

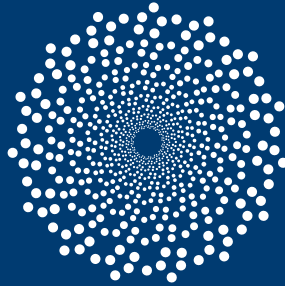


MEDICINE FOR ALL

THE CASE FOR A PUBLIC OPTION IN
THE PHARMACEUTICAL INDUSTRY

Dana Brown

For the Democracy Collaborative



DEMOCRACY
COLLABORATIVE

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September 2019

CONTENTS

- 3 Introduction**
- 11 PART 1: NOT FIT FOR PURPOSE**
The Current US Pharmaceutical Industry
- 31 PART 2: A MODEL FOR A DEMOCRATIC**
PUBLIC PHARMACEUTICAL INDUSTRY
- 73 Areas for Further Research and Exploration**
- 75 Notes**
- 85 About the Author**
- 86 About The Democracy Collaborative**

Acknowledgements

This paper is based on research undertaken with support from the Open Society Foundations. I would like to thank Thomas Hanna, John Duda, Dr. Andrés Cárdenas O’Farrill and Justin Mendoza for their insightful comments on an earlier draft. The final work is much improved as a result. Last but not least, I want to acknowledge the brave, determined, life-changing and life-saving work of the many individuals and organizations that make up the access to medicines movement. You have inspired and informed this work in innumerable ways.



Introduction

The pharmaceutical industry is critically important to any modern society—especially so in the United States, with its aging population, increasing incidences of chronic disease and steadily rising healthcare costs. Though we have a large and highly developed pharmaceutical industry, this essential industry is failing us on a number of fronts. It operates on an extractive model that contributes to inequality and increasingly produces drug shortages, inefficiency, lagging innovation, misinformation and misuse of medications, and most famously, the world's highest drug prices. Here we explore one systemic alternative, a public option, designed to meet the needs not only of our health system but of our society, economy, and democracy.

The US is already the largest pharmaceutical market in the world and that market is projected to keep growing.¹ But the enormous public investments we make into the pharmaceutical industry as it currently operates accrue almost entirely to private beneficiaries—principally a small group of shareholders and industry executives—contributing to growing health and economic inequality as well as rising healthcare costs. It also exemplifies regulatory and lawmaker capture, distorting our democracy. For an industry that eschews transparency, regularly practices anticompetitive behavior, and distorts evidence-based medicine, this is particularly dangerous.



These poor outcomes, however, are the natural consequence of an industry oriented around the singular goal of maximizing profit above all else. That imperative has dictated the design and functioning of the industry’s firms. In order to get different outcomes, we need a different design.

There have been no shortage of regulatory proposals to rein in high prescription prices and address drug safety issues, but no reform currently under serious consideration challenges the fundamental design of the pharmaceutical industry. Over the past several decades, the powerful industry has proven masterful at evading effective controls, and its success suggests that the only option for comprehensive reform is a transformational alternative that would fundamentally shift the balance of power in the sector and provide mechanisms for true transparency and accountability.

This paper outlines a model for one such structural alternative—public ownership in the pharmaceutical sector—and offers initial considerations about the potential benefits of such a model for national health and wellbeing, our economy and democracy.ⁱ Because public ownership is more flexible than private ownership—where shareholders and stock markets demand corporate boards maximize profits at all costs—it can be the vehicle for the designs we need to ensure that public health needs are prioritized by our pharmaceutical industry.

A truly transformed, democratically controlled pharmaceutical industry working for the public interest would be a powerful example for, and important pillar of, a new economy oriented toward the long-term health and wellbeing of communities. This proposal for a “public option” suggests the development of an ecosystem of publicly owned pharmaceutical companies

i Throughout this paper, we use the terms “public ownership” and “publicly owned” pharmaceuticals to refer to entities in which public institutions and bodies have at least a controlling stake. This is in contrast to private ownership, by which we mean any for-profit ownership form whereby non-state actors own at least a controlling stake of the enterprise.



at the federal, state, and local level aimed at aligning research and development (R&D), manufacturing, and distribution with public health needs and democratic principles.

A unique and important element of the model proposed here is its ability to produce improved outcomes for our health, economy, and democracy even in the absence of such interventions as patent reform, compulsory licensing, antitrust action, or changes to our health insurance system. The public option for pharmaceuticals described herein is complementary to each of these actions; however, it is not dependent upon them. Furthermore, a number of elements in the model could be established by subnational jurisdictions, meaning that breaking the stronghold that Big Pharma has on our medicine market does not depend on action from Washington. Each institution we propose can produce measurable benefits for health and society on its own and does not rely on the emergence of the complete ecosystem, though the benefits of the model would be amplified with each entrance into the public supply chain. Together, these aspects make such a public option in pharmaceuticals a powerful and practical approach to driving down prescription costs, ensuring a robust supply chain of safe and innovative medicines, and recentering public health needs.

Anticompetitive behavior in the private pharmaceutical industry can and should be reined in through complementary actions in patent reform and antitrust cases. Long-term affordable and equitable access to medicines would also be more easily achieved in the context of a single national formulary and sole insurance scheme, as we would see with a single-payer system. Nevertheless, a public option in pharmaceuticals should be pursued independent of advances on these fronts. The establishment of publicly owned pharmaceutical companies could even be a boon to some of these efforts by providing a counterbalance to Big Pharma, diversifying the pharmaceutical market, and building up democratically accountable and transparent public institutions that could shore up support for further public intervention in the healthcare sector.



The model proposed here includes federal-level public pharmaceutical R&D, state and municipal-level manufacturing, and a regionally organized distribution system that leverages new and existing public infrastructure to provide a full supply-chain “public option” for essential medicines. It envisions governance and oversight mechanisms for each of these public institutions, which would be designed to assure democratic and transparent operations. This would enhance their ability to meet the overarching goal of providing a safe, adequate, and accessible supply of essential medicines to the US while contributing to the overall health of our economy, democracy, and communities.

Far from a top-down, centralized approach, our model gives voice and power to communities across the country, strengthens local and regional economies, and allows for plurality and institutional innovation at the local level.

Based on an initial analysis of the legal and regulatory landscape, resourcing, and political considerations, recommendations include:

- Creation of a national public pharmaceutical institute within the Department of Health and Human Services (HHS) focused on research and development of new medications (i.e. innovation);
- Establishment of one or more state, municipal (city or county), or regional public pharmaceutical manufacturing enterprises;
- Creation of regional public wholesale distributors to assure efficient and cost-effective delivery of medications across the nation. This system might leverage existing public assets (such as the experience of the US Postal Service and the Veterans Health Administration in pharmaceutical distribution).

While a future system of publicly owned pharmaceutical companies could (and should) produce any number of drugs across all drug classes—eventually spanning the entire spectrum of essential medicines—this paper takes a



closer look at two specific examples, insulin and epinephrine autoinjectors, to illustrate the potential benefits of the model. Around seven-and-a-half million Americans use insulin to manage their diabetes, and one in five health care dollars (one in three Medicare dollars) is spent caring for patients with diabetes.² Millions of Americans also use life-saving epinephrine autoinjectors and numerous schools, childcare facilities, hospitals, and other institutions are required to stock them. Despite the fact that generic autoinjectors are now available in the US, this tightly controlled market still results in high prices and recurring, dangerous shortages.

Throughout the paper, examples of public ownership in the pharmaceutical sector from other countries are included. Examples of public ownership in other sectors of the US economy, principally the energy sector are also drawn upon (though public ownership is also prevalent in transportation, education, water provision, internet broadband, and land).

It is assumed that this model would emerge in a stepwise fashion and that, in the initial phases, public producers and purchasers would still be dependent on private service providers in some parts of the supply chain, but that over time, increased public capacity might obviate the need for private brokers in this industry.

Furthermore, it is assumed that in the short term, the health insurance landscape in the United States will remain a patchwork of public and private, group and individual plans, and that different insurers will retain varying abilities to negotiate drug purchasing prices. If single-payer or other legislation that would dramatically shift the health insurance landscape is passed in the future, there likely would be a number of shifts in the healthcare sector that would affect the pharmaceutical industry, many of which we assume would create further opportunities for public pharmaceutical companies. However, accounting for each of those eventualities is beyond the scope of this work.



Key Terms and Definitions

Access to medicines: The reasonable ability for individuals and populations to acquire the medicines needed to achieve health. The Lancet Commission on Essential Medicines defines the core barriers to access to medicines as “insufficient financing for medicines, unaffordability of medicines, assuring medicines’ quality and safety, appropriate use (e.g. of antibiotics), and missing medicines (i.e. gaps in therapeutic classes).”³

APIs: Active Pharmaceutical Ingredients. Substances used in the manufacture of medicines that have active properties in the final product.

Biosimilar drug: A biopharmaceutical compound designed to have similar properties to those of an already licensed biologic drug (as opposed to generics, which are similar to brand-name, chemically based pharmaceuticals).

Delinkage: According to the global health organization UNITAID, “the term [delinkage] can best be understood as partly technical—the separation of R&D costs from product prices—and partly polemical—a demand that the R&D system be reformed to accommodate universal access to knowledge goods, to induce openness and sharing of knowledge in general, and to make investments in R&D more cost-effective and responsive to the needs of patients and society.”⁴

Epinephrine autoinjector: A medical device that delivers the drug epinephrine, primarily used as an emergency treatment for anaphylaxis, a rapid-onset allergic reaction that can be deadly. It is often referred to in the US by the brand name EpiPen.

Essential medicines: According to the World Health Organization (WHO), essential medicines are those that satisfy the priority health care needs of the population. Essential medicines are selected with regard to disease prevalence, public health relevance, evidence of clinical efficacy and safety,



and comparative costs and cost-effectiveness. The WHO maintains a model list of essential medicines on which many national lists are based.

Insulin: A protein hormone used to treat high blood glucose. As a medication, insulin is not a single drug, but a class of drugs. Insulins may be divided into categories such as fast-acting, short-acting (including “regular insulin”), intermediate-acting (including NPH insulin), long-acting, ultra-long acting, and combination insulin products (among other taxonomies).

“Me too” drugs: Medications that are structurally very similar to others already available on the market, utilizing the same mechanism for the same purpose as the original compound. They offer little to no therapeutic advance compared to already available medications.

Neglected Tropical Diseases: Diseases prevalent in tropical and subtropical zones that disproportionately impact disadvantaged populations and are neglected due to the weak purchasing power of those most affected.

Orphan Drugs: Medications intended to treat rare diseases which, without outside support, are not deemed profitable enough for drug makers to fully develop given how small the market for each treatment is.

PhRMA: Pharmaceutical Research and Manufacturers of America, a trade group headquartered in Washington, D.C., representing a large number of drug companies. It is one of the most powerful lobbies in the US, spending more than \$27.5 million in lobbying in 2018.⁵

Pharmacy Benefit Managers (PBMs): A third party administrator of prescription benefit programs for insurers (including commercial insurers, self-insured employer plans and public programs like Medicare Part D). PBMs develop prescription formularies, process claims, negotiate rebates and discounts with manufacturers and contract with retail pharmacies.



Veterans Health Administration: The VHA is “the largest integrated health care system in the United States, providing care at 1,250 health care facilities, including 172 VA medical centers and 1,069 outpatient sites of care of varying complexity (VHA outpatient clinics) to over 9 million veterans enrolled in the VA health care program.”⁶



PART 1

Not Fit for Purpose

The current US pharmaceutical industry

The US represents the world's largest and most expensive pharmaceutical market, accounting for the majority of worldwide pharmaceutical company profits.ⁱⁱ Directly and indirectly, the industry supports more than 3.4 million jobs across the United States and added an estimated \$790 billion to the economy (as of 2014), though its operations also have significant negative effects on our economy, explored in detail below. The US has among the most favorable regulatory environments in the world for the commercialization of pharmaceuticals, which has played a significant role in the growth of the market over time.⁷

Many of the most powerful and top-earning pharmaceutical companies are US-based, including Pfizer, Merck, Gilead, and AbbVie. As such, their R&D priorities as well as their pricing practices have critical effects on the global supply of and access to medicines. These are generally large multinational companies with global supply chains, typically sourcing the majority of active pharmaceutical ingredients (APIs) from China and India. Most finished pharmaceuticals consumed

ii Due to the large disparity between what US buyers are forced to pay for medications and the prices garnered in the rest of the world, the US market is estimated to account for somewhere between 64 to 78 percent of global pharmaceutical profits.



in the US are manufactured domestically, however, with a significant portion coming from Puerto Rican manufacturing facilities owned by multinationals.⁸

Though smaller start-up companies (particularly in the biopharmaceutical sector) are playing an increasingly important role in the development of the industry, these companies often merge with or are acquired by larger “traditional” pharmaceutical corporations when they begin to show promise.⁹ Many of these alliances are short-lived, though, which can be detrimental to innovation given the complex, long-term nature of the R&D process. As a result, promising research may be discarded or “lost” when certain market targets are not met on timelines dictated by quarterly earnings reports.

In sectors like pharmaceuticals with high initial costs and powerful incumbent players, markets are often far from competitive. Already certain sections of the pharmaceutical supply chain have experienced significant concentration, with the three-firm concentration of US pharmacy benefit managers, wholesalers, and retailers at around 85 percent, 66 percent, and 49 percent respectively (though many reports put wholesale concentration significantly higher, at more than 85 percent).¹⁰ Concentration in generic drug manufacturing is particularly concerning given that generics account for the vast majority of prescriptions filled in the US and many generic essential medicines have seen recent and recurring price spikes (as highlighted in two recent price-fixing lawsuits against at least twenty generic drug manufacturers).¹¹ A National Bureau of Economic Research study of the US generic drug market from 2004-2016 found that “generally, concentration among manufacturers of generic drugs is very high and above Department of Justice horizontal merger guideline thresholds.”¹²

The US pharmaceutical supply chain

Here is how the standard US pharmaceutical supply chain is organized:

- Pharmaceuticals are manufactured in a staged process with the vast majority of APIs purchased from India and China.



- APIs and are then combined with other ingredients to create administrable drugs in the form of tablets, solutions and capsules in secondary manufacturing facilities and packaged in tertiary facilities.
- Finished drugs are then normally purchased by wholesale distributors who sell them on to retail, mail-order and other types of pharmacies at a markup. At this stage, many pharmaceuticals are subject to price negotiations and claims processing, implemented by pharmacy benefit managers (PBMs).
- Medications then go on to be dispensed by pharmacies and ultimately, delivered to patients.¹³

There are variations on this system, however, that occur with specialty drugs (which are not manufactured or distributed in bulk) or direct purchasing (where large institutions have the capacity to buy directly from manufacturers), for instance. Further variations arise as shifts in the industry occur, such as the increasing trend towards vertical integration.

