goods and Public Goods Theory itself has been misinterpreted and misused as a tool to *exclude* most goods from the sphere of public production, allocation, and distribution. Even at their most optimal, the theory's own originators, Paul Samuelson and Richard A. Musgrave, believed markets were ill suited to address political questions – of which health is one – just as markets are constrained in their ability to sort through the thorny ethics of providing goods the market under-resources and must be *made* to invest in.<sup>5</sup>

Related to this first implication, *second*, economics depends on ethics, which themselves depend on politically determined, socially constructed, often diverse, and potentially contradictory “ethical views.”

*Third*, “*laissez-faire* reliance on markets and voluntary exchange public finance both lead to sub-optimal outcomes by not getting the community to the ethically best point on the utility frontier.”<sup>6</sup> Though Samuelson sought to achieve public expenditures that were “efficiency inclusive of equity,” he himself acknowledged it was impossible within purely economic frameworks.

Also related, as a public good (and a global public good), *fourth*, the externalities generated by health can be negative and positive and occur across and between levels of analysis (system, state, individual) as part of global political interdependencies. These externalities can be described simply: if all benefit from good individual or population health, all can be harmed by poor individual or

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<sup>5</sup> For context, this finding is validated through the reexamination of public goods theory by Angela Kallhoff (2011) and Maxime Desmarais-Tremblay (2017), the perspectives of the theory's own originators, Paul Samuelson and Richard A. Musgrave, on the normative potential of economics, including and especially related to questions of social conditions and public goods, is clear. Even at their most optimal, Samuelson and Musgrave believes markets are ill suited to address political questions – of which health certainly is one – just as markets are constrained in their ability to sort through the thorny ethics of providing goods that it under-resources and must be made to invest in. This latter point is well emphasized in Part II's descriptive accounts of state interventionism, but *Chapter 4.3*'s extensive review of how markets are expected to behave, and how health care markets actually behave, affords similar validation.

<sup>6</sup> Samuelson, “The Pure Theory of Public Expenditures.”

population health.<sup>7</sup>

And *fifth*, the marketization of health means some have greater access to health than others. This is because the market is ill-suited to distribute any ‘good’ equitably; it is designed to distribute efficiently and optimally. The market cannot ameliorate or avoid the generation of negative externalities, further driving health inequities and disparities already deepened because of power imbalances.

### 7.1.3 Premise No. 3: Power and Ideas Make Global Health

*Third*, power and ideas shape health at multiple levels of political action and in context with the other Factors (context, process, and content), ‘making’ what we commonly understand to be and practically experience as health. The extant literature on public goods, political economies, globalization, and health reflect a significant body of evidence of the political determinants of health and the health determinants of society, including political and economic relations spanning the level of analysis (i.e., system, national, individual).

The validation of this premise has two implications. *First*, health is liberalized and commodified across levels of analysis by the neoliberal discourse and hegemonic ideas about health, including Flexnerianism, the western biomedical model of medical practice, the individualist-mechanistic ideology of medicine, and synergist-rational concepts of co-production and individualization. Ranging from individual beliefs about one’s own health to globally recognized standards of clinical practice, these dominant *ideas* turn health and the production of health into a commodity and service subject to economic rationalism and free trade rules. This liberalization and commodification – collectively called the marketization of health – drive a global governance for

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<sup>7</sup> For example, the positive externalities of health (e.g, herd immunity from infectious disease) and negative externalities of health (the spread of infectious disease) to the society as a whole are transferable and indivisible, making the benefit (or harm) of health and its component parts non-excludable.



health that sustains and embeds zero-sum dynamics and imbalances across levels of analysis. For example, these dynamics sustain ideas about health rooted in individual choices and behaviors versus the extensive evidence demonstrating the drivers of ill health are *political* not biological.

*Second*, the political favoring of the individualization and marketization of health have facilitated a shift to a global state of quasi-health—that is, the sustained health status of palliation versus prevention and wellness. Such processes have explicit consequences for our own sense of ‘health’ and ‘illness,’ as well as for the differential power of certain forms of health (and associated industries and actors), such as chronic noncommunicable diseases (NCDs), over others. For example, these dynamics have accompanied a shift in the global burden of disease – from communicable, maternal, perinatal, and nutritional diseases to chronic NCDs – over the past few decades. This shift is a significant indicator of the composition of health (status) and the outlook for the global production of health, which is likely to rely on life-long pharmaceuticals for the palliative treatment of NCDs.

#### 7.1.4 Premise No. 4: Health is a Core Issue of the 21st Century Global Political Economy

*Fourth*, health is a core issue of the global political economy and IPE scholarship must holistically account for its inclusion within the field’s research agenda—rather than as an *ad hoc* topic pursuant to health’s adjacency to securitization or economic development priorities. The validation of this final premise has three implications for the global political economy, which may serve as important initial framing for health’s formal inclusion as a core focus within IPE.

*First*, globalization has deepened a global politics of health and elevated the Neighborhood Effect—the idea that dependent on where we live, our health may be made better or worse by neighborhood characteristics—to encompass the entire ‘global village,’ where macro neighborhood characteristics and conditions are interdependent of one another and simultaneously decentralized

and localized. These tensions of ‘framgregation,’ as James N. Rosenau (2018 [1990])<sup>8</sup> first articulated, further complicate the primacy of state actors, their available policy choices, and degree of prioritization of health issues, and their role and privilege (or political salience and power) within a shifting global politico-economic context for pharmaceutical governance. Health is not only interconnected, but the *politics* of health (i.e., hegemonic ideas, contextualizing factors, policy content, and decision-making and governance processes) also and, increasingly, converging in alignment with neoliberal expectations.

*Second*, pharmaceuticals have a primary role in the production of health, whether through actual medical practice,<sup>9</sup> global governance for health, health as a growing element of international trade and economic development or, conceptually, our collective understanding of what *is* health. Increasingly, pharmaceuticals are having not only outsized impact in the production of health via the practice of medicine, but also in the current and future direction of economic development for leading and emerging states. Pharmaceuticals also are a nexus point for processes of globalization, including international regulatory coordination and other precursors to global governance. The subsequent review of globalization and health literature<sup>10</sup> considered the implications of global capitalism, trade and financial flows, income losses, and other *political* determinants of health specific

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<sup>8</sup> Rosenau, “Framgregation.”

<sup>9</sup> The western system of ‘bio-medical’ practice – inclusive, as it is, of Flexnerianism, the individualist-mechanist ideology of medicine, and now ‘bio-pharmaceutical’ reliance – is clearly complicated in its own right, including in terms of its own patients, historical mistreatment of globally marginalized communities, or role as a constructed instrument of hegemonic power. Similarly, the processes of globalization reconstitute western medical practices as informal global health governance of the ideas, norms, and standards governing the everyday experience of health care between doctors and patients, as well as what we consider ‘health’ – together, the production and distribution of health. This complex interplay of coercive and discursive power introduces select health gains and the potential for unevenness and numerous risks, including the elevation of medical science, bio-pharmaceutical innovation, and other health technologies alongside deterioration in key indicators of health, systems-based public health interventions, community health norms and ideologies of medicine in practice, and collective versus individual responsibility for health.

<sup>10</sup> For context, the influence of globalization – of politico-economic structures at the global level, which shape their peers at the national, regional, and local levels, and also ‘individual governance’ – informs the socio-political construction of rules and norms that govern the global-local distribution of health.

to pharmaceuticals.<sup>11</sup>

*Third*, the emerging bioeconomy reflects a complex and interconnected global-local “political economies of medicine,” which encourage the pharmaceuticalization of markets and politics. Specifically, this occurs in two forms: through the political valuation (“political value regime”) of pharmaceuticals in terms of national innovation and competitiveness, which are viewed as essential for states to be able to “expand [] economic prosperity and economic opportunity”—a common top national security priority for advanced economies. Pharmaceuticals also drive an economic value regime designed to optimize the profitability of monetization, assetization, and advanced capital investments, including the biosciences. As Thomas Piketty (2014) noted in *Capital in the Twenty-first Century*, these forces reflect and contribute to broader macroeconomic trends that drive capital overvaluation and financial inflation, instead of quantifiably better health and social conditions (e.g., incomes).<sup>12</sup> Taken together, these dynamic conditions perpetuate a political narrative that economic wellness, and also personal health and well-being, rely on pharmaceutical innovation—the ‘pharmaceuticalization’ of the global political economy built on the ‘marketization’ of health.

#### 7.1.5 Executive Summary of Findings

The contemporary politico-economic dynamics of the global pharmaceutical market are a signal of broader power-driven and normative trends requiring exploration for four reasons:

- *First*, health is political because power is exercised over it.
  - Power and its political expression within health generate imbalances in the distribution of health gains and risks between, within, and beyond states, with

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<sup>11</sup> For example, the International Generic Drug Regulators Program (IGDP) and similar regulatory coordination and harmonization bodies bring together states’ Regulatory Authorities to streamline, align, or establish the mutual recognition of, other state entities’ approval and review pathways for pre-market pharmaceuticals. Akin to the hegemony of western systems of medical practice, a global hegemony of, or globally aligned, pre-market approval and clinical research governance” can be leveraged by pharmaceutical manufactures to streamline pathways to market for their new products

<sup>12</sup> Piketty, *Capital in the Twenty-First Century*.

implications for global governance.

- Distribution imbalances are dependent on political action and amenable to political intervention.
- Global collective inaction on health is rational in terms of the privileging of certain actors and these actors' interests.
- *Second*, health is a public good.
  - Public Goods Theory has been misinterpreted and used as a tool to exclude most goods from the public sphere.
  - Economics is dependent on ethics, which itself is dependent on politically determined, socially constructed, often diverse, and contradictory “ethical views.”
  - Neoliberalism drives sub-optimal health outcomes.
  - The externalities generated by health can be negative and positive and occur across and between levels of analysis (system, state, individual) as part of global political interdependencies.
  - The marketization of health means some have greater access to health than others.
- *Third*, power and ideas shape health.
  - Health is liberalized and commodified across levels of analysis by the neoliberal discourse and hegemonic ideas about health.
  - The individualization and marketization of health have facilitated a shift to a global state of quasi-health—that is, the sustained health status of palliation versus prevention and wellness.
- *Fourth*, health is a core issue of the global political economy.