Analysis of the flow of money through this supply chain suggests that with brand-name drugs, the majority of profit accrues to manufacturers, while with generics, the majority accrues to the various middlemen (wholesalers, PBMs, and insurers).¹⁴

Societal impacts

The modern US pharmaceutical industry is designed to be as financially successful as possible, above all other considerations. High prices are one natural outcome of (rather than a flaw in) this basic design, but there are many others. These can be grouped generally into three broad categories based on the effects they have on our society: harmful effects on population health, distortions of democracy, and economic exploitation.



1. Harmful effects on public health

The pharmaceutical industry's singular focus on profit creates multiple challenges with regards to access to medicines, which affects both population and individual health. According to the World Health Organization (WHO), "a well-functioning health system ensures equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost effectiveness, and their scientifically sound and cost-effective use."¹⁵ However, despite a highly technologically advanced healthcare system, the United States experiences issues in each of these areas: price and cost-effectiveness, quality, supply, safety, efficacy and proper usage.

a. Cost and supply-related access issues

Soaring drug prices have become a hot button issue across the political spectrum in the US—and with good reason. The US pays more for its pharmaceuticals than any other country in the world and many Americans report not filling prescriptions, cutting pills in half, or skipping doses due to costs.¹⁶ Despite increased pressure from politicians in both parties and the public, Big Pharma rang in 2019 with similar price increases as it has in previous years.¹⁷ Price spikes even in off-patent medications have become commonplace and affordability issues, especially for seniors, have garnered particular attention. A recent Senate Committee on Homeland Security and Government Affairs showed that over the last five years, the average annual price increase on the top 20 name-brand drugs prescribed for seniors has outstripped the rate of inflation by a factor of 10.¹⁸

Patients in specific disease groups also confront particularly acute affordability issues, especially when a small number of companies hold the patents on all or most of the available medications used to treat that disease (as is the case with Hepatitis C treatments and insulins, among others). Rising insulin prices have garnered much attention in recent years, with a



recent study reporting that the cost of insulin for Type 1 diabetics doubled between 2012 and 2016.¹⁹ Reports of death-by-insulin-rationing are becoming more frequent, and some studies show as many as “one in four patients ... reported cost-related insulin underuse,” resulting in poor health outcomes.²⁰ With list prices on some insulins having tripled since 2002, it should come as little surprise that lawsuits have been filed against the three major insulin producers for price fixing and deceptive pricing practices.²¹

Given the sheer size of the US pharmaceutical market and the number of medications bought and sold each day, one might assume that at least we have a reliable and sufficient supply of essential medications. However, we consistently see dozens of essential medications in almost all drug classes on the Food and Drug Administration’s (FDA) drug shortage list. A majority of hospitals are affected by these shortages.²² As of this writing, the list included 122 pharmaceuticals, from pain relievers to antibiotics, anesthetics, and chemotherapy drugs. Furthermore, evidence suggests that drug shortages have increased in frequency in recent years, with one report citing over 250 shortages in 2018.²³ At the time of this writing, we were still experiencing shortages of epinephrine after more than two years of public outrage—a dangerous prospect for patients at risk of anaphylaxis since timely treatment is essential to prevent possible permanent brain damage, kidney failure, and death.

In 2017, Hurricane María brought the issue of drug shortages into sharper focus for many both inside and outside the medical field. Since a significant portion of the US drug supply is manufactured in Puerto Rico, the hurricane showed just how vulnerable the supply chain is to disruption. In the weeks after the hurricane, there were shortages for around 40 critical

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Despite a highly technologically advanced healthcare system, the US experiences issues with price and cost-effectiveness, quality, supply, safety, efficacy and proper usage of pharmaceuticals.

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drugs, including some used to treat cancer, diabetes, and heart disease.²⁴ At the time, the entire supply of 13 of those drugs came from a single source—manufactured on the island—making them extremely susceptible to catastrophic “disruptions.” Bags of IV fluids—essential to emergency medicine—remained in short supply for over a year after the hurricane.²⁵ Incentives to seek ever higher margins on pharmaceutical sales have led many companies to vertically integrate, to reduce redundancies, and often rely on a single supplier for essential ingredients or even finished products, making the whole pharmaceutical supply chain increasingly vulnerable to shocks like the one that came with María.

Not only do drug shortages like these put health and safety at risk, they cost our health system hundreds of millions of dollars a year. One 2011 study (well before María) estimated \$200 million in additional annual costs due to the purchase of more expensive alternatives and another \$216 million in additional labor costs associated with shortages.²⁶

A related issue is “missing medicines.”²⁷ For example, the antibiotic development pipeline is drying up because the very nature of antibiotics (so critical to modern medicine) is antithetical to the profit motive. A therapy that is meant to be curative and taken only for a limited time does not a blockbuster drug make, and so pharmaceutical companies have been pulling out of antibiotic development in droves.²⁸ There is also a chronic lack of investment by Big Pharma in neglected tropical diseases, which are becoming more common in the United States due to both increased global travel and climate change.²⁹

b. Quality, safety, and proper usage

Disturbingly, many of the drugs that flood our market are not even safe for human consumption. A recent study showed that between 2001 and 2010, almost a third of novel drugs approved by the FDA had documented safety



issues after being introduced to the market.³⁰ There were 125 FDA drug recalls in 2018 alone, including a series of widely used blood pressure medications found to have cancer-causing impurities.³¹

Furthermore, the pharmaceutical industry has a documented history of dangerous and illegal misbranding of medications. These companies also spend tens of billions of dollars a year to influence doctors' prescribing decisions, using industry-sponsored research, suppression of data, kickbacks and perks for doctors, and much more. As doctor and author Ben Goldacre put it in his comprehensive review of the industry's influence over medical practice, "Since we all want doctors to prescribe medicine based on evidence, and evidence is universal, there is only one possible reason for such huge spends: to distort evidence-based practice."³²

The effects of these practices are perhaps most evident—and most alarming—when we look at the pharmaceutical industry's role in the current opioid epidemic, which has claimed over 400,000 lives so far.³³ It is now apparent that the industry long knew of the addictive and dangerous potential of their opiate products, especially after three top executives from Purdue Pharma pled guilty to criminal charges related to the misbranding of its blockbuster opiate OxyContin and the company announced it would no longer directly market the drug to doctors.³⁴

Over the course of just a few years, Big Pharma has been forced to pay over \$13 billion in fines for a variety of fraudulent and dangerous marketing practices that go way beyond opiates.³⁵ For example, in 2013 Johnson & Johnson agreed to pay \$2.2 billion in fines to settle a case about the promotion of several drugs for uses not approved by the FDA as safe and for the payment of kickbacks to doctors. The year prior, Amgen agreed to a settlement of \$762 million for illegally promoting several drugs for non-medically acceptable uses and even illegally selling one drug at doses that had been explicitly rejected by the FDA as unsafe.



The industry's financialization trend (explored in detail in section 2) is another way the industry's profit-centric orientation adversely affects public health. This is because financialization contributes to economic inequality, itself an important predictor of health outcomes, as well as economic instability, which disproportionately affects marginalized communities.³⁶

The profit motive also encourages differential pricing, which disproportionately affects disenfranchised groups. Cost-related disparities in access to medications in the United States are well documented across age, gender, class, race, geography, educational attainment, and insurance status and type. Centers for Disease Control and Prevention (CDC) data show that 5.3 percent of men versus 7.9 percent of women in 2016 were unable to access necessary medications due to cost and 1.6 percent of the under 18 population had difficulty accessing required medications due to cost as opposed to 9.4 percent of 45-to-55-year-olds. African Americans below the poverty line had more price-related difficulties in accessing medications than their white or Latino counterparts also living below the poverty line, and those in rural areas had more difficulty than those in urban areas.³⁷

Returning to the example of insulin, the most recent version of the American Diabetes Association's detailed annual report, *the Economic Costs of Diabetes in the US*, shows that patients under 45 years of age pay significantly higher prices for their insulin than patients of other age groups, and that non-Hispanic African Americans pay the most per capita of any racial/ethnic group tracked (\$695 per patient per year in 2017 as opposed to the average \$607 per patient per year or the \$498 that non-Hispanic "others" pay).³⁸ Furthermore, public insurers significantly pay more per capita for insulin than private insurers or the uninsured.

The practice of pharmaceutical development as a profit-making enterprise has also had some more direct effects on vulnerable populations, principally through the historic practice of testing medications on prisoners and the



current practice of paying people to participate in trials (which results in an overrepresentation of poor and homeless populations, where there are ethical questions about undue inducement and informed consent). Clinical trials are also a globalized industry (keeping costs low for the industry by “offshoring” the patient population), and in many countries, participation in a trial may be the only way to access treatment for some ailments, raising further questions about the ethics of these trials.³⁹

Pharmaceutical companies have also patented and benefited from indigenous medical knowledge in a practice referred to as “biopiracy.” They claim exclusive rights to traditional treatments, refusing to compensate communities for their knowledge and instead charge the same communities (and the broader public) for access to their “inventions.” They often put local “competitors” out of business though they had provided the traditional treatments for many years.

Lastly, while the poor and disenfranchised are disproportionately penalized by all these trends, the financial gains of the industry largely accrue to a small elite group, further broadening the divide between the “haves” and the “have-nots.” The top 50 pharmaceutical companies are, as a group, significantly below the average in the Fortune 500 when it comes to gender and racial diversity on their boards.⁴⁰ The management teams of those top 50 companies are even less gender-diverse than their boards. In the industry as a whole, men tend to earn significantly more than women and there are considerable racial disparities in wages across job classes in the industry.⁴¹ Furthermore, among companies in the S&P 500, CEOs of pharmaceutical companies (who disproportionately represent our most privileged classes) earned, on average, 71 percent more than CEOs of non-pharmaceutical companies.⁴²



2. Economic exploitation

In many cases the profits extracted by drug companies represent a form of double-taxation, given that public funding underpins R&D. Despite persistent claims by the pharmaceutical industry that their R&D costs necessitate ever higher price tags on prescriptions, research has shown that about 75 percent of new drugs (those that are not just variations of existing medications) are developed with funding from the National Institutes of Health (NIH), which spends upwards of \$32 billion on research annually.⁴³ According to economist Mariana Mazzucato, the NIH has invested close to \$1 trillion since the 1930s in the research that underpins the entire modern pharmaceutical industry.⁴⁴

A 2011 study showed that almost two-thirds of the FDA’s “priority review drugs” (new drugs expected to have a particularly great impact on disease treatment) approved from 1988 to 2005 benefited from government-funded basic research.⁴⁵ A more recent study showed that each and every one of the 210 drugs approved by the FDA between 2010 and 2016 benefitted from NIH-funded basic research.⁴⁶

Other federal agencies support critical biomedical research that leads to breakthrough treatments as well. For instance, Department of Defense (DoD) funding contributed to the development of the highly successful prostate cancer drug Xtandi.⁴⁷ States can also play a role in pharmaceutical research and development, as with California’s investment in stem-cell research through the California Institute for Regenerative Medicine, or with Texas’s Cancer Initiative.⁴⁸

Thus, the public pays upfront for the majority of pharmaceutical R&D and then pays again either through out-of-pocket prescription costs, rising insurance premiums or our contributions to Medicare, Medicaid and other public programs. This is often called “double taxation.”



Government-funded research is heavily weighted towards the early stages of drug development. It accounts for the majority of basic research, which can include analyzing the therapeutic potential of various compounds, studying their toxicology and safety, and determining dosage and stability variables. These early stages of research are time-consuming and risky, with high costs and low returns, but they are essential to scientific progress.

According to Knowledge Ecology International, though the NIH budget as a percentage of PhRMA member R&D (for R&D performed in the US) has seen some decline over time, as of 2017 it still amounted to 52 percent of overall R&D, meaning that the NIH alone still accounts for more than half of the total R&D spend by Big Pharma each year.⁴⁹

Lost public revenue due to industry offshoring of profits and tax evasion is another adverse economic effect of how Big Pharma does business. In fact, 10 of the 30 US companies found to be holding the most money offshore when the Panama Papers were published in 2015 were pharmaceutical companies, together holding over \$506 billion in offshore profits. Pfizer alone was found to be operating 157 subsidiaries in offshore tax havens, where it held \$198.9 billion dollars in profits.⁵⁰

A particularly popular offshoring tactic used by pharmaceuticals is what is referred to as a corporate inversion (or tax inversion), in which a company relocates its legal residence to a lower tax jurisdiction while maintaining its material operations in the higher tax jurisdiction. That effectively makes the original company a subsidiary of the new, foreign-based company, through which profit streams are funneled to avoid paying taxes in the higher tax jurisdiction.

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On corporate inversions in recent decades, as one reporter put it, “No industry went as big or as bold as pharma. Health-care companies have attempted a disproportionate number of such deals. Valeant and Allergan notably used inversions to go on serial acquisition sprees.”⁵¹

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More recently, Eli Lilly was one of 60 companies found to have paid no federal income tax at all in 2018, instead receiving a \$54 million rebate.⁵² Tax avoidance by corporations at this scale can have numerous harmful effects on our society. For one, it increases inequality by shifting the tax burden to residents who are forced to pay their share while giant corporations (that benefit from public infrastructure and in this case, public investment in scientific R&D) are not so obligated. Moreover, the savings for corporations further advantage the richest members of our society who, by and large, are the major shareholders of such businesses. Given how economic inequality affects health outcomes, this pharmaceutical industry practice is particularly egregious. The disparity between what average citizens and powerful corporations must contribute also undermines the perceived fairness of our society and risks undermining state legitimacy.

Also egregious is the way the industry has chosen to spend its money. While public sources account for the majority of R&D funds coming into the industry, pharmaceutical corporations themselves spend more resources on drug marketing in the US—which is outlawed in every other country except New Zealand—than they do on R&D.⁵³

In the example of insulin, where 99 percent of the market is controlled by Eli Lilly, Sanofi Aventis and Novo Nordisk, these three companies’ R&D spending versus marketing spending illustrates this larger trend.⁵⁴ In 2017, Novo



Nordisk spent 12.5 percent of revenue on R&D (as a share of revenue) versus 28.8 percent on marketing and overhead, Eli Lilly spent 23.1 percent versus 28.8 percent and Sanofi Aventis spent 15.6 percent versus 28.7 percent.⁵⁵

Furthermore, despite all the public (and private) funds ostensibly needed to fuel innovation being pumped into pharmaceuticals, by all accounts the industry has become less innovative as it has become more financialized. From the 1960s onward, companies across industries in the US shifted from a “retain and reinvest” strategy, in which profits were reinvested in the company workforce and other productive assets, to one of “downsize and distribute,” in which companies downsized in order to distribute more profit to shareholders.⁵⁶ Pharmaceutical companies were no exception. According to a study by the Institute for New Economic Thinking, many large drug companies “routinely distribute more than 100 percent of profits to shareholders, generating the extra cash by reducing reserves, selling off assets, taking debt, or laying off employees.”⁵⁷ This strategy has the dual effect of generating great returns for a small number of executives and shareholders while dampening innovation. As study author William Lazonick stated in a New York Times interview, “there really is very little drug development going on in companies showing the highest profits and capturing much of the gains.”⁵⁸

Reporting shows that 20 of the 25 pharmaceuticals with the fastest growing prices over a recent two-year period were companies owned in part by hedge funds or private equity firms. The drive to maximize profits for these hyper-extractive shareholders fuels skyrocketing drug prices and puts the profit motive when developing drug pipelines ahead of any public health priorities, resulting in a glut of “me-too” drugs to treat chronic conditions and a dearth of medications for critical illnesses like antibiotic-resistant infections. In fact, the case can, and has, been made that high prices are less a reflection of the costs or efficacy of treatments and more signals to investors about which companies might be the most profitable investments.⁵⁹



The modern pharmaceutical industry also exhibits a number of anticompetitive behaviors that have detrimental effects on our economy. Among these are price fixing and “patent gaming.” According to the Federal Trade Commission (FTC), price fixing is “an agreement (written, verbal, or inferred from conduct) among competitors that raises, lowers, or stabilizes prices or competitive terms.”⁶⁰ A prominent price fixing case in the industry ongoing at the time of this writing alleges anticompetitive behavior among at least 18 generics manufacturers (including Mylan, which controls the majority of the epinephrine autoinjector market) involving more than 300 drugs.⁶¹ According to Connecticut Assistant Attorney General Joseph Neilson, it is “...likely the largest cartel in the history of the United States.”⁶² A complementary case was filed in May 2019 by 44 states.⁶³ Insulin has also been the subject of at least one of its own price-fixing lawsuits.⁶⁴

In “patent gaming,” patent holders seek to lengthen the amount of time their branded products retain market exclusivity, thereby allowing them to continue to extract exorbitant prices. Among their tactics is what is referred to as “pay-for-delay,” in which brand-name manufacturers pay generics manufacturers to delay their competing drug’s entry into the market.⁶⁵ A 2019 Kaiser Health News analysis revealed the impact on the market: 43 percent of the generic drugs approved by the FDA since 2017 are not for sale in the US, often because they have been kept off the market by their manufacturers.⁶⁶ According to the FTC, such deals add \$3.5 billion to drug spending every year.⁶⁷

Among the patent-gaming tactics drug companies employ frequently is the use of “citizen petitions” to the FDA, which force the agency to suspend approval of a generic for 150 days. Industry firms also sometimes simply refuse to turn over drug samples to generics manufacturers for study, impeding their progress towards generic development. Patent holders also take advantage of the 180-day market exclusivity granted to the first generic equivalent of a drug by releasing their own “authorized generic,” which



is actually just their brand-name drug sold under another name.⁶⁸ Finally, some use incentives intended to further research on orphan drugs to extend patent exclusivities on existing treatments by claiming new uses for those drugs.⁶⁹

A related, but distinct, issue arises around medications that continue to garner high prices despite having been off-patent for years. This occurs when no company ever applies to the FDA for approval of a generic equivalent, meaning that the brand name continues to exert monopoly control over that sector of the market despite its patents having expired. Rather than being bribed to stay out of some markets, in this case generics manufacturers may simply decide that the market is too small or the margins too low for them to bother. Unfortunately for consumers (and insurers) this means that, as of March 2017, more than 180 off-patent drugs had no generic equivalent on the US market.⁷⁰ Among those drugs are the antiparasitic Albendazole, which can cost around \$400 for a course of treatment (versus a few cents in other countries where generics are available) or Thyrotropin Alpha, used in the treatment of thyroid cancer, which retails at around \$3,000 per treatment.⁷¹

3. Distortions of democracy

The extraordinary extent of regulatory capture the pharmaceutical industry has achieved is responsible for its most deleterious effects on our democracy. According to the Center for Responsive Politics, pharmaceuticals spent more than any other industry on lobbying in 2018—a grand total of \$282 million—and employed more than two lobbyists per member of Congress (totaling 1,451).⁷² Additionally, there is a well-documented revolving door between Big Pharma and the government agencies tasked to regulate it. According to a recent Kaiser Health News investigation, “in many cases, former congressional staffers who now work for drug companies return to the Hill to lobby former co-workers or employees. The deep ties raise concerns that



pharmaceutical companies could wield undue influence over drug-related legislation or government policy.”⁷³

Looking just at the example of insulin for fiscal year 2018, the insulin Big Three logged \$15,457,600 in total lobbying expenses, Eli Lilly spending \$6,770,000 of that with 62 lobbyists, including 51 “revolvers;” NovoNordisk spent \$4,007,600 with 24 lobbyists, including 17 “revolvers;” and Sanofi Aventis spent \$4,680,000 with 44 lobbyists, including 42 “revolvers.”⁷⁴ The most prominent of those “revolvers” is current Secretary of Health and Human Services, Alex Azar, former Eli Lilly president. While he was president of Eli Lilly, the company increased the price of its blockbuster insulin, Humalog, from \$74 to \$269 per vial. (During the same period in Sweden, the same dosage of Humalog was reimbursed at \$18.38, still a profitable price for Lilly.)⁷⁵

In the epinephrine autoinjector market, dominated by Mylan (but with Pfizer, Teva, and Kaleo playing important roles as well), total lobbying expenses in 2018 were \$17,340,000. Together, these four companies employed 103 lobbyists in 2018, 80 of whom—including all 10 of Teva’s lobbyists—were “revolvers.”

This magnitude of influence over government is reflected in “victories” like a historic amendment to the 2003 legislation that created Medicare Part D, the privately administered prescription drug component of the government-run health plan for seniors. The amendment banned the government from negotiating lower drug prices for the covered medications, resulting in billions of dollars in extra profit for the industry.⁷⁶ A study published by the National Bureau of Economic Research in January 2019 found that “Medicare Part D drug benefit spending has increased 74 percent since 2007, [and] the precipitous growth in government spending has come not primarily from the number of beneficiaries receiving reinsurance *but from the cost per prescription*” (emphasis added).⁷⁷



Perhaps even more concerning is the industry's influence on the FDA, which is responsible for overseeing goods and services worth around one quarter of total US gross domestic product.⁷⁸ Though some of its hearings are public, many "discussions and negotiations that figure prominently into FDA decisions involve *only* FDA employees and drug industry representatives, with the FDA outmanned and out-financed by industry," a 2007 report in JAMA Internal Medicine found.⁷⁹ The industry also partially finances the operations of the FDA (through payments for drug application screening), making the FDA dependent on the industry for its annual budget. In fact, corporate "user fees" now account for at least 70 percent of the funds destined for prescription drug oversight.⁸⁰ In order to keep those funds coming in, the FDA is legally mandated to negotiate with the industry every five years regarding how the FDA undertakes those oversight tasks. The same legislation (passed in 1992) forces the FDA to push drug approvals through much faster than before, and perhaps not coincidentally, the percentage of drug applications approved on their first try has grown exponentially, from 35 percent in 1993 to 95 percent in 2015. Evidence suggests that medications subject to expedited approval pathways like this have higher rates of post-market safety issues.⁸¹

The pharmaceutical industry's inherent lack of transparency is a serious democratic concern, since transparency and democracy are intimately intertwined. Only when citizens have access to information can they fully participate in the political process. As the pharmaceutical industry in its current form is substantially removed from direct democratic control, transparency becomes even more important in empowering the public with the information to hold elected officials and public institutions to account in their regulation and oversight of such business.

As evidenced in the recent push for transparency pricing bills, the public (and lawmakers) find it very difficult to understand exactly where high drug prices come from or even what the true price of any given medication



actually is for a given purchaser. With a myriad of different prices referenced in different contexts (the wholesale acquisition cost, the list price, Medicaid best price, average manufacturer price, average sales price, etc.) it is nearly impossible for consumers (i.e. patients) to have access to the information necessary for them to play their role as “discriminating purchasers” in a market. For the same consumers to then play any meaningful role in holding the industry to account through the democratic process would require much greater access to information about the true cost of their medications and the inner workings of the industry. For consumers to act as informed voters regarding policy proposals put forth to combat high prices, they must be provided clear and comprehensible information about what creates those high prices in the first place, which is patently not the case currently.

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When sufficiently removed from true democratic control, the pharmaceutical industry is permitted to make decisions that are bad for our health.

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Vertical integration further exacerbates confusion over the true cost of our medicines; the flow of money back and forth between different links in the pharmaceutical supply chain in the form of rebates and insurance payments increasingly obscures the actual price of products.⁸² Though there have been several attempts to demand more transparency in drug pricing, there is little evidence that current proposals will actually make a difference in end-user prices.⁸³ The profit motive also incentivizes a lack of transparency about research and clinical trial data, keeping both significant information on drug safety and efficacy from being publicly available *and* slowing down innovation by making information on scientific advances the property of individual firms.

Here we see the issue of transparency intersecting with health outcomes, but also again with the democratic process. As in the case of regulatory capture, when sufficiently removed from true democratic control, the



pharmaceutical industry is permitted to make decisions that are bad for our health—whether that be the decision to rush a potentially unsafe drug to market or the decision to withhold important information about clinical efficacy discovered in the R&D phase from both doctors and patients.

Conclusion

The US pharmaceutical industry benefits from significant support from the public sector, from federal grants to subsidies and tax breaks, as well as a favorable regulatory environment. It is also an industry of strategic importance, as its products are essential for an optimally functioning health system. However, skyrocketing prices, chronic shortages, recurrent safety issues, anticompetitive behavior and distortions of democratic practice reveal that the commanding power of the profit motive has given rise to a pharmaceutical industry that is harmful to our society. Far from being evidence of aberrations in how the pharmaceutical sector functions, the harmful effects of the industry on our economy, health and democracy are directly related to a key design feature of the current industry—a corporate form that puts profit maximization above all else. Public investment in the pharmaceutical sector should be structured to assure maximum public benefit. This is clearly not the case with the current functioning of our pharmaceutical industry. In order to achieve truly different results from the pharmaceutical sector, we must look to a new design for its companies.



PART 2

A Model for a Democratic Public Pharmaceutical Industry

Americans are becoming increasingly aware of the noxious effects of the private pharmaceutical industry's greed and are eager for an alternative.

However, the entrenched power of the industry makes it difficult to regulate. For this reason, attempts to control medicine prices and ensure a sufficient and safe supply have been insufficient. Advances are few and far between, and they are always vulnerable to rollbacks or new strategies by the industry to work around any constraints imposed on it. This is why it is essential that we explore systemic alternatives. Only by fundamentally altering the structure and functioning of pharmaceutical companies will we achieve new outcomes. The alternative we explore here is a “public option” comprised of democratic, publicly owned enterprises across the pharmaceutical supply chain.

As publicly owned enterprises are not beholden to the profit motive, they have a flexibility that for-profit companies do not to be more responsive to community needs, as communities ultimately own these enterprises through the



jurisdictions in which they operate. Public enterprises can be designed to go beyond existing transparency legal requirements to ensure robust popular participation and accountability. They also play an important role in returning revenue to public balance sheets, which, we will discuss later, can be directed to address specific community needs.

Polls already show growing support—across party lines—for public production of medicines.⁸⁴ This corresponds with renewed interest in public ownership across a variety of sectors around the world due to the role it can play in addressing critical public policy needs.⁸⁵ A number of existing international examples show how public ownership in the pharmaceutical sector, in any and all links in the supply chain, can be highly successful at producing positive health outcomes, satisfying health system demand for essential medications, and generating revenue to fund critical public services. Numerous cases of public ownership in other sectors in the US also provide important models that correspond to the country’s unique legal and regulatory context.

What follows is an outline of a model for an ecosystem of democratic, publicly owned pharmaceutical companies directed by public health needs as a transformative alternative for this key sector of our economy. These entities need not, and should not, reflect the highly centralized, top-down and often bureaucratic forms of public ownership of the past. Rather, they should reflect the best practices and lessons learned from more democratic and transparent forms of public ownership emerging around the globe. In an industry that not only represents an important (and growing) portion of our economy, but whose operations directly affect the health and wellbeing of our communities (and the planet), enhancing democratic control, transparency, and accountability is imperative. Furthermore, creating publicly owned institutions that are embedded in and responsive to community contributes to the long-term durability and effectiveness of those institutions.

Cuba's public pharmaceutical success story

Cuba has one of the most robust and fastest growing public biopharmaceutical industries in the world. It is known for achievements in vaccine development and production, as well as the development of drugs to treat chronic kidney disease, reduce the risk of diabetes-related amputations, and manage HIV/AIDS. The industry is characterized by long-term public financial investment, organizational integration, and strategic state control over the allocation of human and financial resources.

The industry's success in Cuba can be measured by its numerous technology transfer agreements, its coverage of the majority of domestic demand for medicines, as well as its exports, profit margins, return on investment and consistently positive cashflow. Its prioritization of public health is evident in its deep integration into the larger healthcare system and its development of affordable vaccines and medications for diseases that most affect poor populations. The industry produces medicines in every therapeutic category, holds thousands of international patents, and has garnered a number of UN World Intellectual Property Organization innovation awards. It both develops first-in-class therapies and manufactures low-cost generics.

Among the innovations to come out of this system is the lung cancer vaccine CimaVax, which garnered acclaim as the first vaccine for the world's most common fatal illness. A reported 5,000 patients worldwide have been treated with the vaccine thus far and each injection only costs \$1 to make. CimaVax is so promising that clinical trials are being run in the US, UK, Canada, Japan and some European countries.

This productive public pharmaceutical industry came to be after the sector was nationalized in 1960. Existing and new companies were then consolidated under the auspices of the Ministry of Health (later transferred to the Ministry of Basic Indus-

try). Starting in the 1980s, the nation really began developing its biotechnology capacity and in the period from 1990-1996 alone invested \$1 billion into that sector. In 1991, the Western Havana Scientific Pole was inaugurated to house many of the industry's companies and in 2012 the biotech and pharmaceutical sectors were integrated through the creation of the corporate entity BioCubaFarma.

Pharmaceutical R&D, manufacturing and marketing occur in a “closed cycle,” much like a vertically integrated industry, though horizontal collaboration is equally important to and integrated into the system. A collaborative approach to R&D has contributed to the industry's impressive innovation track record, especially given the resource constraints of the island. For instance, Cuba's Haemophilus influenzae type b vaccine—the world's first synthetic antigen vaccine—was the result of a collaboration between five institutions spanning academia and industry. Additionally, the industry's patents are owned by the state but the associated information and data are shared freely among firms in the biotechnology cluster to advance new research and product development. Even equipment and manufacturing lines are shared among firms collaborating on projects.