- Globalization has deepened a global politics of health and elevated the Neighborhood Effect—the idea that dependent on where we live, our health may be made better or worse. Health and its politics are globally interactive, interconnected, and, increasingly, converging in alignment with neoliberal expectations.
- Pharmaceuticals have a primary role in the production of health, in terms of medical practice, pharmaceutical manufacturing and export, global health governance, and our collective ‘imagining’ of health.
- The emerging bioeconomy reflects a complex and interconnected global-local “political economies of medicine,” which encourage the pharmaceuticalization of markets and politics, including reliance on pharmaceuticals for economic growth.

## **7.2 Findings of the Descriptive Case Accounts: The Practical Implications of Hegemonic Ideas and Power Imbalances—When Systems Deliver Undesirable Results**

The second part of the analysis – the descriptive accounts – afforded a window through which to observe practically the discursive evidence from the initial analysis. This chapter presents the findings of the secondary analysis in two parts. First, four sources of power imbalances are discussed as drivers of the compelling economic and political value of pharmaceuticals amidst global capitalism (globalization). Reflecting the dynamic interaction between levels of analysis spanning the descriptive accounts of Chapter 6, the sources of power imbalances pit the purely economic gains of health as a market good against collective losses. Second, the Four Factors model is discussed in terms of the practical implications of the factors, as expressions of power, on global health.

### **7.2.1 Finding No. 1: Sources of Power Imbalances in Health, A: Power Drives Interaction and Cost or Benefit Transfers Between Levels of Analysis**

*First (Finding 1-A), the system-individual implications of a hegemonic idea (‘global norm’) are*

dynamic and interactive, reflecting a transfer of costs or benefits between levels of analysis). For example, Flexnerian, individualized, and commodified health *transfers* from the system level to the individual through internalization. Physicians, patients, and others reflect back these assumptions, beliefs, values, and responsibilities. In this way, ideas matter deeply in the making of global health as they are the way we all make sense of the world around us, and our place in it. What is most striking is that, under this norm, health is reconstituted as a commodity subject to economic rationalism and free trade, responsibility for which is beholden to the individual. This global norm is not itself a form of governance in terms of institutional mechanism and structures of decision-making, but it is a *norm-made-physical* once internalized by the individual. Subsequent policy and economic decisions to establish global market governance for health is simply mutually reinforcing.

#### 7.2.2 Finding No. 2: Sources of Power Imbalances in Health, B: Power-driven Ideas, as Global Norms, are Transferable to System-State Dynamics

*Second (Finding 1-B)*, the levels-of-analysis implications of global health norms are transferable to the system-state dynamics. Specifically, market governance of pharmaceuticals is sustained through a global politics of health (system) and an internalized ‘personal political economy’ of medicines (individual), that shift the negotiation of global power imbalances to competition states and market-motivated economic actors.

#### 7.2.3 Finding No. 3: Sources of Power Imbalances in Health, C: State-level Dynamics Internalize and Embed Ideas as Norms

*Third (Finding 1-C)*, while state-level dynamics do not originate the systemic norms relating to health, alike the individual level, states internalize such norms, which inform state actor interests, values, beliefs, and preferences. As noted by the United Nations (UN) Commission on Social Determinants of Health, *The Lancet*-University of Oslo Commission, and the UN Human Development Index (2019), “inequalities persist in life expectancy and mortality,” and such

inequities have “political origins.” The state level of decision-making is where health inequities are most shaped and similarly have the most opportunity for improvement, but states, like individuals, are primed for a certain approach.

#### 7.2.4 Finding No. 4: Sources of Power Imbalances in Health, D: System-level Dynamics Originate Ideas as Norms

*Fourth (Finding 1-D)*, system-level dynamics are the originating forum for ideas as norms and also are the primary forum through which ideas can be adjusted or renegotiated. Otherwise, the system level processes, context, and policy content reinforce these normative ideas downstream to states and other sub-system and micro actors. The system level, however, is the realm least susceptible to influence given the complementing dynamics of material factors and influences. To influence system-level change requires significant actor resources and power atypical for most health care stakeholders, including the individual patient. In this way, it also is least accessible in terms of representative politics, and so doubly insulated from factors that may, in real time, delegitimize certain norm-oriented policy choices.

As these tensions (i.e., the four sources of power imbalances) demonstrate, there are significant political consequences associated with alleviating and sometimes preventing, but rarely curing, disease and illness that contextualize and complicate gains elsewhere. What is less visible, however, are the political *origins*: the role of power in determining, through direct action or indirect influence, the underlying systems implicit in the gains and the risks. For example, the systems of biomedical (“biopharmaceutical”) research and development (R&D); pricing, marketing, and access to the resultant biopharmaceutical innovation; common medical practices that facilitate the prescribing of innovation; and even *our own idea of health* and respective interest in treatment.

Rising disease prevalence and mortality, unaffordable and often inaccessible health care, unsustainable levels of spending, and our overreliance on pharmaceuticals to fix every ill—whether

from sickness or slowing economies—present political complexities that demand continued examination by scholars and policymakers. The Covid-19 pandemic is an expressly current and consequential example of the complexities of commodifying and individualizing health. Absent global health governance responsive to globalization’s asymmetries and externalities – “there is no single worldwide authority in health matters”<sup>13</sup> – national governance and international collaboration represent key levers to manage these deep-set asymmetries. It reflects the extant literature – from Friedrich Engels on the Industrial Revolution in the 1840s to Vincent Navarro on medicine under capitalism in 1970s America – that demonstrates a causal relationship between politico-economic systems of power and health, explicitly politicizing health and recentering politico-economic structures as a health determinant, versus individual biology and behavior alone. Following the accelerated market integration of the late 20th and early 21st centuries, the long-observed interdependencies between health and politico-economic systems have deepened and ‘gone global,’ firmly rooting health care independently within the global political economy and the International Political Economy (IPE) discipline—a placement whose acceptance has been too long awaited.

Governance, whether by law, treaty, or regulation, is one such mechanism for sharing or dividing power. But the pharmaceutical industry is one of the most regulated sectors, which fairly raises the following critique: is governance sufficient? Is it a matter of the extent or degree of governance (‘more regulation’), its locale (supraterritorial or national), or its focus (profitability, safety, efficacy)? Or, again, is negotiating a health-favoring balance of power between these competing poles of health and influence—an actual conflict between the *body* and the *body Politik*—a matter that existing forms of power sharing *is even equipped to manage*? Many tensions in health arise from poor power-sharing systems—that is, the governance and regulation of our collective health

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<sup>13</sup> Cockerham and Cockerham, *Health and Globalization*. Page 186.



system are ill-suited as it does not account for the invisible political processes and *ex ante* factors that can shape and influence outcomes well before policy and regulatory design, decision, and outcome.

Whether countertendencies (e.g., national security concerns, state sovereignty over public health, public support for social models of health) can balance globalization's powerful commodifying and liberalizing effects are "a function of the adjustment costs" that primarily state actors face in altering their alignment with neoliberalism. Will state actors – competitive as they are – and their market-motivated non-state partners willingly temper or forego the direct economic gains associated with the current model—losing out on immediate gains but sustaining the overall system by softening globalization's 'rough edges' amidst the growing opposition of domestic constituencies?

#### 7.2.5 Finding No. 5: Systems and Processes Deliver Expected but Undesirable Results

The second part of the analysis – the descriptive accounts – afforded a window through which to observe practically the discursive evidence from the first analysis. In each account, this quote by Trevor Noah (2021) came to mind:

The system and policing is doing exactly what it's meant to do in America. I feel like you get to a place where you go, 'Oh, we're not dealing with bad apples. We are dealing with a rotten tree that happens to grow good apples.'<sup>14</sup>

Similar, though far more human in impact, to the organizational design adage of 'design for the outcome you want,' it was striking how clearly far apart intentional decision-making design and desired global governance for health outcomes are—and the implicit role of power and norms in this widening gap. While this dissertation has always been about generating evidence to center health within the discipline, the more immediate finding may be one of concern. But before the alarm bells are raised, a quick discussion of what, conceptually, stood out amongst the descriptive cases must first be examined. (The following examples of graphically depicted in Figure 7.2).

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<sup>14</sup> Noah, "Police in America - Where Are the Good Apples?" See also Todd, "Meet the Press with Chuck Todd."

Figure 7.2. Expressions of power across the pharmaceutical lifecycle



Author-generated image based on findings.

The descriptive accounts – from collaborative research forums to patent protections to expedite review programs – highlighted the importance of the Four Factors in examining the influence and expression of power in global governance for health, and how and why certain outcomes may be generating. Specifically, state power is being expressed through *context* (i.e., the geopolitical importance of competition states and their interventions to secure national advantage), *content* (policies to directly invest in specific diseases), *processes* (to streamline innovation and lower R&D investment costs through cross-industry collaboration), and *ideas* (about the value of biopharmaceutical innovation, the value of scientific solutioning, the role of the market to generate research efficiencies) to influence the investment decisions of nonstate actors.

#### 7.2.5-A Targeting Innovation and Discovery

Within the set of descriptive accounts, three findings are evident relating to the influence of the Four Factors. *First*, ideas, content, context, and process influence commercial priorities for

pharmaceutical research and development. These factors may not only influence, but *set* the practical, industry priorities early in the pharmaceutical lifecycle, including favoring R&D that meets the criteria for long-term monopolistic pricing opportunities instead of R&D that serves significant global health needs. *Second*, state intervention early in the lifecycle reflects approaches intended to position the state as a competition state, employing pharmaceutical policy and investment as a determinant of competitive national advantage. And *third*, the shaping of the pharmaceutical industry through the Four Factors practical undermines all state priorities, including market competition, pharmaceutical price deflation, and investment in areas of health that are under-resourced, including neglected diseases and curative or preventative treatments.

#### 7.2.5-B Financing Innovation

Within the second set of descriptive accounts, two findings are evident relating to the influence of the Four Factors. *First*, the ideational and contextual factors are sustained by actors across levels of analysis. The Kalydeco® case is a powerful example of the role of ideas, particularly, hegemonic ideas of market-based solutions, in influencing the interests and behaviors of actors. Here, a patient-advocacy group whose mission was to cure a disease financially benefited from the marketization of the disease and the bodies of its patient members—not only in terms of the R&D processes, but subsequently in the valuation of their royalties, which reflects *the value of a life with treatment*. As the Kalydeco case demonstrates the combination of ideas and also policy content, processes of biomarker targeting within R&D, and context resulted in a fundamental shift in actor interests and preferences *in alignment with* neoliberal and state interests. Practically, these Factors promoted the incorporation of market-oriented goals, particularly, of capital accumulation, into *patient* advocacy and using patient members in the co-production of health for the advocacy organization's financial gain.