Sources: “Cuban experience with local production of medicines, technology transfer and improving access to health,” *World Health Organization*, 2015, https://www.who.int/phi/publications/Cuba_case_study121115.pdf; “Polo Científico del Oeste de La Habana,” EcuRed, https://www.ecured.cu/Polo_Cient%C3%ADfico_del_Oeste_de_La_Habana; “Treatment research for lung cancer,” Cancer Research UK, <https://www.cancerresearchuk.org/about-cancer/lung-cancer/research-clinical-trials/research-treatment>; Rob Baggott and George Lambie, “Enticing case study” or “celebrated anomaly”? Policy learning from the Cuban health system”, *International Journal of Health Planning and Management*, September, 2017: <https://onlinelibrary-wiley-com.proxy-um.researchport.umd.edu/doi/full/10.1002/hpm.2451>; Andrés Cárdenas, “The Cuban Biotechnology Industry: Innovation and universal health care,” Institute for Institutional and Innovations Economics, University of Bremen, Germany, November 2009, <https://pdfs.semanticscholar.org/df8b/95006fb835075a7b50a51cf3f61273b00304.pdf>; Deborah Evenson, “Cuba's Biotechnology Revolution,” *MEDICC Rev.* 2007;9(1):8-10, <http://mediccreview.org/cubas-biotechnology-revolution/>; Alan Gomez and Liz Szabo, “Cuban cancer vaccine to be tested in US sparks a new scientific bond,” *USA Today*, May 13, 2015, <https://www.usatoday.com/story/news/2015/05/13/cuba-lung-cancer-vaccine-scientific-collaboration/27241137/>; Neel Patel, “Cuba Has a Lung Cancer Vaccine--and America Wants it,” *Wired*, May 11, 2015, <https://www.wired.com/2015/05/cimavax-roswell-park-cancer-institute/>; Erin Schumaker and Anna Almendrala, “Cuba's Had A Lung Cancer Vaccine For Years, And Now It's Coming To The US” *The Huffington Post*, May 14, 2015, http://www.huffingtonpost.com/2016/02/22/cuba-lung-cancer-vaccine_n_7267518.html



This model seeks to balance the high-level coordination and strategic planning required to ensure efficiency across the supply chain and the responsiveness and democratic accountability of locally controlled institutions through an ecosystem of independent, but interconnected, publicly owned pharmaceutical entities at various jurisdictional levels. There are unique roles for federal versus state and local-level enterprises due to the difference in the size of the budgets available to these jurisdictions, the existing capacities for scientific R&D and key differences in legal and regulatory contexts. However, at every level, it is imperative that the mission to provide a safe, adequate and accessible supply of essential medicines to the US (and beyond) be embedded in the charters or authorizing statutes of each entity.

Any transition to a public pharmaceutical model such as the one put forward here would likely occur in a stepwise fashion, with openings for change perhaps occurring first in one state or locality, rather than all at once across the nation. Therefore, after a summary of various components of a future public pharmaceutical ecosystem, each of the individual elements of that system are discussed in further detail, given that many could make significant contributions to public health and democracy even as stand-alone interventions and be deployed in different contexts and geographies.

The full model we explore here includes:

- A national public pharmaceutical research and development institute focused on developing new drugs according to public health needs;ⁱⁱⁱ
- State, local, and/or regional public pharmaceutical manufacturers;

iii This suggestion does not rule out the possibility of sub-national public entities engaging in biomedical R&D for medicines and medical technologies. In fact, some such entities already exist. For simplicity's sake, we describe here what we see as a critical need that could be met by strategic national investment in publicly controlled pharmaceutical R&D at the federal level, however such a strategy could be complemented by existing or future sub-national initiatives as well.



- Regionally owned and operated public wholesale distributors;
- The US Postal Service as a key partner for pharmaceutical distribution (providing home delivery of mail-in prescriptions).

Once each of these institutions is in place, the basic supply chain would function as follows: The federal R&D institute would develop new medications (alongside privately owned pharmaceutical companies, which would still be free to engage in R&D). The R&D institute would license public manufacturers (or perhaps private manufacturers in certain cases) to produce the medications it develops. The manufacturers would in turn develop contracts with purchasers (including public wholesalers, who would charge a fixed percentage by sales volume, rather than price) and set a unitary sales price for their product. Retailers would purchase from the wholesale distributors who would also charge them a fixed percentage based on the volume of prescriptions processed, rather than by sales price. Just as there are currently variations in the prescription supply chain, there would continue to be variations on this basic process and some of these are discussed below in the more detailed descriptions of the various elements of the model.

Though not explored in any detail here, it may also be beneficial to consider public or community/worker ownership in some retail pharmacy markets in order to address issues of corporate consolidation and market failure. Particularly in cases where large conglomerates (like CVS or Walgreens) play multiple roles in the pharmaceutical supply chain—and increasingly in insurance and pharmacy benefit management—antitrust action could be used to separate retail from other operations and local retail locations could be converted either to public or worker-owned entities. Nevertheless, many of the large-scale effects Big Pharma has on our democracy, economy and health originate much higher up the supply chain than retail. As such, our model is not dependent on any change of ownership in retail markets in order to create significant positive impact.



Elements of a Democratic Public Pharmaceutical Industry

1. A national public pharmaceutical innovation institute

A new public entity should be created within the Department of Health and Human Services—most likely to be housed at the NIH—with a mandate to engage in full-cycle pharmaceutical R&D.^{iv} Other countries give us a sense of what this might look like, most prominently Cuba, whose fully public pharmaceutical sector is known for innovations in vaccine development and immunotherapies. Brazil, Thailand, China, and other countries also have publicly owned pharmaceutical innovation enterprises, which are often relied upon to advance R&D of medications specific to local needs and for which privately owned pharmaceuticals have few incentives to invest, like neglected tropical diseases.

Already the world's largest public funder of biomedical research, the NIH is well placed to incubate a pharmaceutical R&D institute for the US. Such an institute could build from the NIH's existing intramural research program, which involves over 5,000 investigators across NIH institutes in a synergistic approach to biomedical science. The program has already provided the world with numerous important scientific breakthroughs key to the understanding and treatment of many diseases.^v

iv The creation of a new NIH institute would require an amendment to the Public Health Service Act (PHSA) Section 401(d). The PHSA has been amended many times, most recently in 2018, indicating that this would not necessarily be an impediment. Additionally, though the existing Scientific Management Review Board is charged with reviewing and making recommendations on the organizational structure of the NIH every seven years, and could, theoretically, recommend a reorganization, that would empower a new unit within the NIH to focus on full-cycle drug development.

v In recent years, the intramural program identified and isolated antibodies that could aid in fighting Ebola, developed a new treatment for a genetic disease that compromises the immune system and developed a skin patch that could be used in the management of Type 2 diabetes, among many other accomplishments.



The national pharmaceutical R&D institute would benefit from close collaboration with existing NIH institutes, many of which are already advancing scientific understanding of specific disease groups. The work of the new institute would help address the decline in innovation of the pharmaceutical sector because, not having a profit motive directing research priorities, a public R&D institute would have no incentive to develop “me-too” drugs, but would develop the drugs most needed by our society. The NIH already establishes its research priorities based on a balance of “the opportunities presented by the best science, public health needs, and the unique ability of NIH to address challenges in human health that would otherwise go unmet.”⁸⁶ A new pharmaceutical R&D institute would fit well within these priorities.

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The creation of a federal pharmaceutical R&D institute would allow the public to retain the patent rights on the medications it develops.

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Critically, the creation of a federal pharmaceutical R&D institute would allow the public to retain the patent rights on the medications it develops. Whether the institute contracted with a public or private manufacturer to produce the medication, the intellectual property (IP) would remain with the public (via the institute), meaning that the medicines could essentially be distributed at generic prices and any revenues generated from the sale of the medicines could be used for purposes that benefit the wider public (rather than accruing to a wealthy elite and driving increasing inequality).⁸⁷

Pharmaceutical innovation is a good fit for a national entity in this ecosystem for a variety of reasons. First, as previously mentioned, federal entities already fund the majority of basic research that results in pharmaceutical innovation. Second, the NIH itself already conducts some drug development research in-house and runs a number of its own clinical trials. Opening a new institute focused specifically on that task would build upon existing capacities and expertise at the NIH. Third, the levels of financing available to



federal agencies are generally greater than those available to state and municipal agencies, and therefore a federal R&D institute is more appropriate for the strategic, long-term investment required for new drug development.

A national public R&D institute would also be in position to substantially advance open and collaborative science (which could stimulate further innovation at both public and private institutions) by ensuring open access to the data associated with the IP on their inventions as well as the clinical trials undertaken.^{vi} That is, the institute could be chartered in such a way to mandate that its inventions are patented (to protect against private companies that might patent public inventions and raise prices), but also maintained in a patent pool subject to a copyleft-type license, akin to what Cuba's pharmaceutical industry does.^{vii} An open approach to IP like this would build upon the NIH's existing Public Access Policy for research papers and pave the way for further advancement in open, collaborative science. Additionally, the NIH could choose to license its patents to others, including for-profit entities, and use royalties from those licenses to fund further research. An open approach to the scientific discovery process could also reduce R&D costs over time by allowing for greater learning from the failures or unexpected outcomes that inevitably occur.^{viii}

Contributions to international patent pools, like the WHO's Medicines Patent Pool (MPP), should also be encouraged, if not mandated. The MPP

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- vi Open Science can be defined as “the practice of science in such a way that others can collaborate and contribute, where research data, lab notes and other research processes are freely available, under terms that enable reuse, redistribution and reproduction of the research and its underlying data and methods,” <https://www.fosteropenscience.eu/foster-taxonomy/open-science-definition>
 - vii Patent pools are an agreement between two or more patent owners to license one or more of their patents to one another, or to third parties. They reduce transaction costs and can help speed up scientific innovation.
 - viii Private pharmaceutical companies are not required to publish the data from all of their trials, so often, only successful findings are published, distorting evidence-based medicine and encumbering the scientific process by not sharing the lessons learned through unsuccessful experiments.



negotiates access to licenses from patent holders on medications used to treat diseases like HIV, Hepatitis C, and tuberculosis, which affect billions worldwide. They then sublicense those patents to generics manufacturers (often local) to produce and distribute low-cost versions of the medications where they are needed most. Contributions of IP to such projects by public US institutions would support the stated aims of existing public programs like USAID's Global Health initiative. It could even offset costs associated with the involvement of publicly funded programs (like USAID) in the treatment of HIV, tuberculosis, and other diseases by eliminating the need to purchase expensive, brand-name versions of medications from private pharmaceutical companies, all while contributing to local economies by allowing the funding to be directed to local manufacturers and distributors.

Operationally, a national pharmaceutical R&D institute's basic process would be as follows. First, research priorities would be defined, taking into consideration the mission and objectives of the institute as defined in the enabling statute or authorization. Scientists at the institute would engage in the research and development of pharmaceuticals, documenting and making public their findings (whether positive or negative) at each step in the process so that the larger scientific community can benefit from the learnings.^{ix} When a unique discovery is made, the institute would seek to patent it and all patents would be retained by the institute in a patent pool. Once the institute successfully develops a new drug, it would seek FDA approval to bring that drug to market in the US through the same process

ix There is an important tension here, however. Without significant changes to our intellectual property regime, a truly open approach to science may yield some unintended consequences, such as a largely public discovery being patented first by private industry and becoming inaccessible to much of the public due to high prices. Potential reforms to intellectual property law regarding biomedical innovations merits much further discussion and investigation.

Public pharmaceutical production around the world

A number of countries have invested in the public production of medicines as a way to combat supply chain issues and assure their health systems can access high quality, cost-effective essential medicines. Many have considered public manufacturing as part of larger industrial strategies, which have contributed to their economic independence.

China and India's state-owned pharmaceutical companies produce a large number of APIs, chemical and biologic drugs purchased worldwide. Sweden's public company, APL, is one of the largest specialty pharmaceutical manufacturers in Europe. Poland's public Polfa Tarchomin has been an important supplier of human insulin since the 1950s. In Brazil, state-owned labs and retail pharmacies were essential to the establishment of the country's Popular Pharmacies program, which provides low-income patients over 100 medications used to treat the most prevalent diseases at free or deeply reduced rates.

Public production capacity can also provide state actors with leverage in negotiating drug prices with the private industry and serve to produce medications for domestic distribution in cases of compulsory licensing. Both Thailand and Brazil have leveraged their public manufacturing capacity to produce and distribute low-cost antiretrovirals pursuant to compulsory licenses, making cost-effective access to these essential medicines widely available and reducing overall health system expenditures in treating HIV/AIDS.

Public manufacturing can also be structured in a number of ways and owned by jurisdictions at various levels in accordance with local needs, resources and priorities. For instance, Thailand's Government Pharmaceutical Organization (which also engages in pharmaceutical R&D) is a national company. Many of Brazil and Argentina's public manufacturers are owned and operated by provinces. India's Rajasthan Drugs and Pharmaceuticals Ltd. is an example of a joint venture between central and state governments.