*Second*, ideas and context (i.e., global competition among states) undermine actor interests

and preferences. While the Kalydeco case also demonstrates this finding, it is multi-level, in that other actors in the system – namely, states, particularly, advanced economies – are motivated to adopt policy incentives that shift an entire market from a focus on accessible, affordable, and mass-producible pharmaceuticals—to *one of precision medicine, of personalized health care innovation*. The content of these policies drive innovation, which states seek, but at significant cost. Such innovation, now insulated from market forces for even longer, is immediately unaffordable and inaccessible, driving the adoption of further governance approaches to rebalance the power imbalance incurred by the prior policy.

#### 7.2.5-C Clinical Trial Research And Market Approval

Within this third set of descriptive accounts, which focused on the implications of international regulatory coordination for rural communities in China and India, the multi-level and discrete influence of the Four Factors can be observed. Specifically, two findings are meaningful. *First*, the political economies of medicine are embedded, multilateral, self-sustaining, and consequential to economic and political relationships. Here, biopharmaceutical innovation and investment are instruments to achieve western-style industrialization and Keynesian economic growth. Specifically, the political economies of medicine promote the valuation and valorization of private biopharmaceutical investment, innovation, and production, which are created in contrast to the devaluation and devalorization of individuals and their health, collectively, public health, which only attains value and valor in the *context* of production or consumption.

*Second*, narratives of innovation and health promotion are co-opted to sustain these relationships despite overall system and actor costs. For global decision-makers and power brokers, bio-innovation becomes a narrative component of global health gains and what is “necessary to help

the rural poor.”<sup>15</sup> As the descriptive case accounts of the clinical research organization (CRO) industry and global governance of pharmaceutical safety, manufacturing, clinical guidelines, and approval illustrate, national health sectors have become the clients meant “to ensure the prosperity of” these efforts, with their citizens the thankful patients benefiting from “miraculous” innovation and cures.<sup>16</sup>

#### 7.2.5-D Marketing, Pricing, And Access

The final set of descriptive accounts explore the commercialization and access to pharmaceutical innovation, particularly, focusing on price and purchasing power. There are two findings of note. *First*, pharmaceutical innovation, investment, and production rely on state-created and sustained market viability or, if lacking such viability, an opportunity to generate good will with political actors for future opportunities in constructed markets. The global pharmaceutical market remains a market, but the political influence points are vast and employed by states to incentivize market actors to make particular investments. Market actors are motivated, to participate in such markets if those incentives *remain*, or are assumed to remain, generating market actor choices *even absent a market* that aligns with state preferences. *Second*, economic and political power privilege certain actors over others, including state actors: seeking pools of public research investment (e.g., Horizon 2020 program), negotiating favorable pricing terms (external referring pricing), or immediate availability of scarce goods (Covid-19 vaccines). Conversely, what the bioeconomy has meant for less powerful actors, however, is not innovation styled as access to cures or prevention but testing grounds for the cure and treatment of others.<sup>17</sup>

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<sup>15</sup> Sunder Rajan, *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine*.

<sup>16</sup> Seiter, *A Practical Approach to Pharmaceutical Policy*.

<sup>17</sup> Sunder Rajan, *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine*, Sunder Rajan's (2017) case study of the pharmaceutical industry in India well captures the on-the-ground “benefits” of the bioeconomy for particularly disempowered actors: the subjects of clinical testing and the many unable to afford needed medicines. See.

### 7.2.6 Implications of Findings for Global Health

So far, the majority of the evidence, with limited potential exceptions, is clear that public financing of health does not counter the negative externalities generated by globalization as such public financing mechanisms exist within and interact with market-oriented global politico-economic systems. The relationship between advanced economics who publicly finance health care and their pharmaceutical exports market is just as significant; the size and scope of the pharmaceutical markets of Germany, Ireland, and Belgium, and the U.K., are striking examples. For example, three of the top five pharmaceutical exporters fund approximately three-quarters of total health expenditure (THE) through public sources (Table 5.5). Regardless the share of total health expenditures from public sources, the underlying norms and their consequences are visible in the outcomes. Public financing on its own cannot curb these influences because they are systemic consequences – dependent variables – of democratic capitalism gone global—of “globalization and its new discontents,” per Joseph E. Stiglitz (2003, 2016).<sup>18</sup>

Globalization’s influence on health, and of health (as a good and as a human condition) on the global political economy, warrant a greater focus within IPE not limited by the bounds of securitization of disease, medicalization of international development aid, or the marketization of health. The IPE discipline and its scholarship must reflect the global experience it seeks to examine. The discipline must not only incorporate health within its bounds, redefine its own ‘scholarship space,’ as it were, beyond the neoliberal bounds of health for trade’s sake, but center health – for health’s sake – as a core issue of the 21st century global political economy.

This dissertation has argued repeatedly for International Political Economy (IPE) to regard health as a central research concern and articulate clear and present examples of social distribution

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<sup>18</sup> Stiglitz, *Globalization and Its Discontents*.

questions that must be prioritized in IPE, including pricing and access of pharmaceuticals.

Distributing health (in terms of outcomes) and health care is distinctively political in cause and consequence and sufficiently different from global poverty, inequality, development, and security studies as to constitute a unique object of inquiry. The findings from Part I reveal there is much to examine of pharmaceuticals in national economies and the global political economy as a proxy for the global imperative that is health. Part II's findings are much deeper than anticipated, demonstrating a complex web of politico-economic intricacies and interrelationships spanning the system-state-individual nexus. Intricacies that demonstrate power imbalances, politically oriented narratives, and reinforcing preferences and processes that, increasingly, incorporate select nonstate actors for legitimacy and risk mitigation (e.g., patient advocacy groups, rural hospitals, pharmaceutical manufacturers, WHO).

Returning to Speaker O'Neill and Professor Drezner, as much as domestic politicians prioritize the perspectives of their local constituencies, health is as intimate an issue that affects every such constituency – and not solely in terms of our actual good or ill health. The international political economies of health, including medicines, influences our global, national, and local economic opportunities, public policy agendas and scope of policy choices, and salience to influence outcomes in line with our interests and preferences. All health politics are global, and it is imperative that their politico-economic contexts and constraints and market-informed power and politics be examined and understood. If it is impossible to address power sharing through workable global governance of pharmaceuticals and other health priorities, including public health risk surveillance, it will be impossible to address the downstream inequities that will continue to plague our world into

the future.<sup>19</sup>

### 7.2.7-A Executive Summary of Findings: Critical Literature Review

Global norms reconstitute health as a commodity subject to economic rationalism and free trade, responsibility for which is beholden to the individual. These global norms – these ideas about health – were present in the descriptive case studies, even if the level of analysis was two micro-level entities. Before evaluating potential governance alternatives, ensuring applicability across the levels of analysis will be key to have any hope for equitable governance and policy design:

- *First, the system-individual implications of a hegemonic idea*, wherein global norms transfer from the system level to the individual through internalization; physicians, patients, and others reflect back these assumptions, beliefs, values, and responsibilities.
- *Second, the levels-of-analysis implications of global health norms are transferable to the system-state dynamics*; for example, market governance of pharmaceuticals is sustained through a global politics of health (system) and an internalized ‘personal political economy’ of medicines (individual).
- *Third, while state-level dynamics* do not originate the systemic norms relating to health, alike the individual level, states internalize such norms, which inform state actor interests, values, beliefs, and preferences.
- *Fourth, system-level dynamics are the forum for which practical policymaking reflecting these norms originates*—but it is also the realm least accessible to influence given the complementing dynamics of material factors and influences.

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<sup>19</sup>Helen Milner, Joseph E. Stiglitz, Thomas Piketty, and others have noted a reemergence of levels of inequality so dangerous as to “generate extreme discontent and undermine democratic values including global capitalism, in the *developed* world. See Piketty, *Capital in the Twenty-First Century*.



### 7.2.7-B Executive Summary of Findings: Descriptive Accounts

The Four Factors represent meaningful variables that can examine the influence of power on actor choices and behaviors. Specific to the descriptive accounts, these influences are noted:

- *First, ideas, content, context, and process influence commercial priorities for pharmaceutical research and development.* These factors may not only influence, but set the practical, priorities and choices of actors.
- *Second, state policymaking and decision-making reinforces global norms* because it is intended to position the state as a competition state.
- *Third, ideas, context, content, and process influence actor behavior* in ways that undermine their own interests and priorities.
- *Fourth, the ideational and contextual factors are sustained by actor choices across levels of analysis.* For example, the political economies of medicine are embedded, multilateral, self-sustaining, and consequential to economic and political relationships.
- *Fifth, narratives of innovation and health promotion are co-opted* to sustain these relationships despite overall system and actor costs.
- *Sixth, pharmaceutical innovation, investment, and production rely on state-created and sustained market viability* or, if lacking such viability, an opportunity to generate good will with political actors for future opportunities in constructed markets. This is not only further evidence of the public good nature of health, but of the implicit conflict between these global norms and the neoliberal discourse itself.
- *Seventh, economic and political power privilege certain actors over others, including in terms of access to innovation funding, favorable pricing, and life-saving public health resources.*

## 7.3 Limitations

The aim of this dissertation has been to review and synthesize, in an interdisciplinary fashion, scholarly work, theory, and modeling on these topics, but it may not be exhaustive. Similarly, the dissertation has tried to quantify a range of pharmaceutical governance and policies, decision-making processes venues, contextualizing factors relating to globalization and health, and the outcomes of enacted rules or policies, but such effort cannot be considered comprehensive. The paper has provided a narrative synthesis that utilizes the conceptual analytical model to shed additional light on the role of power in global health, and how such power dynamics are reflected in decision-making processes at other levels of action. The research begins with power – a firmly rooted orientation within IPE and International Relations – and seeks to understand how and why it manifests at different levels of analysis, and whether it manifests *differently in terms of policy outcomes* in health, and medicines

Rather than an exclusive focus on the *visible* outcomes of these power dynamics and their relationship to select actors (e.g., mechanisms of global governance for health, actual regulatory coordination, international treaties), which this research has no doubt discussed extensively, the findings suggest that equitable scholarly focus and practical solutioning must be applied to the often *invisible* demonstrations of power to address the influence and consequence of power asymmetries. These demonstrations include the implicit and indirect expression of power through hegemonic ideas, structured decision-making processes, and self-limiting contexts, which collectively are at play in matters of global health—just as they are in other elements of geopolitical and politico-economic relations. Such approaches should be both theoretical (conceptual) and practical, including scholarship examining the actual interactions and outcomes consequential to power and health.