Sources: Polfa Tarchomin, <http://www.polfa-tarchomin.com.pl>; Luiza, Vera L et al. "Applying a health system perspective to the evolving Farmácia Popular medicines access programme in Brazil." *BMJ global health*, vol. 2, Suppl 3 e000547. 7 Feb. 2018, doi:10.1136/bmjgh-2017-000547; Eduardo Muniz Pereira Urias "Improving access to HIV/AIDS treatment in Brazil: When are compulsory licenses effective in price negotiations?," *Universitaire Pers Maastricht*, 2015, <https://www.merit.unu.edu/training/theses/urias.pdf>; Rajasthan Drugs and Pharmaceuticals Ltd., <https://www.rdpl-india.in/>



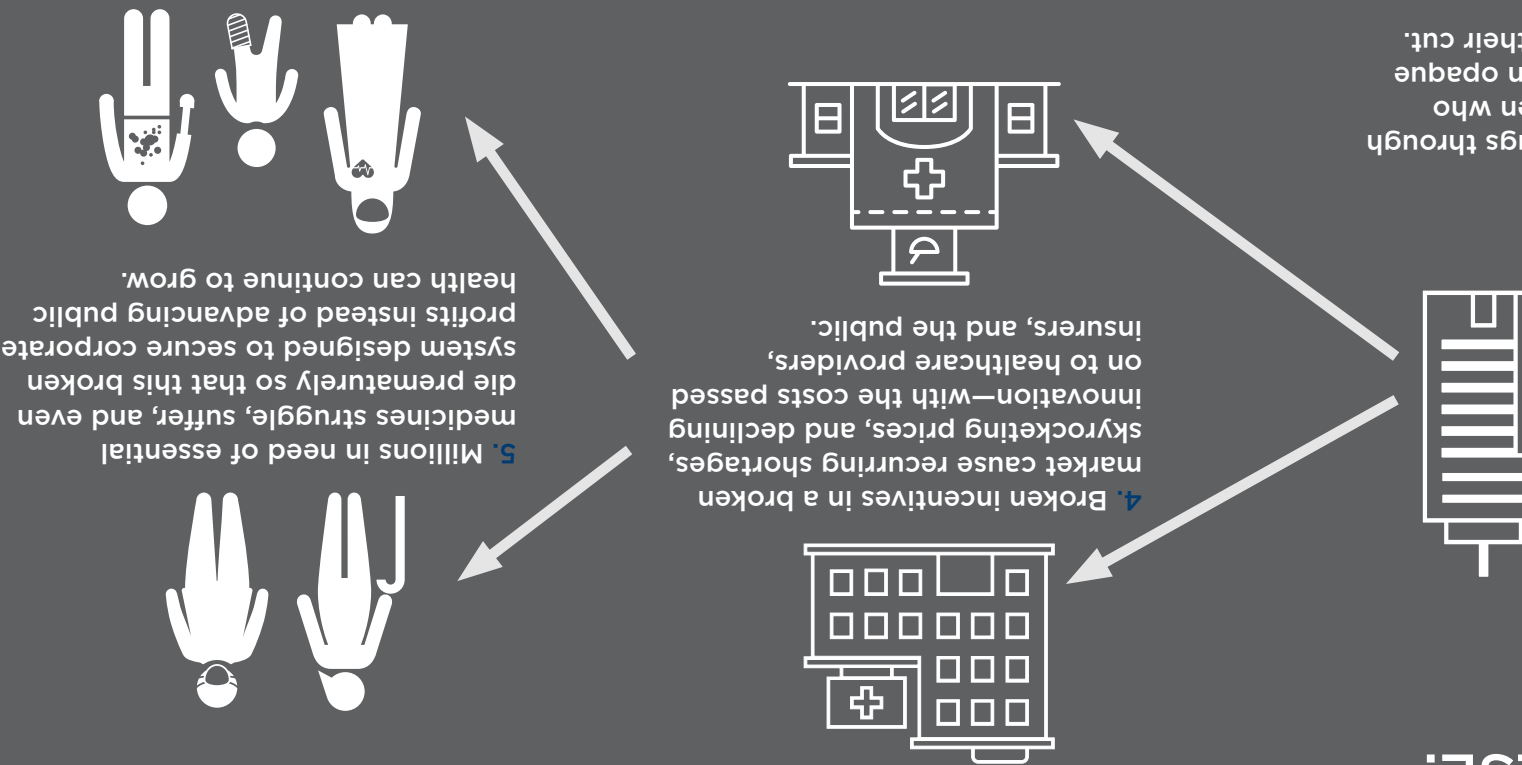
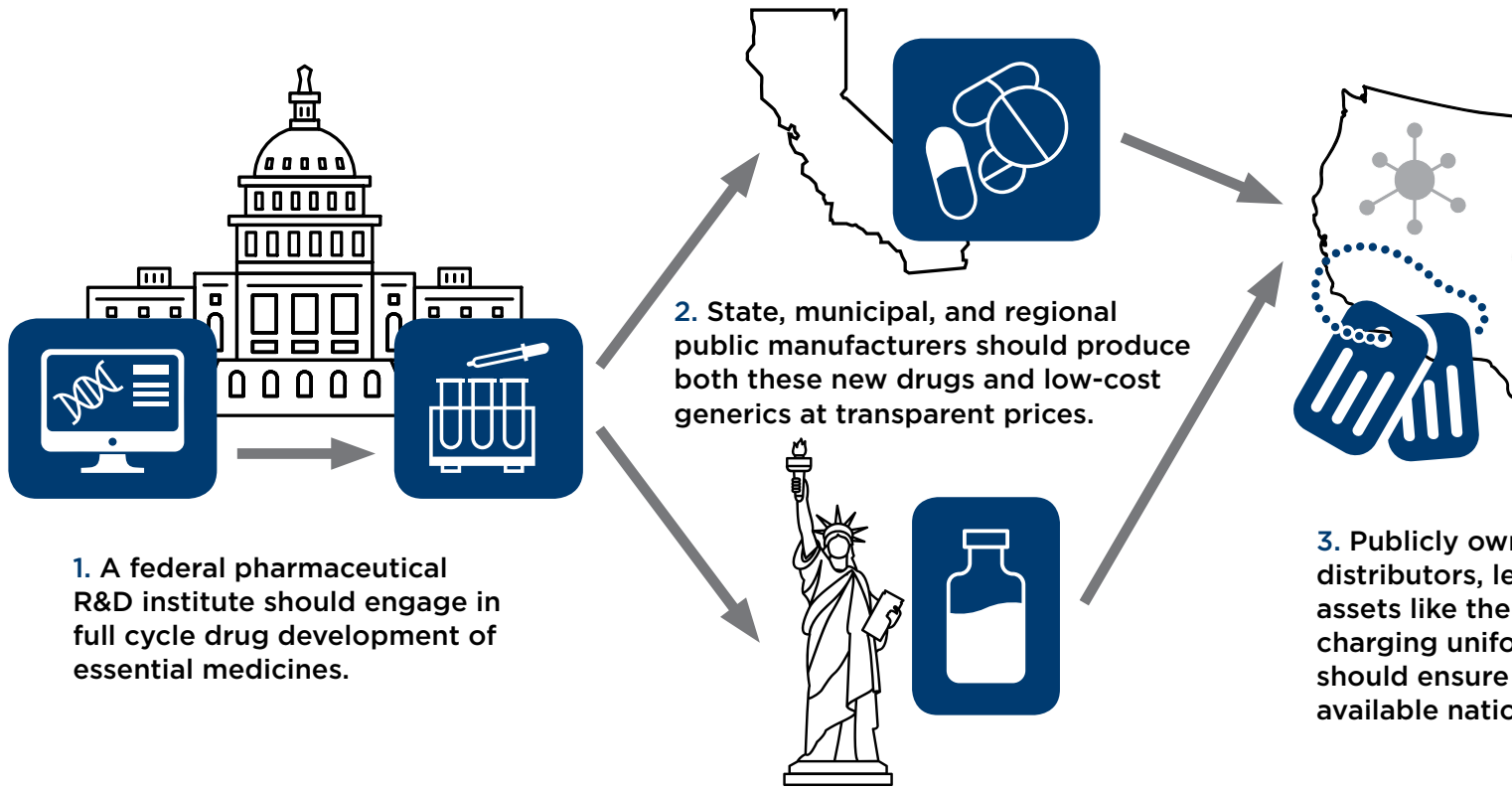
that private companies follow.^x It would then contract with manufacturers to produce the medication. If public manufacturers (such as those described in the state and municipal section below) are operating, they would be a natural choice to contract for production. The public R&D institute could also contract a privately owned manufacturer, simply retaining the patent rights on its inventions so as to assure accessible pricing.

One drug class where the intervention of a national public pharmaceutical R&D institute could clearly make an important public health impact would be insulin. As an essential medicine (whose initial development occurred in a public lab) controlled by an oligopoly of private interests and priced out of range for many patients, there is a clear public interest in providing more accessibly priced insulins to the US market. The national pharmaceutical institute could play a role in addressing this crisis through one of two strategies: 1) it could work to develop new insulin technology, which it would patent and bring to market at generic prices; or, 2) for more immediate impact (both on patients and the larger insulin market itself) HHS could issue a compulsory license on an existing patent-protected insulin and authorize public production of a biosimilar.

As shown in a recent British Journal of Medicine study, insulin biosimilars could currently be offered—even in the context of competitive, market-based pricing—at much lower cost than the insulins currently available for sale in the US. The study authors estimate manufacturers could bring biosimilar analog insulins (the latest generation of insulin technology) to market at the *profitable* price of \$48-\$71 per patient per year.⁸⁸ Current market prices on insulins vary by type, but the average cost of the insulins most widely used to manage Type 1 diabetes cost nearly \$6,000 per patient per year in 2016.⁸⁹

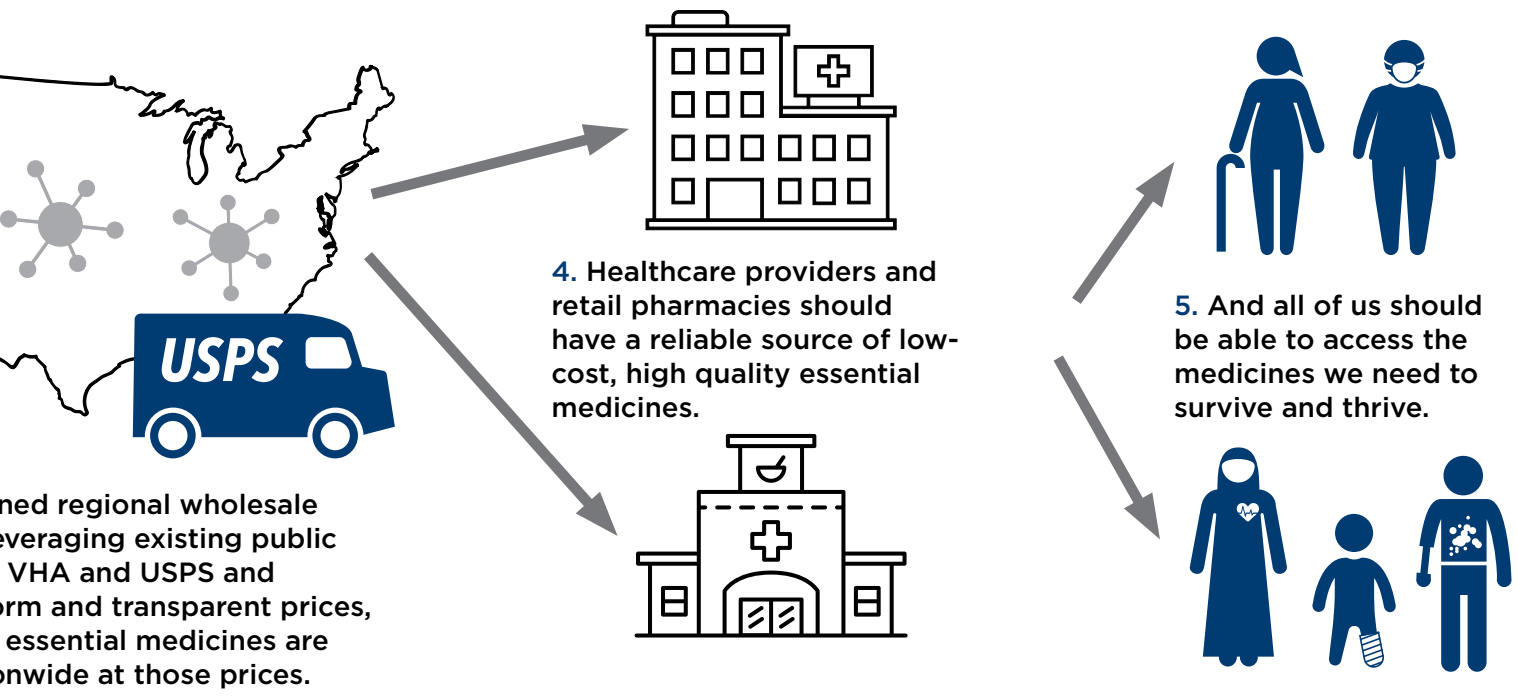
x Additionally, the institute could seek approval from other countries' regulators to bring their product to market there as well. Or manufacturers located in those countries might request licenses and seek regulatory approval themselves.

OUR PHARMACEUTICAL SECTOR CAN AND SHOULD BE DESIGNED TO MEET PUBLIC HEALTH NEEDS:



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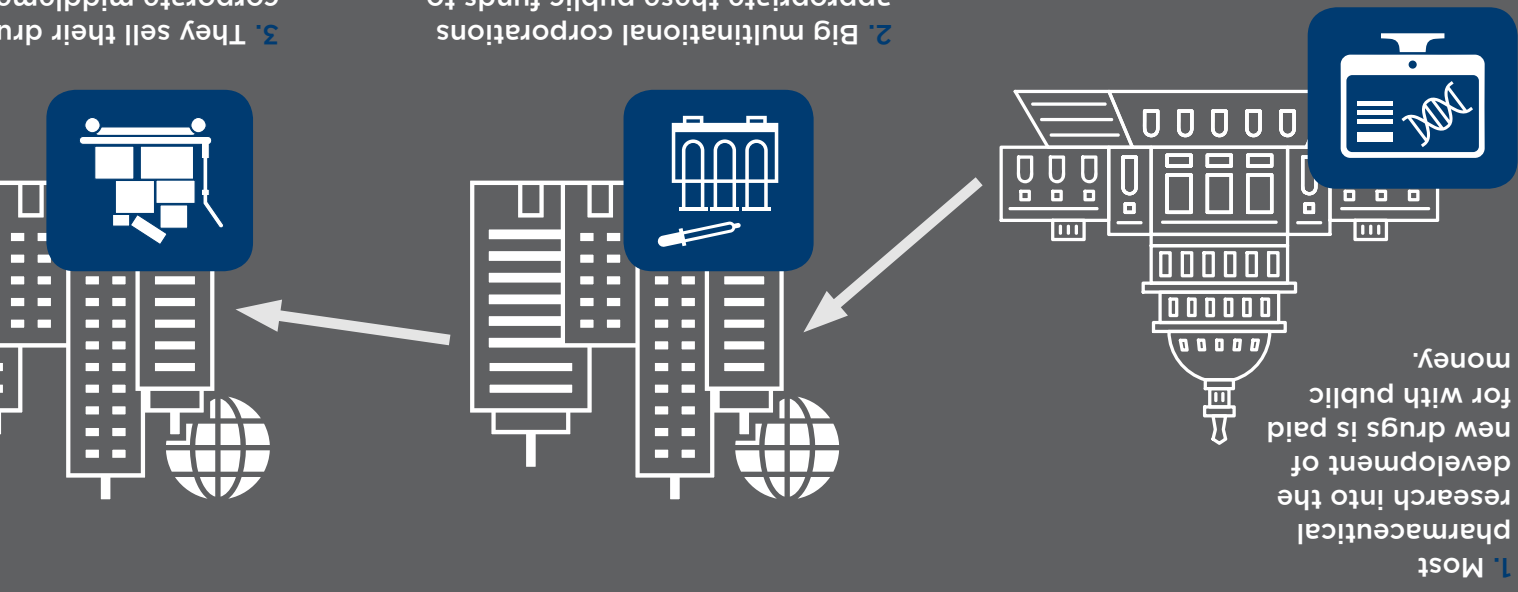
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3. They sell their drugs
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2. Big multinational corporations
 appropriate these public funds to
 make only the most profitable drugs,
 and distort evidence-based medicine



BUT OUR UPSIDE-DOWN PHARMACEUTICAL SECTOR
 TO MAXIMIZE CORPORATE PROFIT ABOVE ALL ELSE



2. State and municipal public manufacturers

States and municipalities are well placed to make an impact on the generics market through the creation of publicly owned pharmaceutical manufacturers. In our federal system, it is often the states and localities that innovate first—the so-called laboratories of democracy. In the healthcare sector, Maryland pioneered an all-payer system with global budgets, San Francisco implemented the first municipal universal health coverage program and Montana and New Mexico run their own health clinics for state employees. These subnational governments could also take the first step towards establishing a “public option” in pharmaceuticals for the nation by creating public entities to manufacture generic medications.