A natural limitation is that the research does not present a quantitative accounting of the hypothesized influence of hegemonic ideas and the other modeled factors (of content, context, and process) on global governance, nor of the resultant power asymmetries on health or policy

outcomes. Rather, the research contributes a conceptual framework to clarify ideas as power, which are actualizing and actualized through actor choices, as one of four primary drivers of power asymmetries and balancing in the global political economy. This unexplored area of potential scholarship – the quantitative accounting or agent-based modeling of actor choices – should be an area for future research, and we hope this model can contribute to such efforts.

It is important, however, to remember there are natural limitations to quantitative or positivist approaches seeking to explain complex behaviors and interactions. This research has intentionally adopted a normative approach in the discussion of Positivism, Normativism, and Rationalism. Future scholarship should similarly balance positivist means and rationalist modes with normative ends, so it is relevant and operational, versus overly ideal and perfectly replicable but practically unrelatable.

#### **7.4 Concluding Remarks**

In the first analysis, this dissertation proposed that power asymmetries sustain and embed market-oriented global norms, which shape the political salience of actors and ideas, and have corresponding impacts on what is considered global health and *actual* health equity. To examine power as a constructive and discursive force on health, the dissertation synthesized the IPE, IR, *BMC: Globalization and Health* journal, Public Health, Macroeconomics, Medical Sociology, and Microeconomics literature and theoretical approaches. This analysis revealed certain ‘hegemonic’ ideas, including Neoliberalism, Flexnerianism, and Rationalism, are embedded in our collective understanding of health consciousness—down to one’s own understanding of health. These hegemonic ideas suggest three areas of complexity with the global political economy:

- *First*, these ideas serve as Ideological Mechanisms “to insure the exclusion from the realm of debate of ideologies that conflict with the [dominant] system,” whether globalization or democratic capitalism.<sup>20</sup>
- *Second*, these ideas have formative repercussions for power relations between states and for geopolitical and strategic investment calculations by states.
- *Third*, these ideas reveal a fundamental gap between the value the international system (as it is structured) believes that *it* has and the perceived actual value of the system by those within it. This last conclusion suggests ideational, and material, factors comprise the legitimacy gap facing capitalist-adjacent democratic institutions and systems.

In the second analysis examining power as a practical and coercive force in global governance for health, the dissertation also proposed a novel analytical model to examine power expression in governance and policymaking. The model asserts four primary mechanisms as consequential to actor influence in power relations across levels of analysis: content, context, ideas, and process. To examine fully the political determinants of health – the role of power in health – analyses must pay attention to the contextualizing conditions, ideas, and processes, besides the policy content or outcomes, which are operating at various levels of analysis. The descriptive case accounts demonstrated the utility of this approach by articulating how *ex ante* influences – fingerprints of power if you will – cannot be seen if we are not intentional in treating power as integrative and multifactorial. This finding imparts three conclusions:

- *First*, efforts to address global health inequities and the political origins of ‘ill-health’ must comprehensively account for the role of power and avoid false dichotomies that assume an

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<sup>20</sup> Navarro, *Medicine Under Capitalism*, 210.

*absence* of power, including “if a system is publicly financed, power must be restrained by structure alone.”

- *Second*, such efforts must critically acknowledge and counter the influence of hegemonic ideas – which often are more resilient and politically salient than actors alone – in the conceptualization and, articulation of what health is and what inequities are not.
- *Third*, because power shapes not only the policy *outcomes*, but also the context, ideas, and processes upstream to that final decision point, it is necessary to examine mechanisms for injecting representative or direct engagement processes as far upstream as possible.

## 7.5 Contribution to the Literature and Recommendations

To center health as a core issue area of the 21st global political economy, the overall research proposed a topic and framework that would generate evidence and lines of inquiry contributory to health’s placement in the IPE discipline. Besides generating such evidence and a novel analytical model that could be applied to other issues of ‘low’ political in the global political economy, the research identified three interconnected observations that should be incorporated into future scholarship on health within IPE, and global governance and power relations:

- *First*, significant dysfunction in global governance and regulatory processes persist. While quantifying such dysfunctions are themselves a body of research in IPE, at a minimum, responsive governance should prioritize representative or direct engagement processes as far upstream as possible. Should incorporate opportunities for nontraditional decision-makers and issue stakeholders (e.g., for health issues, actual patient voices) across all phases of policy design, decision-making, election, and implementation—including initial conversations to determine stakeholder engagement frameworks.

- *Second*, levels of analysis are essential to observe and examine the dynamism of power relations and norm interactions and influences. Specifically, theoretical and analytical models must be mindful of how processes and actors are operating at various levels of analysis, as it is both essential for examining the dynamism between levels of power relations but equally essential for designing more responsible decision-making processes.
- *Third*, the push-pull in global pharmaceutical governance reveals the flaws in modern political representation. Urgent solutioning is needed in this area of global social life.

To examine fully the wealth of connections between health and IPE this dissertation articulates and to advance a range of scholarship that is solution-oriented, future research should understand and work to address, to the extent feasible, an interdisciplinary approach that incorporates gap areas

This research, intentionally, did not devote significant attention to the ‘medicalization’ of security or the ‘securitization’ of health.<sup>21</sup> Much scholarship has been devoted to exploring the interaction between globalization, *infectious* disease flows, and global governance (or other perceived global or regional or local health challenges). Rather, this dissertation has focused on the role of health within IPE and IR. Scholarship on health within IPE but also IR, however, is one of relevance *only when* it comes into conflict with, or to support, global *economic* progress. Scholars including Stephen Elbe (2009, 2010, 2021), Christopher Long (2020), Lee and Dodgson (2000) are foremost in this area of research, including recent elaborations on security at the molecular level.<sup>22</sup> This research is intended to cover ‘new ground,’ or at least to articulate issues of health presently atypical to the fields of IPE and IR, with the aim of orienting health as a core issue of the 21st century global political economy *in its own right*, not because of its adjacency to the ‘high’ politics of

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<sup>21</sup> Elbe, *Security and Global Health*.

<sup>22</sup> Elbe and Long, “The Political Economy of Molecules: Vital Epistemics, Desiring Machines and Assemblage Thinking”

trade or security.

This exclusion of other health scholarship is not a dismissal of their significance. The issues of infectious disease flows and global governance for global infectious disease and health risk management are and have been important, instrumental areas of scholarship. This research critiques the linkage to the ‘academic space’ that IPE affords health, which is mutually constitutive. These topical explorations create an exclusionary space for health in IPE, rather than a centering space. Such research *itself* prioritizes certain actors and interests over others, particularly, the politico-economic and security priorities of leading advanced economies, and exclude states and peoples disproportionately affected (e.g., Covid-19 vs. malaria) by the dominant politico-economic relations that define IPE’s locus: global market integration. Just as health has been framed within the context of dominant global paradigms and to excluding alternatives, so, too, has the IPE research agenda. IPE aligns with hegemonic ideals of positivism, Rationalism, and marketization, rather than an intellectual expansiveness and inclusive curiosity fit to the breadth of the actual global politico-economic experience.

This research has set out to make visible the ideational factors underpinning health’s depoliticization and IPE’s ‘de-medicalization.’ It also has proposed an initial, working framework for applying an international political economy approach to the major social issues that dominate the contemporary global agenda, including and especially health. Future IPE research should examine the potential for implicit biases within the discipline and their implications for IPE’s own research ‘space.’ It also should articulate, as BBC North America Bureau Chief and former BBC Middle East & Asia Bureau Chief Paul Danahar (2021) captures well, mechanisms for political decision-making and metrics of ‘success’ separate from market determinants of global and cross-national priorities, including and especially health: “we need to have a plan; we need to have a structure so that we just don’t allow the market to decide things that are very geopolitically

important.”<sup>23</sup>

Specific to the IPE analysis of international policies and national policies-turned-global (via regulatory coordination and harmonization), future research also may evaluate the practical implications of idea exclusion from global policymaking processes. For example, rather than an exclusive focus on health’s visible outcomes, to address the influence of power asymmetries, the research asserts that equitable scholarly focus and practical solutioning must be applied to the Four Factors that make global health: our *ideas* about health, policy *content*, development and design *processes*, and globalization and neoliberal *contexts* that make global health. Similarly, within Public Health, Medical Sociology, and Health Policy, as demonstrated by *BMC: Globalization & Health* journal, closer scholarly linkages and partnerships with IPE and IR would strengthen not only the scholarly research, but the political *value and relevance* of such findings with international and national policymakers and thought leaders. Partnerships between the academic, policymaking, and business communities are essential to shaping a more equitable global governance for health, and the national health policies that global governance informs and is informed by.

The practice of medicine has now become the prescribing of medicine, for good and for ill. We must reexamine our relationship as individual patients, scholars, and policymakers with the *ideas* behind the biomedical model of health, but such a reappraisal must not be isolated to select medical practices or fields of scholarship—it must happen systematically. As the practice of medicine continues to evolve across global society – incorporating holistic notions of health and community, of equity and health as social justice, of collaboration and interaction – so, too, must our own ideas of what health is and could be. Applying a *public health approach* to IPE scholarship and the policy challenges of the global political economy will promote a healthier world.

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<sup>23</sup> As interviewed by Boodhoo, “The News Roundup — International” (June 11, 2021). Danahar is the author of *The New Middle East* (2015 [2013]).



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## APPENDIX A

### GLOSSARY OF TERMS

Terms	Description
Actors**	The entities in the global political economy, including states and other individual and collective entities, with these three features: (1) “should have the autonomous capacity to determine their own purposes and interests;” (2) “should have the capability to mobilize resources to achieve these purposes and interests;” and (3) “their actions should be significant enough to influence state-to-state relations or the behavior of other nonstate actors in the international system.” <sup>1</sup> May be applied to subsystem levels of analysis, referring to entities with these features whereas (3) refers to involvement in the governance or policymaking “process and might enter the debate over the policy’s fate.” <sup>2</sup>
Beliefs	An individual’s subjective understanding of cause-and-effect relationships, including normative assumptions about what is ‘good’ or ‘bad,’ <sup>3</sup> that serve as an “operational code” and set parameters for permissible behaviors (i.e., actions or choices). <sup>4</sup> Can be philosophical and instrumental, but always subjective and cannot provide accurate or objective assertions about the world. Serve as a “colored lens” through which individuals make sense of the world. <sup>5</sup> Within International Relations, refers to the limits on the capacities of actors to view policy debates holistically, which effectively constrain the available policy choices or alternatives actors consider in policymaking.

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\*\* Double asterisks denote terms and working definitions essential of operational value to the analytical and theoretical frameworks.

<sup>1</sup> Kan, “Actors in World Politics,” 179–80.

<sup>2</sup> Reich, “The Politics of Reforming Health Policies,” 139.

<sup>3</sup> Jervis, “Understanding Beliefs,” 644–45.

<sup>4</sup> Alexander L. George as quoted by Larson, “The Role of Belief Systems and Schemas in Foreign Policy Decision-Making”

<sup>5</sup> Op. cit., George in Larson (1994).

Term	Definition or Description
Bretton Woods Institutions (BWIs)	Established at the United Nations Monetary and Financial Conference held in Bretton Woods, New Hampshire in July 1944. Examples include the International Monetary Fund, which is responsible for monitoring international exchange rates and lending reserve currencies to states with balance-of-payment deficits, and the International Bank for Reconstruction and Development, now known as The World Bank or World Bank Group, which originally was responsible for assisting with the reconstruction of Europe after World War II and currently the economic development of low- and middle-income countries.
Capture Theory	Instead of acting in the interests of civil society (the public), a government agency acts instead for the interests of the industry it regulates. Otherwise described as ‘interest capture’ or ‘regulatory agency capture.’ <sup>6</sup>
Chronic Diseases	Including many noncommunicable diseases (NCDs), diseases not passed from person to person in terms of infectious transmission, are of long duration, and progress slowly. The four main types are cardiovascular diseases (e.g., heart attacks, stroke); cancers, which may have infectious origins; chronic respiratory diseases (e.g., chronic obstructed pulmonary disease, asthma), and diabetes. Other examples include chronic respiratory conditions, such as asthma, and mental health and substance use conditions. <sup>7</sup>
Collective Action Problem	Absent coercion or other device to incentivize or require a group of individuals to act in their common interest, individual actors will fail to cooperate – though they would be better off – because of conflict minority interests. <sup>8</sup>

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<sup>6</sup> Potter, Olejarski, and Pfister, “Capture Theory and the Public Interest: Balancing Competing Values to Ensure Regulatory Effectiveness”

<sup>7</sup> By employing the World Health Organization (“Noncommunicable Diseases: Overview, Country Profiles, and Related Health Topics” 2020) definition instead of that of the U.S. Centers for Disease Control and Prevention (“About Chronic Diseases” 2021), the definition incorporate chronic respiratory conditions, such as asthma, and mental health and substance use disorders. The definition of the CDC includes neither, which reflects the variance in typologies of this essential public health term. For more on this debate, see Bernell and Howard, “Use Your Words Carefully: What Is a Chronic Disease?”

<sup>8</sup> Olson, *The Logic of Collective Action*.



Term	Definition or Description
Commodification**	Processes whereby the practices of marketization “qualitatively reconstitute” health in ways it becomes understood as a commercial good or commodity under common economic metrics, “produced for sale,” and able to be traded-off in policymaking, <sup>9</sup> in the style of “fictitious commodities.” <sup>10</sup>
Competition State**	States securing and sustaining national competitive advantage in the global political economy by leveraging market investment, production, exports, and imports to sustain its competitive edge economically and politically.
Co-production	“The voluntary or involuntary involvement of public service users in any of the design, management, delivery and/or evaluation of public services.” <sup>11</sup>
Constructivism	“Intersubjective knowledge” (i.e., consciousness), ideas, and “knowledgeable agents” have dynamic, mutually constitutive effects on society and social relations—that is, knowledge and ideas are dependent variables in social explanations. <sup>12</sup> Reflecting their reciprocal relationship with social systems, <sup>13</sup> changes in world politics reflects changes in the collection of knowledge and ideas about the world, including material and ideational factors. <sup>14</sup> Depicts the global political economy as a collection of “understandings, subjective knowledge[,] material objects,” structures, and processes that “only acquire meaning for human action through the structure of shared knowledge in which they are embedded.” <sup>15</sup> Favors a levels of analysis approach that is ‘top-down,’ asserting the need to center “social wholes and internal relations rather than individual[ actors].” <sup>16</sup>

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<sup>9</sup> Fraser, “Can Society Be Commodities All the Way down? Polanyian Reflections on Capitalist Crisis,” Hoppania and Vaitinen, “A Household Full of Bodies: Neoliberalism, Care, and ‘the Political,’” Vaitinen, Hoppania, and Karsio, “Chapter 27: Marketization, Commodification and Privatization of Care Services.”

<sup>10</sup> Polanyi, *The Great Transformation: The Political and Economic Origins of Our Time*.

<sup>11</sup> Osborne, Radnor, and Strokosch, “Co-Production and the Co-Creation of Value in Public Services,” 639.

<sup>12</sup> Adler, “Constructivism and International Relations,” 96 and 102.

<sup>13</sup> As Emanuel Adler (2005 [2002]) explains, “interests are ideas; that is, they are ontologically intersubjective [knowledge] but epistemologically objective interpretations about, and for, the material world.” See op. cit., Adler, 102.

<sup>14</sup> Fearon and Wendt, “Rationalism v. Constructivism: A Skeptical View,” 58.

<sup>15</sup> Wendt, “Constructing International Politics,” 73.

<sup>16</sup> Op. cit., Fearon and Wendt.

Term	Definition or Description
Critical Constructivism**	Theoretical branch of Constructivism that aims to interrogate social practices, ideas, and norms that produce and reproduce power relationships toward issues of justice, equity, and fairness. The ontological status of actors “is an artefact of a continual process of reproduction that performatively constitutes its identity” <sup>17</sup> in relation to the “social constraints and cultural understandings” that create and reproduce systems of power relations. <sup>18</sup>
Critical Theory	“Habits of thought, reading, writing, and speaking which go beneath surface meaning, first impressions, dominant myths, official pronouncements, traditional clichés, received wisdom, and mere opinions” are explored so as “to understand the deep meaning, root causes, social context, ideology, and personal consequences of any action, event, object, process, organization, experience, text, subject matter, policy, mass media, or discourse.” <sup>19</sup> As a theorem, “takes the world as it finds it, with the prevailing social and power relationships... as the given framework for action,” <sup>20</sup> reflecting “explicit historicism” <sup>21</sup> marked by an “inseparable unity between [] normative and analytical” modes of analysis. <sup>22</sup>
Defined Daily Dose (DDD)	World Health Organization metric of normalizing the count of pharmaceuticals of varying intended uses and dosages for analytical and comparative purposes. Specifically represents a standard day of therapy for a maintenance dose and does not reflect actual treatment.
Diamond of National Advantage**	The determinants of national competitive advantage, or what sets competition states apart, as the rate and efficiency with which factors of production are created, upgraded, and deployed (factor conditions); the composition and character of the domestic market—not the size (demand conditions); the advantage of close working relationships between related and supporting industries, and the ability to mutually benefit from downstream efficiencies; and the convergence of firm strategy, structure, and practices with the modes favored by the state because of their alliance with the state’s sources of competitive advantage.

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<sup>17</sup> Campbell, “Cultural Governance and Pictorial Resistance: Reflections on the Imaging of War,” 57–58.

<sup>18</sup> For Critical Theorists, power is “exercised in every social exchange, and there is always a dominant actor in that exchange.” See Hopf, “The Promise of Constructivism in International Relations Theory,” 185.

<sup>19</sup> Shor, *Empowering Education: Critical Teaching for Social Change*, 129–30.

<sup>20</sup> Cox and Sinclair, *Approaches to World Order*, 88.

<sup>21</sup> Morrow, *Critical Theory and Methodology*, 3: 13.

<sup>22</sup> Rexhepi and Torres, “Reimagining Critical Theory,” 697–98.

Term	Definition or Description
Economy, Advanced**	Pharmaceutical markets of high and upper-middle income countries, which are two of four income groups (i.e., low, lower-middle, upper-middle, and high) defined by The World Bank based on countries' gross national income per capita in USD. Classifications are updated annually. Excludes those economies with emerging pharmaceutical markets. Also called “developed markets,” a subset focusing on the 10 largest countries with high incomes and with pharmaceutical spending greater than \$10 billion. Includes Australia, Canada, France, Germany, Italy, Japan, South Korea, Spain, the United Kingdom (U.K.), and the United States of America (U.S.).
Economy, Emerging**	Elsewhere described as “pharmerging markets,” refer to countries with emerging pharmaceutical markets, which are defined as having per capita income below \$30,000 per year and five-year absolute growth in pharmaceutical spending greater than \$1 billion. These countries are Algeria, Argentina, Bangladesh, Brazil, Chile, China, Colombia, Egypt, India, Indonesia, Kazakhstan, Mexico, Pakistan, Philippines, Poland, Russia, South Africa, Saudi Arabia, Thailand, Turkey, and Vietnam.
Economy, Lower Income	Lower-middle and low income per the World Bank's income bands.
Endemic	Referring to the spread of a disease present within a localized area or peculiar to persons in such an area.
Epidemic	Referring to the spread of a disease attacking or affecting many persons simultaneously in a particular community or area, including a country; a widespread occurrence of disease that is not global.
Excess Cost Growth	The growth in public health spending over gross domestic product growth after controlling for aging <sup>23</sup> that “is higher than the norm, whether measured against other countries' experiences or against relevant economic patterns within [a] country,” which is “disproportionate to the health it produces.” <sup>24</sup>
Excludability	One of two essential traits of public goods, whereas it is difficult, if not impossible, to exclude others from having access to, or profiting from, such a good or resource.

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<sup>23</sup> See Clements, Coady, and Gupta, *The Economics of Public Health Care Reform in Advanced and Emerging Economies*. Figure 3.1, Page 38; and Congressional Budget Office (U.S.), “The 2020 Long-Term Budget Outlook.”