The establishment of publicly owned entities at the state and local level that produce essential medications could have a number of benefits for these jurisdictions, not least of which are the projected savings to the public health programs and to residents. Well-designed public institutions in this sector could bring the additional benefits of providing greater transparency in the pharmaceutical market, creating avenues for citizen participation and democratic oversight, and serving as a source of good public sector jobs that could contribute to the development of local economies.

Public manufacturers also stand to make an important impact on the US generics market even in the absence of the other public institutions proposed herein. Generics account for 80 percent of US pharmaceutical sales by volume, but for many medications there are currently only one or two companies that produce the whole country’s supply.⁹⁰ More than 500 drugs have only one marketed generic and the FDA has found that “on average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price...For products that attract a large number of generic



manufacturers, the average generic price falls to 20 percent of the branded price and lower.”⁹¹ A clear way for state and local public manufacturers to contribute to the expressed overarching goal of the public pharmaceutical ecosystem would therefore be to ensure there is always sufficient competition in the generics market, especially for essential medicines.

Furthermore, as referenced previously, there are over 180 off-patent drugs for which there is no generic equivalent available due to a lack of market incentives and/or “pay-for-delay” deals struck between private brand-name and generics manufacturers. Public generics manufacturers could play a critical role in ensuring an adequate and accessibly priced supply of such medications.^{xi}

Operationally, such a manufacturer in the US would likely begin by creating a committee to establish a set of criteria for the selection of the initial medications it chooses to produce, much like the process CivicaRx (the US’s only nonprofit pharmaceutical company) recently undertook.⁹² The criteria chosen might include public health needs, market conditions (such as number of annual prescriptions dispensed and number of competitor manufacturers for a given drug or drug class), the relevant regulatory context, and access to suppliers for the APIs involved in manufacturing the particular medication.

Once a medication is chosen, the manufacturer would seek FDA approval to bring its generic to consumers. It could then either produce the medications in-house, or contract with existing manufacturing facilities to do so.^{xii}

xi State or municipal pharmaceutical entities could manufacture brand-name medications if contracted by entities that develop them (most likely the new pharmaceutical development entity housed within HHS that we propose here), and they could also choose to invest in new drug development themselves. However, given the amount of resources required over long periods of time to develop new medications, it is most likely that the majority of new drug development would occur at the national level.

xii This choice would depend on a variety of factors, not least of which is the in-house manufacturing capabilities. Some manufacturers may be set up to produce mostly chemical (i.e.



Like other drug manufacturers, they could then sell to wholesalers and/or to those large purchasers that have traditionally bought medicines directly from manufacturers.

An initial list of drugs to be manufactured could be tailored to local public health needs and municipalities, like states, could work closely with their public health apparatus, as well as public and nonprofit hospitals and health centers to distribute medications. Alternatively, if the national public R&D institute proposed here is already operating and has developed new medications, contracts to manufacture these medications could be the initial source of work for state or municipal manufacturers.

For example, California might be a good candidate for a publicly owned pharmaceutical manufacturer for a number of reasons. First, it has a robust economy with a highly developed biomedical sector. If it were a country, it would be the fifth largest in the world in terms of GDP. Second, the state benefits from a highly skilled labor force in the biomedical field and a number of public sector institutions engaged in scientific R&D and production. The experience of, and the network provided by, public institutions like the University of California system, the California Institute for Regenerative Medicine, and the California Association of Public Hospitals and Health Systems could be leveraged to support an intervention into the pharmaceutical market. Third, the state's expansive public hospital and health systems (as well as local community health centers) in particular would be important in identifying high value medications to produce and likewise provide a natural market for those medications.

Moreover, Governor Gavin Newsom's January 2019 Executive Order on State Prescription Drug Spending makes it clear that reigning in prescription costs is a political priority for the state, and there is sufficient evidence that public

small molecular entity, or traditional pharmaceuticals) but not maintain the capacity to produce biologics. While it may be beneficial for states and localities to bring manufacturing jobs to their communities, such a plan could be enacted over time, and while manufacturing facilities were being constructed or updated, production could be contracted out to any number of existing, FDA-approved manufacturers.



production of essential medications is one way to achieve that goal. In 2018, Californians filled more than 333 million prescriptions at retail pharmacies, with over 166 million of those being paid for by Medicare and Medicaid (the most of any state).⁹³ Successful collaboration between public purchasers, insurers, and public manufacturers in selecting medications to be produced, and defining prices, contract terms, and quantities could ensure a net savings for the state's health system.

If California were to establish a public generics manufacturing entity, it would likely be considered an agency of the state under California law. The agency could be set up to have a two-tiered structure, though, with a governing body constituted as a state agency and an operating body constituted as a public trust (much like the University of California system). This would give the manufacturer some independence from the political process and could open up opportunities for participatory mechanisms in which patient or community representatives would serve on one of the boards (discussed further later in the governance section).

Legally, it is likely that the manufacturer could receive initial capitalization funds from a variety of sources, including general obligation bonds, state loans, and possible equity financing. However, *revenue bonds* (repayment of which is linked to a specific source of revenue) might be the most practical choice, with the manufacturer repaying the bonds from revenue made through drug sales.^{xiii} Both the CIRM and Texas's Cancer Prevention and Research Institute were capitalized with *general obligation* bonds (where repayment is guaranteed by the government by any means necessary), but the use of such a mechanism requires a ballot measure that garners the approval of the majority of voters (at least in California) and may be seen as a more politically risky or controversial form of financing, especially for

xiii There is some ambiguity as to whether the new entity could be capitalized through loans from the state's general fund, and while general obligation bonds do appear to be an option, but it would likely be more difficult and more political as their use requires the approval of the majority of California voters in a given election.



an institution that should be able to produce the revenue needed to meet revenue bond obligations.^{xiv}

In addition to states like California, some municipalities—especially larger ones—could also establish generic manufacturing entities to produce medicines for their local markets and beyond.

For example, New York City might be an excellent candidate for a publicly owned pharmaceutical enterprise due to its history of innovation in public health, its large patient base, its unique role in the modern access to medicines movement, and the fact that it houses the largest public municipal healthcare system in the United States. With a plan for near-universal health insurance coverage of NYC-residents and an existing public option health plan, it is clear that access to affordable healthcare (including pharmaceuticals) is a priority for the city’s policymakers. “No one should have to live in fear. No one should go without the health care they need. Health care is a human right. In this city, we’re gonna make that a reality,” stated Mayor Bill de Blasio in a news conference announcing the city health plan.⁹⁴

Additionally, the AIDS activism of New Yorkers over the last three decades has been central to the modern access to medicines movement. The city is also home to a number of civic organizations and movements at the forefront of current struggles for affordable access to safe and effective treatments across disease groups. These constituents could provide an important support base for a publicly owned manufacturer oriented towards meeting the public health needs of the local community and beyond.

Public entities in the city also have a history of healthcare innovation. For example, at the end of last century, the New York City Health Department played a pivotal role in developing testing for and treatment of diphtheria,

xiv The proposals for the form and functioning of a California state pharmaceutical manufacturer are informed by a legal analysis undertaken by the Sustainable Economies Law Center which can be accessed at <http://thenextsystem.org/California-Public-Pharma>.



which had reached epidemic levels and caused thousands of deaths in the city. The city health department also made a key discovery related to the control of cholera and offered free laboratory analyses to assure patients were able to be diagnosed and treated. In more recent years, the city's Department of Health and Mental Hygiene helped create NYCRx, an initiative aimed at increasing access to low-cost medicines for New Yorkers primarily through supporting safety net providers in leveraging the federal 340B program.

In this context, New York City is well placed to house, and reap the benefits of, a municipal pharmaceutical enterprise.

There are a number of medicines that would likely be good candidates for initial manufacture by a publicly owned entity at the city or state level. One of these is epinephrine autoinjectors, given that: 1) high prices on this medication have been a consistent barrier to access;^{xv} 2) there is a significant market—over 3.6 million people held prescriptions for the autoinjectors in 2015, and they are also stocked in schools and at health facilities across the nation (and by local mandate in NYC in child care centers), as well as in emergency kits carried by paramedics and on airplanes, some restaurants, daycare facilities, sports arenas and more; 3) there have recently been a number of critical shortages of this product⁹⁵; and 4) there are few other manufacturers currently producing them.⁹⁶

In order to bring its epinephrine autoinjector to market, a public pharmaceutical company would apply for FDA approval in the form of an Abbreviated New Drug Application. After receiving approval from the FDA (a matter of 6-10 months) the company could produce the generic drug in-house or contract with existing manufacturing facilities. The company, like other

xv Though there is one generic epinephrine autoinjector on the market in the US now (produced by Teva Pharmaceuticals and approved by the FDA in August, 2018), it has not driven down the price of epinephrine autoinjectors much, and has been available in limited quantities.



manufacturers, would be able to sell its product to consumers 1) through wholesalers and or 2) directly to those health facilities, retail pharmacy chains and mail-order services, which have historically engaged in direct purchasing. If the public wholesale distribution apparatus described below is in operation, manufacturers could sell to it. In their absence, existing private wholesalers would be utilized.

All available information suggests that publicly produced epinephrine auto-injectors could easily be priced much lower than the current equivalents on the market. As was widely reported in 2016 during a period of public outrage about price hikes on the product, expert analysis shows that EpiPens hold only about \$1 worth of epinephrine.⁹⁷ Around the same time, a Silicon Valley engineering consultancy performed a teardown analysis of the EpiPen and estimated the when adding that \$1 of epinephrine to the additional manufacturing and packaging costs, total production costs for an EpiPen would come to \$8-10 for a two-pack.⁹⁸ A separate analysis by industry insiders estimated the total cost of production at \$20-\$30.⁹⁹ In congressional testimony given that same year, Mylan stated they were purchasing each of their EpiPens from a subsidiary of Pfizer at \$34.50 per pen (ostensibly still a profitable price for Pfizer).¹⁰⁰

Even assuming some inflation in those costs since 2016, and a percentage of profit that the public manufacturer might want to charge in order to invest in future capacity, we can easily imagine publicly produced epinephrine autoinjectors being sold for around \$40, possibly less. This would be a significant savings over the \$300+ average retail price of the current offerings on the market.

Insurers would have every incentive to include the publicly produced epinephrine autoinjectors in their formularies because it would likely be the most cost-effective option in its class. Patients and other purchasers across the country could purchase the publicly produced generic at their retail



pharmaceuticals or directly from the manufacturer. Charging unitary prices (offering no rebates or other “kickbacks” to purchasers or distributors) and making those prices public would also help assure that essential medications like epinephrine autoinjectors are distributed at or even below cost to ensure broad access of this life-saving medication and equitable prices for end users.

3. Regional wholesale distributors

After medications are developed and manufactured, they must be delivered to the various purchasers in the market—primarily retail pharmacies and hospitals. Though some large institutions are able to purchase directly from manufacturers, many rely on wholesalers, who generally also act as distributors in the US market, hence the term “wholesale distributors.” They enable manufacturers to ship bulk quantities of their product to a limited number of warehouses rather than sending smaller quantities to each of thousands of retail locations.

For our model, we recommend that regional public entities be created, together serving the whole country with the wholesale and distributing functions in our public supply chain. These could provide a low-cost, more efficient and transparent alternative to the existing for-profit players in this sector (which, as described in Part I of this paper, forms one of the most highly concentrated and anticompetitive nodes in the supply chain). As with other links in the supply chain, regional public wholesale distributors could be a source of good jobs and restore profits to public balance sheets.

Regional organization is a natural fit for wholesale distributors as the distribution of pharmaceuticals (and many other goods) is already largely organized around regional warehousing and distribution networks for

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reasons of efficiency and scale. Additionally, regional organization in this node of the supply chain would allow for smaller states and municipalities, which may not be able to support their own pharmaceutical enterprises, to reap the benefits of democratic public ownership in this sector by banding together.

Thus, we suggest that these public wholesale distributors be jointly owned by the states and municipalities in each region. While regional wholesale distributors could be set up as federal-state partnerships (much like the Tennessee Valley Authority or the Appalachian Regional Commission examined below), for reasons of democratic participation and oversight, we find it most advantageous to devolve control to the lowest level practical for the operations of the industry. We do not find a compelling need for federal coordination of pharmaceutical distribution, and therefore suggest that regional arrangements would create a balance between the economies of scale required and the ability for decisions to be taken at the lowest possible level of governance (i.e. closest to the population served).

A number of existing regional public enterprises in the US can serve as examples of arrangements that have helped foster economic development and cooperation in various regions. Additionally, our experience in public distribution of a variety of goods at all jurisdictional levels provides evidence of its potential advantages. Lastly, our model for public pharmaceutical distribution is informed by the experience of Sweden, which provides further insights into how public ownership in this node of the supply chain can be beneficial.

One of the largest and most enduring regional public institutions in the United States is the Tennessee Valley Authority (TVA), which provides electricity to 10 million people across seven states. The TVA is a federally owned corporation aimed at providing electricity, flood control, navigation and other services to the region while also serving as a regional economic

Sweden's nationalization kept prices low, availability high

Much of the Swedish pharmaceutical sector—including retail and specialty drug development and manufacturing—was nationalized in 1970. The state-owned company, Apoteket, was the only pharmacy authorized to purchase prescriptions for retail sale in Sweden, thus serving as the country's sole wholesaler. Manufacturers sold directly to Apoteket, though Apoteket contracted with two private companies to assist with distribution to its nearly 900 retail sites. The distributors authorized to operate in Sweden at the time acted purely as logistical centers, dispatching drugs from central facilities along regular routes to Apoteket's retail locations. As they did not purchase drugs from manufacturers for resale to pharmacies, the margins the distributors commanded were among the lowest in Europe. Together with the low retail mark-up Apoteket claimed, Sweden was able to maintain low pharmaceutical prices compared to other OECD countries, despite paying manufacturers comparatively well.

For special doses or preparations unavailable from other manufacturers, or required only in small quantities, Apoteket manufactured those pharmaceuticals itself in its laboratory division. The company also employed a group of sales agents in rural areas that delivered medications directly to patients' homes or made them available at local grocery stores (a program that continues today).