<sup>24</sup> Tollen, Keating, and Weil, “How Administrative Spending Contributes to Excess U.S. Health Spending”

Term	Definition or Description
Flexnerianism**	Refers to the Flexner Report by Abraham Flexner, which critiqued medical schools in the U.S. and Canada at the turn of the 20th century for not following 'laboratory' medicine, which the American Medical Association (AMA), Johns Hopkins University, and other medical thought leaders strongly supported. Teaching institutions closed, merged with others, or were restructured to adopt Flexnerianism approaches. According to Waitzkin, "the closure of many medical schools not based in laboratory science led to fundamental changes in the class composition of the profession, changes that went hand in hand with reduced competition and higher individual incomes for doctors." <sup>25</sup>
Four Factors Model of Power Expression in Governance and Policymaking**	A novel analytical model whereby that posits actors involved in policymaking and governance are informed by four interactive factors: first, the outward display and codification of actors' preferences and interests in the policy outcome and excluding failed or alternative policy options (content); second, the normative ideas that comprise actor's individual worldviews and frame the collective discourse; third, the systemic context; and, fourthly, the processes that govern decision-making, often serving as a pre-negotiated mechanism for sharing or dividing power in policy decision-making.
Fragmegration	A contraction of fragmentation and integration reflecting "diverse and contradictory forces" observed in the competing dynamics of globalization, specifically, centralization versus decentralization, integration versus fragmentation, and internationalization versus localization. <sup>26</sup>
Game Theory	Branch of Mathematics concerned with the analysis of strategies for dealing where the outcome of a participant's choice of action depends on the actions of other participants. When applied to International Relations, International Political Economy, and Political Science, refers to the analytical framework to examine politico-economic relations among competing actors, usually states, in terms of gain-maximizing behavior.
Global Commons	Type of common pool-resource "understood as any natural or man-made resource that is or could be held and used in common." <sup>27</sup>

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<sup>25</sup> Waitzkin, "The Marxist Paradigm in Medicine," 686.

<sup>26</sup> Rosenau, *Turbulence in World Politics: A Theory of Change and Continuity*.

<sup>27</sup> Hardin, "The Tragedy of the Commons;" Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action*; Berge and van Laerhoven, "Governing the Commons for Two Decades: A Complex Story."

Term	Definition or Description
Globalization**	The consistent and inconsistent globalizing of the processes of modernity and rationality, which are simultaneously constructed and applied through political means that magnify asymmetries in power and resources, thereby, both enhancing and lessening the costs, benefits, and trust-risk dynamics of complex interdependence and global consciousness. <sup>28</sup>
Global System of Disease	The global political economy of health is intricately linked to operating global markets, capitalist productions, and credit flows, resulting in the linkage between patterns of health and disease and the global capitalist system.
Governance**	The way rules, requirements, norms, and actions are structured, sanctioned, sustained, regulated, and held accountable. Occurs within and across a variety of levels of political engagement, including the individual, local, national, regional, and supranational or global levels, and can be established by a variety of actors, including state and nonstate actors (e.g., corporate governance).
Governance, Global**	The collection of authority relationships designed to establish, monitor, enforce, sustain, and amend or restrict any international rules and regulations, including hard law treaties, soft law declarations, private orders, recommended codes of conduct, and other formal global norms and practices upheld in the global political economy. <sup>29</sup>
Governance, Global Health	Any means or mechanisms used by various public and private actors, acting at sub-national, national, and international levels, which seek to control, regulate, or ameliorate the global system of disease.
Gross Domestic Product (GDP)	The value of the goods and services produced in a particular market. It is a common measure of economic activity, and its rate of growth is commonly interpreted as a reflection of a market's overall economic health.

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<sup>28</sup> This research adopts an author-created combined version of Anthony Giddens' (2012 [1990]) and Ethan B. Kapstein's (1999, 2000, 2001) respective typologies of globality and globalization. See Giddens, *The Consequences of Modernity*; and Kapstein, "Distributive Justice as an International Public Good: A Historical Perspective;" "Winners and Losers in the Global Economy;" and Kapstein and Milanovic, "Responding to Globalization: Social Policy in Emerging Market Economies."

<sup>29</sup> Drezner, *All Politics Is Global: Explaining International Regulatory Regimes*, 11–12.

Term	Definition or Description
Health**	“A state of complete physical, mental, and social well-being, and not merely the absence of disease or injury” <sup>30</sup> that is “a resource for everyday life, not the object of living. Health is a positive concept emphasizing social and personal resources, as well as physical capacities. Therefore, health promotion is not just the responsibility of the health sector but goes beyond healthy life-styles to well-being.” <sup>31</sup>
Health, Equity in	Fairness in that individuals’ or populations’ needs guide the distribution of health care services and opportunities for well-being. <sup>32</sup>
Health, Resources of	“Peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice, and equity.” <sup>33</sup>
Health, Global**	“Health issues that transcend national boundaries and governments and call for actions on the global forces that determine the health of people,” and, in terms of research, “collaborative trans-national research and action for promoting health for all.” <sup>34</sup>
Health, Individual	Personal health and wellness and the range of medical, pharmaceutical, and other health care services, interventions, treatments, and approaches oriented at the individual level of action, specifically, one-on-one patient-to-provider interactions. When contrasted with population health and context, represents health that is immune, causative, preventive, and doomed: “individual health remains good irrespective of population health or context;” “is boosted in favorable population health or context;” “is compromised when population health or context is unfavorable;” and “is compromised irrespective of the population health or context,” as distinguished by Onyebuchi A. Arah (2009). <sup>35</sup>

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<sup>30</sup> World Health Organization, Constitution of the World Health Organization (2006 [1948]).

<sup>31</sup> World Health Organization, Ottawa Charter for Health Promotion (1986).

<sup>32</sup> World Health Organization Division of Analysis, Research, and Assessment, “Equity in Health and Health Care: A WHO/SIDA Initiative.”

<sup>33</sup> World Health Organization, Ottawa Charter for Health Promotion (1986).

<sup>34</sup> Koplan et al., “Towards a Common Definition of Global Health;” Beaglehole and Bonita, “Invited Editorial: What Is Global Health?”

<sup>35</sup> Arah, “On the Relationship between Individual and Population Health.”

Term	Definition or Description
Health, Policy	Reflecting the WHO Ottawa Charter (1986), reflects the explicit concern for health and equity in all areas of policy and governance and by an accountability for health impact. In this way, the main aim of health public policy is to create a supportive environment to enable people to lead healthy lives by making healthy choices possible or easier for citizens and enhancing social and physical environments to support health. <sup>36</sup>
Health, Population	Considers the health of a population in relationship to and within the context of individual health in that “individual and population health is a matter of <i>ubi mel ibi apes</i> —where there is honey there are bees” (Arah, 2009). In this way, characterizes the broader idea of health and health needs as representative of the “functioning (the achieved) and capability (the achievable): a means to life’s other vital goals or capabilities as well as an end in itself.” <sup>37</sup>
Health, Promotion	“The process of enabling people to increase control over and to improve their health.” <sup>38</sup>
Health, Public	“The art and science of preventing disease, prolonging life and promoting health through the organized efforts of society.” <sup>39</sup> Primarily concerned with the health of the entire population, rather than the health of individuals. Its features include an emphasis on promotion of health and the prevention of disease and disability, a recognition of the multidimensional nature of the determinants of health, and a focus on the complex interactions of factors in development effective interventions. <sup>40</sup>
Hegemony**	A specific actor or entity (hegemon) “that is so powerful that it dominates all [] other[s] in the system.” <sup>41</sup>

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<sup>36</sup> The Ottawa Charter for Health Promotion (1986) notes that health promotion extends beyond the practice of medicine and must be on the policy agenda in all sectors and at all levels of government from the standpoint of accountability and investment. It emphasizes that governments are ultimately accountable to their people for the health consequences of their policies, or lack of policies. Similarly, investment for health is a strategy for optimizing the health promoting impact of public policies. See, op. cit., World Health Organization (1986).

<sup>37</sup> Op. cit., Arah, 237.

<sup>38</sup> Op. cit., World Health Organization (1986).

<sup>39</sup> Acheson, Public Health in England: The Report of the Committee of Inquiry into the Future Development of the Public Health Function (“Acheson Report”).

<sup>40</sup> Kass, Paul, and Siegel, “Ethical Principles and Ethical Issues in Public Health.”

<sup>41</sup> Mearsheimer, *The Tragedy of Great Power Politics*, 41.

Term	Definition or Description
Hegemony, Cultural	The contestation for the common-sense of society, including the political, economic, and cultural norms that prevail within social formations, which develop within the context of power across the production of relationships, ideas, structures, and processes of the global political economy. <sup>42</sup> The idea “that man is not ruled by force alone, but also by ideas.” <sup>43</sup>
Ideas**	The internalized, pre-existing “clusters of beliefs,” cognitive short-cuts, mental aids, heuristic devices, and principles—the “cognitive maps”—held by individual actors or adopted by a group of actors to understand the human condition in its environment, including social relations and systems of power relations. <sup>44</sup> May be heuristic (i.e., help actors make sense of the complex world around them <sup>45</sup> ) or subjective. Range from the specific to the programmatic, diagnostic to philosophical, including ‘understandings’ <sup>46</sup> akin to those that form social consciousness or awareness. <sup>47</sup>
Ideational Factors**	In the International Relations theoretical tradition of Constructivism, the “distribution of ideas and knowledge” that establish “both actors’ identities and interests” <sup>48</sup> and therefore are important to systems of political relations in ways beyond constraining behavior because they “constitute the rules of the game, which define roles, identities, interests, and criteria of legitimacy and justification.” <sup>49</sup> Are “the building blocks of international reality” and a core component of power (alongside material factors). <sup>50</sup> Also formative in the Public Policy discipline as a variable in explanations of policy outcomes. <sup>51</sup>

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<sup>42</sup> Gramsci, *Selections from the Prison Notebooks*.

<sup>43</sup> Bates, “Gramsci and the Theory of Hegemony.”

<sup>44</sup> Quotations refer to Holsti, “Foreign Policy Formation Viewed Cognitively,” 20. The conceptual definition, however, refers primarily to Béland and Cox, *Ideas and Politics in Social Science Research*, 6. The extant literature on what comprises ideas is extensive; see also Brummer, “Fiasco Prime Ministers: Leaders’ Beliefs and Personality Traits as Possible Causes for Policy Fiascos,” Burdein, Lodge, and Taber, “Experiments on the Automaticity of Political Beliefs and Attitudes,” Foyle, “Public Opinion and Foreign Policy: Elite Beliefs as a Mediating Variable,” Radaelli and O’Connor, “How Bureaucratic Elites Imagine Europe: Towards Convergence of Governance Beliefs?” and Renshon, “When Public statements Reveal Private Beliefs: Assessing Operational Codes at a Distance.” For an extensive review of the literature on ideas, see Swinkels, “How Ideas Matter in Public Policy: A Review of Concepts, Mechanisms, and Methods.”

<sup>45</sup> Jones 2017

<sup>46</sup> For literature exploring specific and programmatic ideas, see Kingdon, *Agendas, Alternatives, and Public Policies* and Schmidt, “Discursive Institutionalism: The Explanatory Power of Ideas and Discourse.” For diagnostic beliefs and principles, see op. cit., Jervis, and Van Esch and Snellens, “From Belief to Behavior: Using Cognitive Maps to Test Ideational Policy Explanations.”

<sup>47</sup> Robertson, “Glocalization: Time-Space and Homogeneity-Heterogeneity.”

<sup>48</sup> Wendt, *Social Theory of International Politics*, 24.

<sup>49</sup> Jackson, *Russian Foreign Policy and the CIS: Theories, Debates, and Actions*, 22–23.

<sup>50</sup> Ruggie, “What Makes the World Hang Together? Neo-Utilitarianism and the Social Constructivist Challenge,” 879.

<sup>51</sup> See, for example, Cairney 2019 and Mehta 2011.



Term	Definition or Description
Income Bands	Classifications of countries such as high, upper middle, lower middle, and low by gross national income and are based on World Bank methodologies.
Infectious Diseases	“Caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another. These diseases can be grouped in three categories: diseases which cause high levels of mortality; diseases which place on populations heavy burdens of disability; and diseases which owing to the rapid and unexpected nature of their spread can have serious global repercussions.” <sup>52</sup> Also incorporates the term communicable disease (CD), which are diseases that can be transmitted from one person to another. <sup>53</sup>
International Political Economy (IPE)	Referring to the academic field or discipline that examines the “parallel existence and mutual interaction of ‘state’ and ‘market’ in the modern world create ‘political economy.’” Core tenets assume markets are natural forces that seek efficiency absent state and nonstate actors: “In the absence of the state, the price mechanism and market forces would determine the outcome of economic activities; this would be the pure world of the economist. In the absence of the market, the state or its equivalent would allocate economic resources; this would be the pure world of the political scientist.” <sup>54</sup>
Internationalization**	Refers to a corporate strategy whereby a firm increases its market share beyond its country of domicile by making its products, services, or goods adaptable and available to enter different national markets. Within IPE, can also describe actions or processes whereby an idea or belief, norm, policy, system, or structure is made international, or its implications or context become international (global).
Levels of Analysis**	The location, size, or scale of a research target in the Social Sciences. The macro (large), meso (medium), and micro (small) division of system sizes is one common example that often is applied in International Relations and International Political Economy as system or world (macro), state or other system-level actor (meso), and individual or other state or sub-system actor (micro). This research employs the macro-meso-micro and system-state-individual scales interchangeably.

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<sup>52</sup> WHO, “Infectious Diseases.”

<sup>53</sup> WHO and International Federation of Red Cross and Red Crescent Societies, “Infections and Infectious Diseases.”

<sup>54</sup> Gilpin, *Global Political Economy*.

Term	Definition or Description
Market-clearing Price	Also called the equilibrium price, the price of a good or service at which quantity supplied (profit maximization) is equal to quantity demanded (utility maximization). Contemporary microeconomic theory asserts that markets, on their own, will move toward this price.
Marketization**	Referring to the processes where health and health care are governed by the market or market-like mechanisms. Under marketization, health is commodified, conceived in terms of quantifiable goods or service products, bought and sold at a market price, and constructed in terms of market efficiency. These processes are visible within states which structure their health care financing through both “strong public welfare systems” and private firms and individual payment but are “most visible” in the former’s “neoliberal processes of restructuring. Once recurrently simplified, subdivided, and rationalized in the processes of marketization, care over time becomes understood, operationalized, and practiced in market terms.” <sup>55</sup>
Material Factors	In the International Relations (IR) theoretical traditions of Realism and Neoliberal Institutionalism, the defining component of power and “the most fundamental fact about society,” <sup>56</sup> referring to distributing material capabilities, <sup>57</sup> which are the “specific assets or material resources that are available to a[n actor].” <sup>58</sup> In terms of the origins and causality of actor behavior, precedes such behavior and are independent of it, being primary in the hierarchical ordering of behavior-determining factors, <sup>59</sup> with ideational factors (or ‘institutional factors,’ ‘moral standards’) and social environmental factors (‘social issues’) subordinate to the materialist power concerns of states and other actors across levels of analysis. <sup>60</sup>
Morbidity Rate	A measurement of the rate of illness or disease in a population.
Mortality Rate	A measurement of the rate of death, whether from a specific illness or disease or reflect the overall rate of death in a population.

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<sup>55</sup> Vaitinen, Hoppania, and Karsio, “Chapter 27: Marketization, Commodification and Privatization of Care Services”; Meagher and Anttonen, “Mapping Marketization: Concepts and Goals.”

<sup>56</sup> Wendt, *Social Theory of International Politics*, 23.

<sup>57</sup> Mearsheimer, “A Realist Reply,” 91.

<sup>58</sup> Mearsheimer, *The Tragedy of Great Power Politics*, 58–60.

<sup>59</sup> Op. cit., Wendt, 25.

<sup>60</sup> John J. Mearsheimer and John R. Searle refer to ideational factors as institutional factors or moral standards, respectively. See Op. cit., Mearsheimer, 58; and Searle, *The Construction of Social Reality*, 34–35.

Term	Definition or Description
Novel Active Substance/ New Active Substance (NAS)	At the time of market approval, pharmaceuticals with at least one active ingredient not previously marketed globally or within a particular market, including combinations of existing active substances with at least one new substance; or the medicine features a novel mechanism of action (e.g., ribonucleic acid-based inhibitors).
Neoliberalism**	Market-oriented policies and/or reforms including eliminating price controls, deregulating and creating new capital markets, lowering trade barriers, and overall reducing state influence and role in the economy (“privatization”), whether the market is international, national, or local.
Noncommunicable Disease (NCD)	Chronic diseases “of long duration and generally slow progression.” <sup>61</sup> Represent the leading cause of global mortality (70% in 2015) and a significant share (27%) of premature mortality. The main risk factors include tobacco use, physical inactivity, harmful use of alcohol, and unhealthy diet, which influence individual and community health but are determined by social, political, and economic factors outside the domain of health care practice.
Normativism	Development and testing of statements and solutions that impart the normative value of the potential and observed phenomena of life (that is, of the particular examined subject, such as economic fairness), or what social relations – whether of the economic or political variety – should be or ought to be by answering questions in terms of ‘how-and-why.’ Often juxtaposed with Positivism.
Obesogenicity	In terms of a built or physical environment, “the sum of influences that the surroundings, opportunities, or conditions of life have on promoting obesity in individuals or populations,” as developed by Swinburn and Egger (2002). <sup>62</sup>
Pandemic	A global epidemic of disease.
Pharmaceuticalization**	The “process of understanding and/or treating social, behavioral, or bodily conditions with pharmaceuticals; reducing public health strategies from a broad array of disease prevention efforts to one seeking to improve the health of populations with pharmaceuticals.” <sup>63</sup> (Figert and Bell, 2014)

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<sup>61</sup> World Health Organization, “Key Facts: Noncommunicable Diseases.”

<sup>62</sup> Swinburn and Egger, “Preventive Strategies against Weight Gain and Obesity,” 291.

<sup>63</sup> Figert and Bell, “Big Pharma and Big Medicine in the Global Environment.”

Term	Definition or Description
Pharmocracy**	“The global regime of hegemony of the multinational pharmaceutical industry,” which “operates to institute forms of governance across the world that are beneficial to its own interests,” including through policy harmonization on clinical trials and intellectual property rights, which are not global regulation, per se, but the “expansion of multinational corporate hegemony.” <sup>64</sup>
Policy Convergence**	The “narrowing of national policy differentiations” <sup>65</sup> or gaps in national standards.
Policy Coordination**	The mutual adjustment of national rules and regulations in recognition of other countries’ regulatory frameworks.
Policy Harmonization**	Reflecting the below definition of policy convergence, convergence of standards, policies, or rules to the same harmonized regulatory practice and procedure, resulting in a single, global regulatory standard.
Politics**	The processes for determining how power and resources (i.e., who gets what, when, and how <sup>66</sup> ), whether political, social, or economic, are allocated and distributed in a society. Typically excludes recourse to violence.
Political Salience	The relative power of actors in the system based on the resources available to each and usable by them (to express power to attain an objective), and the values associated with the actor’s available, usable resources. <sup>67</sup>
Polypharmacy	The use of multiple medicines or more than are medically necessary.
Positivism <sup>68</sup>	Development and testing of objective, verifiable statements about the world (i.e., what is in the world) and why it operates as it does, or ‘why-and-what’ lines of theoretical inquiry. Often juxtaposed with Normativism.

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<sup>64</sup> Sunder Rajan, *Pharmocracy: Value, Politics, and Knowledge in Global Biomedicine*, 5.

<sup>65</sup> Drezner, “Who Rules? The Regulation of Globalization.”

<sup>66</sup> Lasswell, *Politics: Who Gets What, When How*.

<sup>67</sup> Based on the Michael Reich’s (2002) conception of political salience. See Reich, “The Politics of Reforming Health Policies,” 139.

<sup>68</sup> Originally a Microeconomics concept and methodological approach, may refer specifically to positivist economics models, for example.

Term	Definition or Description
Power**	“The production, in and through social relations, of effects that shape the capacities of actors to determine their circumstances and fate.” <sup>69</sup> It is relational and relative, meaning it is expressed differently whether the social relations are interactive or constitutive. The effects it produces are relative in their specificity (“specific/direct or diffuse/indirect”). <sup>70</sup> Conceptualizations may be compulsory, institutional, structural, or productive. Specific types of power include physical coercive, economic coercive, regulatory, discursive, capital, moral, expert, and network. <sup>71</sup>
Premature Mortality Rate	A measurement of the rate of death between the ages of 30 and 70.
Prisoner’s Dilemma	An example of a game analyzed in Game Theory wherein two rational actors may not cooperate, even if it appears cooperation would be in their best interest, as both actors are motivated to minimize their own individual risk, rather than cooperate to achieve the best overall outcome; a variation of the collective action problem. <sup>72</sup>
Privatization**	Referring to the processes whereby the state is made to withdraw or not occupy a particular space of human activity (health), as the provision of goods are opened up to, or deferred to, private firms to produce, sell, and profit from. Within the context of health, replaces health as a public good with the production of health as a form of commerce. <sup>73</sup>
Public Good**	A good or service product that often, though not always, is under-provided in a free market because they are non-excludable and non-rivalrous.
Public Good, Global (GPG)	A public good “marked by universality,” that is, the benefits of which are available to all of humanity, whether countries, population groups, or current and future generations. <sup>74</sup>

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<sup>69</sup> Barnett and Duvall, “Power in International Politics,” 39.

<sup>70</sup> Navarro et al., “Politics and health outcomes.”