Originally a single state-owned company, during the process of deregulation in 2009-10 the retail and production entities were divided and now operate as two separate state-owned companies. Post-deregulation, the companies have remained profitable and retain significant market share. Both companies are also deeply engaged in environmental sustainability efforts. Apotek Produktion &

Laboratorium, the manufacturing entity, is still one of the largest manufacturers of specialty medicines in Europe with a catalogue of 2,000 products sold in 35 countries around the world, including the US. Apoteket AB, the retail company, now operates around one-third of all pharmacies in Sweden and continues to expand services, hours of operation, and locations. Both companies pay annual dividends to their only shareholder—the Swedish state.

Sources: “About APL,” Apotek Produktion & Laboratorium AB, <https://www.apl.se/in-english/about-apl.html>; Moïse, P. and E. Docteur, “Pharmaceutical Pricing and Reimbursement Policies in Sweden”, *OECD Health Working Papers*, No. 28, 2007, OECD Publishing, <http://dx.doi.org/10.1787/135870415741>; “The Swedish pharmacy market,” Swedish Medical Products Agency, <https://lakemedelsverket.se/english/overview/About-MPA/pharmacy-market/>



development agency. After its creation in 1933, the TVA was responsible for a dramatic increase in electrification of the region, served as the source of many new jobs, and allowed local communities to determine their own rates. It has generally been popular with both liberal and conservative officials, and as such, has successfully resisted a number of attempts at privatization. Nevertheless, the TVA has certainly suffered from political infighting at times, and is much criticized for falling short of its commitment to robust citizen participation.

Jurisdictions looking to form a regional public pharmaceutical distribution enterprise would do well to study institutions like the TVA to understand the factors responsible for its success in providing high quality service to the region and maintaining enduring political support across party lines. It would be equally important to interrogate its limitations regarding participatory processes in order to inform a more democratic design.

Other existing regional public entities like the Appalachian Regional Commission (ARC) and the Delta Regional Authority (DRA) might be leveraged for their expertise, or even become implementing partners for new public wholesale distributors.^{xvi} Both the ARC and the DRA have missions that include the economic and social concerns of their respective regions and they already implement programs aimed at improving access to and equity in healthcare services in their regions. It might be possible for such agencies to provide some initial investment capital, or aid in the identification of sources of capital, to establish public pharmaceutical enterprises in their regions, seeing these as promising regional economic development and job creation programs.

xvi The Appalachian Regional Commission is a regional economic development agency that represents a partnership of federal, state, and local government. It was founded in 1965 and serves the population of the 13-state Appalachian region. The Delta Regional Authority is a federal-state partnership formed in 2000 to “create jobs, build communities, and improve the lives of the 10 million people who reside in the 252 counties and parishes of the eight-state Delta region”



While not always organized regionally, a number of jurisdictions in the US already have experience with distribution, both of pharmaceuticals and other products. For instance, many states have experience with public ownership and control of alcohol distribution, including the operation of warehouses, logistics centers and retail locations. These arrangements can help ensure compliance with state law and regulations, and serve as an important source of income for the state. For example, Virginia’s Department of Alcoholic Beverage Control (ABC) employs over 3,000 people and provides critical income for the state. The ABC has transferred more than \$9.5 billion to the state’s general fund since 1934, an important source of finance for education, police, public works and other services.¹⁰¹

On the national level, the Veterans Health Administration operated all of its pharmaceutical distribution in-house prior to the early 1990s, with a network of warehouses for the acquisition and storage of medicines and other medical products.¹⁰² Its Procurement and Logistics Office (one of the largest US government procurement operations) still manages pharmaceutical distribution, though it now contracts with third parties to implement distribution. The VHA’s experience with and expertise in both the in-house and contracting models could be leveraged to serve an emergent public pharmaceutical supply chain and could inform that operations of regional public wholesale distributors.

Together, existing public institutions like the VHA and public hospitals, or publicly supported nonprofits (like community health centers), could be leveraged as part of a future public pharmaceutical distribution network.^{xvii} New regional public wholesale distributors could consult with these institutions about their needs and existing purchasing practices to inform their operations. Many of these locations already operate in-house pharmacies

xvii Community Health Centers—also known as Federally Qualified Health Centers, or FQHCs—provide care regardless of patients’ insurance status or ability to pay. There are nearly 1,400 health center organizations with more than 11,000 locations in urban, suburban and rural communities across the country. They can be found in all 50 states and US territories.



and likely invest significant time and resources in negotiating contracts with multiple private wholesale distributors in order to secure the best prices on the medications they purchase.

Public wholesalers could simplify the process and potentially reduce overhead for purchasers by charging a fixed percentage based on volume of sales (rather than price).^{xviii} They could also charge a fixed mark-up on the other end, to the manufacturers from which they purchase. These fixed percentages (which could be reevaluated and adjusted on a periodic basis) should be made public, increasing transparency about the true costs of pharmaceuticals and providing information that could serve as leverage in negotiations with private suppliers. Ideally, each regional wholesale distributor would charge the same percentage for their services so as not to create or exacerbate regional disparities or create incentives to do business in one another's regions, pitting one region against another in a race to the bottom.

The wholesale distributors could also find efficiency in contracting with the US Postal Service (USPS) to assist in delivery from regional warehouses to the hospitals, clinics, retail pharmacies and consumers (in the case of mail-order prescription services) that purchase prescription drugs. This would be a natural, and likely mutually beneficial, public-public partnership to pursue given the logistical and technical expertise of the USPS distribution network and its coverage of the entire national geography.

The USPS says it has “the nation’s largest retail network—bigger than McDonald’s, Starbucks and Walmart combined, domestically,” and already

^{xviii} Currently wholesale distributors charge manufacturers a distribution fee based on a percentage of the list price of the medication, which is an inflated price including none of the rebates and discounts that are negotiated. Thus, the fees that wholesalers charge from manufacturers can add significantly to end-user prices. Wholesalers negotiate discounts with each manufacturer separately and, on the other end, with retail pharmacies. This introduces inefficiencies in the system that could be avoided by having a wholesalers charge a standard percentage by volume.



serves every community in the United States.¹⁰³ Postal delivery of prescriptions has been increasing in popularity over recent years and the USPS is already contracted to deliver the majority of prescriptions processed by large PBMs like Express Scripts, providing important experience in the technical aspects of handling prescription delivery. Managing a current volume of 493.4 million mail pieces a day to over 157 million addresses in all US territories, the USPS already has much of the regional warehousing and distribution infrastructure needed to support pharmaceutical delivery.¹⁰⁴ Furthermore, increased utilization of the USPS for this service could shore up this critical public institution as the demand for letter delivery declines.

In the US, we recommend integrating wholesaling and distributing within the regional public entities we propose, as has become the norm in private sector pharmaceuticals. As an ecosystem of publicly owned pharmaceutical companies emerges in the US across the different nodes of the supply chain, it is possible that the need will arise for other regional public mechanisms as well.

For instance, a number of state and municipal public manufacturers may find it advantageous to come together to purchase APIs and finance infrastructure projects, negotiate contracts or engage in large-scale market analysis and planning. A regional mechanism that allows for this coordination and aggregation increases economies of scale while still allowing for local control and oversight. Each manufacturer could still be structured according to local regulations and in response to local needs while accessing the services provided by the larger network.

An example from the energy sector illustrates what this might look like. The utilities' Joint Action Agencies (JAAs) allow individual utilities to pool their resources to purchase power wholesale and jointly finance projects such as the construction of generating plants. Beginning in the 1950s, dozens of JAAs were established to help smaller utilities maximize their resources.



Over the years, they have evolved to meet the changing needs of their member utilities, finding creative ways to support members' transition to greater renewable energy portfolios, navigating natural disasters and monitoring legal and regulatory reforms that affect the membership. The JAAs are revered for creating the economies of scale needed to provide high quality, low-cost services, while supporting the community responsiveness of local ownership.¹⁰⁵

Governance

Though the exact governance structure and operations of each of the institutions suggested here may vary based on local regulations and priorities as well as the specialized technical needs of the enterprise, each should be designed around:

- A shared goal to provide a safe, adequate and accessible supply of essential medicines to the US (and beyond);
- The broadly recognized need for greater transparency and accountability in this key sector of our economy;
- The democratic, social, and health benefits related to enhanced broad-based public control and participation.

The statutes or authorities establishing each of these entities should therefore clearly state the overarching, shared goal and further define the specific objectives of the given institution that would contribute to achieving that common goal. They should also define the composition and terms of the board or boards that would oversee the operations of each entity to assure adequate representation of the multiple stakeholders contributing to and affected by the operations of that entity. For example, boards could be comprised of a mix of appointed and elected representatives that include patient advocates, healthcare professionals, local officials, biomedical



researchers, the entity's employees, and consumers. Boards could further be mandated to assure representation across gender, ethnicity and other factors that reflect the diversity of the population served.

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One of the advantages of public ownership is the ability to restore revenue to public balance sheets and direct those resources to meet public needs.

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The California Institute for Regenerative Medicine (CIRM), a public research lab for stem-cell science created by voters in 2004, provides one example of what that might look like. The CIRM is governed by a 29-member board of Californians with expertise in biomedical research, biotechnology, management, FDA processes, patient advocacy, and ethics. Representation for a number of disease groups most affected by the institute's work is required by statute, including diabetes, neurodegenerative diseases, spinal cord injuries, HIV/AIDS, and mental health disorders. Another example comes from the public and nonprofit Community Action Agencies located throughout the US. Established in the 1960s to fight poverty, they are mandated to have tripartite governing boards that include public officials, low-income community members and local private sector leaders in equal numbers. Finally, the thousands of community health centers that serve communities throughout the US are federally mandated to have 51 percent of their board come from the patient population served by the health center.

The statutes creating publicly owned institutions in the pharmaceutical sector should also define the transparency measures to which the entity must comply. Most public agencies and enterprises in the US are already subject to public records and open meetings laws, and further transparency measures such as public hearings, popular consultation or limitations on closed, executive sessions may be possible in some jurisdictions.



Lastly, in designing these institutions, special consideration should be given to how surplus revenue might be directed. One of the advantages of public ownership is the ability to restore revenue to public balance sheets and direct those resources to meet public needs. In pharmaceutical innovation, it might make sense to reinvest any and all revenue in further scientific development, helping create a self-sustaining institute that would not be dependent on recurring appropriations from governing bodies whose political priorities could shift over time. However, in entities operating at other points in the supply chain, it might be best to funnel some portion of revenues specifically to upstream investments in social determinants of health (i.e. housing, education, workforce development) or allow voters to decide on a regular basis how best to allocate the surplus.¹⁰⁶

Potential benefits of the democratic public pharmaceutical industry model

As previously discussed, high prices are just one of a number of harmful effects of the design of the for-profit pharmaceutical industry. Likewise, the benefits of publicly owned pharmaceuticals would extend beyond lower price tags. Though the savings in prescription spending would, of course, be an important gain in and of itself, public ownership in the pharmaceutical sector could deliver broader benefits for our democracy, economy, health, and wellbeing.

1. Economic benefits

As described in the examples above, there would likely be some immediate economic benefits both to patients and to the larger health system related to public production and distribution of medicines. These will primarily be realized through the direct and indirect effects of reduced costs for consumers and public/nonprofit institutions. These savings would then



contribute to larger macroeconomic gains through a multiplier effect. Lower prescription prices for consumers would free up spending power that could be used on other goods and services, boosting the economy as a whole. Savings for public and nonprofit institutions (gained through lower prescription prices, and greater supply chain efficiencies) could lead to greater investment in services and hiring as well as increased wages.

With public entities already funding the majority of the basic research and a portion of the applied research that leads to pharmaceutical development, the public stands to save when more of those funds are directed to public, nonprofit institutions. As a greater proportion of the public funds we already dedicate to biomedical R&D is redirected into public institutions, we will see a corresponding reduction in the double taxation associated with pharmaceuticals. Likewise, if additional public funds are dedicated to public pharmaceutical development and manufacturing, we will avoid creating new instances of double taxation related to pharmaceutical expenditures in the future. If publicly owned pharmaceutical companies begin to displace privately owned pharmaceuticals, we would expect to see further savings in this area.

Additionally, we would see further efficiency in the deployment of research funds through:

- The elimination of much of the advertising and marketing associated with for-profit pharmaceuticals;
- Channeling of funds towards long-term, strategic scientific goals (rather than activities that provide short-term gains for shareholders);
- Committing to an open science approach, which reduces redundancies and speeds innovation by promoting learning from failure;
- Lower executive pay (as compared to the private sector).



With a public R&D institute developing new medications in the public interest, we would see more pharmaceuticals made available to the public at accessible prices, as more intellectual property related to pharmaceutical development would be held by public institutions.

Each of these factors should contribute to overall savings, which could be used to reduce prescription prices and invest in the continued operations and improvement of these institutions. That in turn would stimulate spending and job growth in the larger economy.

Public ownership in the pharmaceutical sector could contribute to several other positive economic effects beyond those directly associated with lower prescription costs. Among them:

- Reducing the unequal financial burdens that prescription drugs currently impose on different population groups;
- Increased lifespan, earnings, and reduced disability as a result of increased access to essential medications;
- Less economic inequality as a) profits are returned to public balance sheets, b) differences are reduced in what patients pay for the same drug, and c) the public sector expands, where women and people of color enjoy higher employment rates than in the private sector;
- Opportunities for publicly owned pharmaceuticals to serve as anchor institutions for inclusive economic development projects.

First, it is important to note that in our current system the extraordinarily high list prices on many medications have led to the creation of a complicated and opaque system of rebates and discounts that results in an unequal and discriminatory pricing system. Depending on insurance coverage, geography, and access to and ability to navigate the healthcare system, one



patient might be forced to pay thousands of dollars for a prescription where another may pay next to nothing. This—together with the massive financialization and tax evasion of the industry—contributes to rising economic inequality, which is an overall drag on the economy. As a 2014 study for the Organization of Economic and Co-Operation and Development (OECD) illustrated, inequality affects the overall economic performance of a country, producing a “sizable and statistically significant *negative* impact on growth.”¹⁰⁷ This is in part because inequality negatively affects “growth drivers,” such as the ability of individuals to invest in educational opportunities, and that can hamper labor productivity. Inequality also affects macroeconomic stability. According to a 2015 International Monetary Fund report, “rising influence of the rich and stagnant incomes of the poor and middle class have a causal effect on [economic] crises.” All together, these factors can lead to an erosion in public confidence in the institutions of society, contributing to conflicts that further dampen investment and growth.¹⁰⁸

Returning to the example of insulin once more, recall that there are currently many disparities in price-related access to insulin in the US. As referenced in the first section of this paper, the burden of high insulin prices is born most by young people and people of color—groups that are already economically disadvantaged in a number of other ways. Already saddled by educational debt and hindered by workplace discrimination, the added burden of sky-high insulin prices can prevent them from participating in the economy in other important ways (i.e. purchasing a home, making investments, etc.), contributing to further inequalities, which are a drag on the overall economy.