<sup>71</sup> Barnett and Duvall, “Power in International Politics,” Dahl, “The Concept of Power,” Dahl, Robert, *Who Governs? Democracy and Power in an American City*, Moon, “Power in Global Governance: An Expanded Typology from Global Health,” and Bourdieu, “The Forms of Capital.”

<sup>72</sup> Wagner, “The Theory of Games and the Problem of International Cooperation.” See also Rousseau, *A Discourse on Inequality*.

<sup>73</sup> See Vaitinen, Hoppania, and Karsio, “Chapter 27: Marketization, Commodification and Privatization of Care Services”; Marchand and Runyan, *Gender and Global Restructuring: Sightings, Sites and Resistances*.

<sup>74</sup> Kaul, Grunberg, and Stern, *Global Public Goods: International Cooperation in the 21st Century* (1999).

Term	Definition or Description
Rationalism	Methodological approach or analytical framework for theorizing world politics and social relations that applies, either formally or informally, Rational Choice Theory, Microeconomic theory (e.g., public goods), Game Theory, or any other positivist exercise in explaining socio-political and economic relations, primarily from the 'bottom-up' in terms of gain-maximizing or goal-seeking behavior. <sup>75</sup>
Rational Choice Theory	Actors, including states and individuals, rely on rational calculations to make rational choices that result in outcomes aligned with their own best interest.
Realism	A leading school of thought in International Relations and International Political Economy that assumes sovereign states are the principal and leading actors in the international system; the global system itself is anarchic; states are motivated solely by national interests; and states will compete and conflict to produce absolute, not relative, gains.
Reference Pricing	A pharmaceutical pricing and access (P&A) policy wherein actors purchasing or reimbursing for pharmaceuticals derive the maximum allowable cost (MAC), ceiling price, or maximum allowable reimbursable price for a particular drug referring to other prices, whether those prices are 'internal' (i.e., other prices paid for the same drug by that state, firm, or other actor) or 'external' (i.e., other prices paid for the same drug by other states, firms, or other actors).
Reference Pricing, External**	Example of pharmaceutical P&A policy wherein the negotiated or established price; profit controls; rate of return regulation; or other mechanisms for setting either a fixed maximum price or the parameters that can influence the purchase price of a pharmaceutical protected by intellectual property rights is established based on a comparison to international prices. One of two forms of reference pricing.

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<sup>75</sup> Suggested by Katzenstein, Keohane, and Krasner (1998) as one of the main axis of debate in International Relations, the other being Constructivism; see "International Organization and the Study of World Politics." This research applies the Fearon-Wendt (2005 [2002]) definition and extends it to the study of international economic relations, as well as politics; see "Rationalism v. Constructivism: A Skeptical View," 54. For further discussion of Rationalism specifically, see Johnston and Callender, "Multiple Perspectives on Economic Rationalism and the New Managerialism: Power and Public Interest?"

Term	Definition or Description
Reference Pricing, Internal	Example of pharmaceutical P&A policy wherein the negotiated or established price is derived based on the relative or comparative value or efficacy of a particular pharmaceutical referenced against the prices of therapeutic equivalents to drive medicine use to more cost-effective therapies. The policy ultimately negotiates or directly establishes the price paid for such medicines within a specific class either the maximum of the more cost-effective alternative or on pricing terms that aim to encourage access to the more cost-effective medicine. One of two forms of reference pricing.
Regulation, International**	The elevation of converged or harmonized policy to the level of international rules and obligations, including hard law treaties, soft law declarations, private orders and codes of conduct, and other formalized global norms and practices upheld in the global political economy, whether by states themselves or nonstate actors.
Regulatory Coordination**	The codified mutual adjustment of national standards, policies, and rules to recognize or accommodate other countries' regulatory frameworks.
Rivalry	One of two essential traits of public goods, referring to the benefits of a good that accrue to one do not diminish the benefits left for others.
Selection Mechanism	State action through direct and indirect expressions of power (e.g., formal policy and rules, influence of international priorities, public statements), that generates, stimulates, and determines a positive firm response favorable to capital accumulation. A negative variant would discourage or exclude anticapitalist possibilities in policy and practice.
Social Determinants of Health (SDH)	“The conditions in which people live and work, and that affect their opportunities to lead healthy lives,” <sup>76</sup> which include “the range of personal, social, economic, environmental, and political factors which determine health status and outcomes.” The WHO and extant literature note the significant correlation with the main risk factors for noncommunicable disease (NCDs), which exist outside the domain of the health sector. Examples include poverty, globalization, trade, education, urbanization, climate change, employment conditions, and gender disparities, among others. <sup>77</sup>

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<sup>76</sup> Labonté and Schrecker, “Globalization and Social Determinants of Health: Introduction and Methodological Background,” 2.

<sup>77</sup> Dorch, Bailey, and Stoto, Understanding Health and Its Determinants; Braveman and Gottlieb, “The Social Determinants of Health: It’s Time to Consider the Causes of the Causes,” Commission on Social Determinants of Health and Organization, Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health.

Term	Definition or Description
Specialty Pharmaceutical	Medicines that treat chronic, complex or rare diseases, and that have at least four out of seven additional characteristics related to the distribution, care delivery and/or cost of the medicine, including: list prices exceeding 600 USD per annum, requiring administration by a physician (i.e., not self-administered), requiring special handling, distributed through non-traditional channels, and requiring additional patient monitoring of therapy, among other qualifiers.
Structural Adjustment Program (SAP)	Loan packages conditioned on the adoption of neoliberal reforms and related domestic economic policies for developing countries promoted by the World Bank Group and International Monetary Fund.
Values**	Rank-ordered ideas about what is desirable, transcending specific situations, which guide behavioral choices and influence evaluations.
World Bank Group (TWB)	Established at the United Nations Monetary and Financial Conference of 1944 as the International Bank for Reconstruction and Development (IBRD), though its name has since changed. Includes the IBRD, International Development Association (IDA), International Finance Corporation (IFC), Multilateral Investment Guarantee Agency (MIGA), and International Center for Settlement of Investment Disputes (ICSID).



## APPENDIX B

### TARGETS, INDICATORS, DIMENSIONS OF INEQUALITY, AND GOALS RELATED TO THE UNITED NATIONS SUSTAINABLE DEVELOPMENT GOAL (SDG) 3

Target	Indicator	Dimensions of Inequality
2.2.1	Stunting prevalence in children aged <5 years (%)	Age; Economic Status; Education; Place of Residence; Sex
2.2.2	Overweight prevalence in children aged <5 years (%)	Age; Economic Status; Education; Place of Residence; Sex
2.2.2	Wasting prevalence in children aged <5 years (%)	Age; Economic Status; Education; Place of Residence; Sex
3.1.1	Maternal mortality ratio (per 100,000 live births)	
3.1.2	Births attended by skilled health personnel (in the two or three years preceding the survey) (%)	Economic Status; Education; Place of Residence
3.2.1	Under-five mortality rate (deaths per 1000 live births)	Economic Status; Education; Place of Residence; Sex
3.2.2	Neonatal mortality rate (deaths per 1000 live births)	Economic Status; Education; Place of Residence; Sex
3.3.1	Number of new HIV infections (per 1000 uninfected population)	Sex
3.3.2	Tuberculosis incidence (per 100 000 population)	Age; Sex
3.3.3	Malaria incidence (per 1000 population at risk)	
3.3.4	Hepatitis B incidence (per 100 000 population)	
3.4.1	Mortality rate attributed to cardiovascular disease, cancer, diabetes mellitus, or chronic obstructive respiratory disease (%)	Sex
3.4.2	Suicide mortality rate (per 100,000 population)	Age; Sex
3.5.1	Coverage of treatment interventions for substance-use disorders (%)	

Target	Indicator	Dimensions of Inequality
3.5.2	Total alcohol per capita consumption in adults aged 15+ (liters of pure alcohol)	Sex
3.6.1	Road traffic mortality rate (per 100 000 population)	
3.7.1	Demand for family planning satisfied – use of modern methods (%)	Age; Economic Status; Education; Place of Residence
3.8.1	Universal health coverage service coverage index	
3.8.2	Proportion of population with >10% household expenditures on health (%)	Place of Residence
3.9.1	Mortality rate attributed to household and ambient air pollution (per 100,000 population)	Sex
3.9.2	Mortality rate attributed to unsafe water, unsafe sanitation and lack of hygiene (per 100,000 population)	Sex
3.9.3	Mortality rate attributed to unintentional poisoning (per 100,000 population)	Sex
3.a.1	Prevalence of tobacco use among persons over 15 (%)	Sex
3.b.1	DTP3 immunization coverage among 1-year-olds (%)	Economic Status; Education; Place of Residence; Sex
3.b.1	Measles immunization coverage among 1-year-olds (%)	Economic Status; Education; Place of Residence; Sex
3.b.1	Polio immunization coverage among 1-year-olds (%)	Economic Status; Education; Place of Residence; Sex
3.d.2	Proportion of bloodstream infections due to antimicrobial resistant organisms (%)	
4.2.1	Proportion of children aged <5 years developmentally on track (health, learning and psychosocial well-being) (%)	
5.2.1	Proportion of women (15-49) subjected to violence by current or former intimate partner (%)	
5.6.1	Proportion of women (15-9) who make their own decisions regarding sexual relations, contraceptive use and reproductive health care (%)	
6.1.1	Proportion of population using safely managed drinking-water services (%)	Place of Residence
6.2.1	Proportion of population using safely managed sanitation services (%)	Place of Residence

Target	Indicator	Dimensions of Inequality
16.2.1	Proportion of children (aged 1-17) experiencing physical or psychological aggression (%)	
7.1.2	Proportion of population with primary reliance on clean fuels (%)	
11.6.2	Annual mean concentrations of fine particulate matter (PM <sub>2.5</sub> ) in urban areas (µg/m <sup>3</sup> )	
16.2.1	Proportion of children (aged 1-17) experiencing physical or psychological aggression (%)	
66.10	Prevalence of raised blood pressure among persons aged 18+ years (age-standardized) (%)	Sex
66.10	Prevalence of obesity among adults (%)	Sex
66.10	Prevalence of obesity among children and adolescents (5-19) (%)	Sex
68.3	Number of cases of poliomyelitis caused by wild poliovirus (WPV)	
68.3	Proportion of health facilities with essential medicines available and affordable on a sustainable basis (%)	
68.3	Vaccine coverage for epidemic-prone diseases	

Author-compiled based on Adhanom Ghebreyesus, “World Health Statistics 2021: Monitoring Health for the SDGs, Sustainable Development Goals,” 119, Table A4.1.

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