By bringing prices on many medications down significantly, and by charging unitary prices with no rebates or discounts allowed, publicly owned pharmaceuticals could eliminate differential pricing in many instances and therefore the unequal financial burden born by patients of different population groups. Furthermore, any potential regressive effects of a unitary pricing system could be further addressed by subsidizing below-cost or even free



access to certain medications for the most vulnerable populations, as Brazil did for HIV and AIDS treatments, or as the US already does in the case of vaccines for certain groups.

Second, illness is expensive to individuals and society. Insofar as the high prices, drug shortages, and missing medications of our current pharmaceutical system contribute to rates of chronic illness and disability, we would expect that expanded access to essential medications through public R&D and production to have a corresponding positive effect on lifespan, earnings, productivity and labor force participation (due to a reduction in disability). Turning to the insulin example once more, *The Economic Costs of Diabetes in the US* reports that diabetes cost the country \$90 billion in reduced productivity in 2017 alone due to increased absenteeism, inability to work due to disability, and premature death. Though optimal management of diabetes requires more than access to affordable insulin, that access would undoubtedly have positive economic effects for the individuals and communities most impacted. Patients that see significant savings in their insulin costs might utilize a portion of those savings for complementary treatments, high-quality food and other supports that aid in disease management and healthy lifestyles.

Third, as the public pharmaceutical sector expands over time and begins to displace more and more of the extractive private pharmaceutical sector, we would expect to see corresponding positive effects on economic inequality related to the economic activity of that sector. These effects would derive primarily from the return of profits to public entities (where they can be used to support social and economic services for lower income communities) and away from continued accumulation by traditional elites who most benefit from the industry's current structure. Furthermore, by shifting public resources away from an industry that shows significant internal wage disparities—and where top positions are overwhelmingly held by people of privilege—to the public sector, where rates of unionization and wage parity



are higher and where there are no private shareholders (who also by and large represent people of privilege) to extract value, we should see positive effects for economic equality.

Lastly, though it is beyond the scope of this paper to explore this strategy in detail, public ownership in the pharmaceutical sector would present the opportunity to engage in large-scale inclusive economic develop-

ment projects that could form a part of a broader industrial strategy for our nation, ensuring access to stable, good

jobs across the country for years to come. Publicly owned R&D, manufacturing, wholesale and even retail pharmacies could serve as local “anchor institutions”— usually public or not-for-profit enterprises such as universities and hospitals that are rooted in local communities through their mission, relationships and investments—in localities throughout the nation.

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Public ownership in the pharmaceutical sector would present the opportunity for inclusive economic development projects that could form a part of a broader industrial strategy.

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As place-based enterprises that manage vast economic, human, and institutional resources, anchors have the potential to create significant benefits for local communities.

They are uniquely qualified to contribute to what we term “community wealth building,” an approach to economic development that focuses on fostering collaborative, inclusive, and locally controlled thriving economies. Community wealth building strategies are aimed at broadening ownership and fostering democratic participation in order to ensure that the gains of economic activity are equitably shared, and that communities are strengthened in the process.

Healthcare institutions in the US and beyond are increasingly embracing their “anchor mission” to consciously and deliberately deploy their



long-term, place-based economic power and human resources, to improve the welfare of the communities in which they operate.

With healthcare institutions, this trend is due in part to a growing understanding of how social determinants affect individual and population health and therefore how upstream investments by healthcare anchors can help foster healthier local communities in what is essentially a preventative medicine approach. In the preface to the 2018 report, *Embracing an Anchor Mission: ProMedica's All-In Strategy*, ProMedica Board Chair Robert LeClair states, “We need to look beyond a singular focus on pure clinical and financial success. We need to focus on how we can have truly significant impact on health outcomes and in our communities by addressing the root causes of health and well-being.”¹⁰⁹ ProMedica is one of the founding members of the Healthcare Anchor Network, in which dozens of health systems from across the US commit to leveraging their assets to maximize their positive impact on the communities in which they operate.

Publicly owned pharmaceutical companies could also be powerful contributors to thriving local and regional economies if similarly engaged in anchor strategies, maximizing their economic impact on local communities by assuring that their hiring, procurement and asset use best matches community’s needs. With a mission to serve public health needs, an anchor approach to community wealth building would be a natural fit for democratic public pharmaceutical companies and could have lasting effects on the health and wellbeing of the communities in which they operate.

2. Benefits to democracy

A national system of publicly owned pharmaceuticals that starts displacing a portion of the for-profit industry would bring important benefits to our democracy by reducing corporate influence in politics. This includes reducing regulatory capture in the sector (thus ensuring that regulations



are primarily oriented towards evidence-based protections of consumer health and safety rather than company profitability) and shrinking lobbying and corporate contributions from the sector. These effects would be proportional to the market share that public pharmaceuticals (and such other alternatives as nonprofit pharmaceutical companies) are able to achieve.

Another positive effect for democracy emerges when each publicly owned institution created in the pharmaceutical sector is designed to maximize democratic practice, with mechanisms for transparency, participation, and accountability.

It would be unlikely to be controversial to propose a transparent and accountable public pharmaceutical institution, as both a growing portion of the public and our elected officials have begun to demand the same of the existing pharmaceutical industry. A number of states have already enacted transparency legislation regarding pharmaceutical pricing and at the national level, and a group of seven bills related to transparency in drug pricing (all of them bipartisan) were eagerly debated recently in a public hearing held by the House Energy and Commerce Committee. This keen interest in obtaining more information on the flow of money through the pharmaceutical supply chain, to inform policy-making regarding access to medicines, could be met in part by embedding robust transparency mechanisms into each of the publicly owned institutions created in this sector.

The NIH, for instance, already utilizes a comprehensive reporting tool that could be a model for the proposed public R&D institute. It allows the public to access reports on NIH expenditures, results of NIH-supported research, and other data and analysis achieved through its work.¹¹⁰ Furthermore, it provides Congress (and the public) biannual reports that give further insight into the how public funds are used and what progress is being made on the scientific priorities outlined in the institutes' strategic plan. Embedding a



new public R&D institute into the NIH would automatically make it subject to these measures.

As a greater share of public funds are directed to publicly controlled institutions that are transparent about their costs and operations, the public would gain increased insight into the flow of money through the pharmaceutical supply chain, which would inform future policy-making. That same cost transparency would pressure the private pharmaceutical industry to follow suit, further advancing the aims of the policymakers and others already advocating for such change.

Also critically important is a set of participatory mechanisms, including stakeholder representation on boards, public hearings, and planning and consultation processes.

Citizen participation in activities associated with healthcare planning and health services is already widely regarded as essential to improving public health. In addition to board membership, there are a number of patient and community-participation models from the healthcare sector that can inform the design of publicly owned pharmaceutical companies, and those companies' relationship to other agencies and programs in the healthcare sector.¹¹¹ For instance, community-based participatory research has been used for decades across the US and the world to better understand and combat community health issues. The results of such research could be used to inform the priorities set by local pharmaceutical manufacturers and contribute to R&D priority setting at the national level. Regional and local health councils, public consultations and citizen juries have been a part of the healthcare landscape in many countries for years and may be useful in informing national and regional healthcare planning that includes a specific role for publicly owned pharmaceuticals.



3. Health benefits

Finally, public ownership in the pharmaceutical sector would have a beneficial impact on individual and population health, in large part for reasons that are deeply intertwined with the benefits to democracy and the economy.

Some of the positive effects would be directly related to expanded equitable access to medications as a result of lower costs, little to no differential pricing, and deliberate strategies to prevent drug shortages and “missing medications.” Major purchasers of medications, like hospitals, are deeply affected by drug shortages and missing medications, which are both costly and dangerous. Strategies pursued by publicly owned entities in the pharmaceutical supply chain to build in redundancies and assure adequate production levels would go a long way towards addressing shortages that can cause multiple problems for individual and community health.

There would also likely be fewer post-market safety issues with publicly produced medications. The financially motivated rush to get drugs to market to ensure the longest possible period of exclusivity and the practice of marketing drugs for unapproved (“off-label”) uses which create so many of the safety issues we see today would not be central motivations of publicly owned pharmaceuticals. Furthermore, if publicly owned pharmaceuticals are properly embedded in communities with the transparency and accountability measures outlined above, when safety issues were to occur, the structures would be in place to address them effectively.

Such access to safe, affordable medicines is essential for a healthy society, and it can be a question of life or death for many patients. Nevertheless, studies have shown that only about 20 percent of health outcomes are attributable to the care we receive.¹¹² As social determinants like housing, employment and education account for a full 40 percent of health outcomes, much of the potential that public ownership in the pharmaceutical



sector has to affect health is through the deliberate and strategic restoration of profits to public balance sheets (allowing for greater investment in public services across sectors) and the increased opportunities for employment in the public sector, which is characterized by long-term opportunities with good wages and working conditions—especially for women and people of color who are often excluded from similar private sector jobs.¹¹³

The economic benefits discussed earlier of anchor strategies undertaken by publicly owned pharmaceutical enterprises would also have corresponding health benefits, due to the strong correlation between economic wellbeing and physical health. Moreover, the greater the proportion of our health system that is taken under public ownership, the greater the incentives will be for intentionally planning resource deployment for maximum benefit across the population. Essentially, as more responsibility for care provision is removed from the private sector, the state would be internalizing the costs of social and economic inequality, creating strong incentives to move resources upstream to address the social determinants that so affect health outcomes.

Lastly, evidence also suggests that civic engagement has benefits for health and wellbeing. The decentralized, participatory design of the institutions we propose here could therefore benefit populations by increasing their sense of agency and community belonging.

Conclusion

Despite the important role it plays in both our economy and our health, we have allowed the US pharmaceutical industry to evolve into a prime example of extractivism, anticompetitivism and disregard for public needs. Due to its outsize political power, it has become very difficult to regulate and is becoming ever better at maximizing shareholder value while becoming worse at meeting public needs. As awareness of and discontent with “business as



usual” grows among the American public, we must rise to the challenge of reimagining this key sector of our economy, for now and for the future, in a more democratic, transparent and health-oriented fashion. To achieve new outcomes, we need a new design. Democratic public ownership can be the vehicle for the designs we need to assure the pharmaceutical industry delivers superior outcomes for our health, economy and democracy.

By reclaiming a portion of the US pharmaceutical market for the public interest, creating new democratic and transparent institutions responsive to public needs, we can secure good public sector jobs that contribute to thriving local economies, bring down drug costs, and recoup the fruits of public investment in pharmaceutical R&D.

This paper only presents an initial investigation into the potential design and functioning of a “public option” in pharmaceuticals; further economic, legal, and regulatory research and modeling would need to be done to fully develop the model. Nonetheless the evidence presented here suggests that pursuing such a model further would yield a number of positive benefits for society. Properly designed, publicly owned pharmaceutical enterprises could help restart our innovation engine so that we are developing the critical medications of the future while also meeting pressing health needs today. They could help combat drug safety issues and mitigate costly and dangerous shortages. Democratic public ownership in this key sector could also help direct revenue upstream to address social determinants of health, empower communities by opening up avenues for participation and oversight, and create greater transparency into the flow of money through the pharmaceutical supply chain—all of which would result in broader gains for our economy and society.



Areas for further research and exploration

In the transition to a “public option” for pharmaceuticals, should public ownership conversion (i.e. nationalization) of any US corporation—or the US holdings of any transnational corporation—in the pharmaceutical supply chain play a role? Would it be beneficial, politically possible or preferable to take a large pharmacy benefit manager into public control? Should a company that holds a monopoly on life-saving medications be nationalized to assure access (not unlike the Bach and Trusheim proposal for the US government to buy Gilead in order to save money on Hepatitis C treatment)?¹⁴

What might be the trade implications of this model? The US is party to 14 trade agreements with 20 countries. Would its establishment of publicly owned pharmaceutical enterprises be challenged as unfair to competition? (For instance, countries including the US have either threatened economic sanctions or brought suit against a number of other countries under The Agreement on Trade-Related Aspects of Intellectual Property Rights when those countries, sometimes through public manufacturing, first produced low-cost anti-retrovirals using compulsory licensing.)

What unintended consequences might this model cause through disruption of the pharmaceutical industry (potential for job loss, disruptions in production of some medications, etc.)?

Are antitrust rulings needed to break up conglomerates like CVS and Walgreens that now occupy more than one link in the chain of pharmaceutical distribution? Could antitrust action be used to facilitate a public ownership conversion of one or more of the holdings of some of these corporations?



What potential might there be for massive employee-ownership conversion in the retail pharmacy sector, particularly if large conglomerates that now occupy several links in the pharmaceutical supply chain and payment structure (including retail) are broken up due to antitrust action?

What existing contractual relationships between different actors in the supply chain (manufacturers, wholesalers, PBMs and retail) might affect the market entry possibilities for new, publicly owned manufacturers and wholesale distributors?



Notes

- 1 “Report: Us Pharmaceutical Market Projected To Grow At Cagr Of 4.4% Up To 2020 Praveen,” Pharmaceutical Technology, January 19, 2017, <https://www.pharmaceutical-technology.com/research-reports/researchreportreport-us-pharmaceutical-market-projected-to-grow-at-a-cagr-of-44-up-to-2020-5720032/>.
- 2 “Insulin: A Life-Saving Drug Too Often Out of Reach,” Congressional Diabetes Caucus Co-Chairs Representatives Diana DeGette and Tom Reed, <https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf>. Lindsey Verano and Mary Laxton, “High Cost and Rising Insulin Prices Affect the Neediest in Our Community,” <https://medium.com/@CBUHP/high-cost-and-rising-insulin-prices-affect-the-neediest-in-our-community-8a637b263778>.
- 3 Veronika Wirtz et al, “Essential medicines for universal health coverage”, *The Lancet*, Vol 389, no 10067 (2017).
- 4 “An Economic Perspective on Delinking the cost of R&D from the Price of Medicines,” *World Health Organization* (2016), https://unitaid.eu/assets/Delinkage_Economic_Perspective_Feb2016.pdf.
- 5 Nicholas Florko, “PhRMA spent a record-breaking \$27.5 million in lobbying in 2018, new filings show,” *Stat*, January 22, 2019, accessed July 31, 2019, <https://www.statnews.com/2019/01/22/phrma-spent-a-record-breaking-27-5-million-on-lobbying-in-2018-new-filings-show/>.
- 6 “About VHA”, *Veterans Health Administration*, accessed July 18, 2019, <https://www.va.gov/health/aboutVHA.asp>.
- 7 “2016 Top Markets Report: Pharmaceuticals”, *International Trade Administration*, 2016, accessed May 10, 2018, https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.
- 8 The US International Trade Administration reports that the country only imports about 25 percent of finished pharmaceuticals by value (“2016 Top Markets Report: Pharmaceuticals”) while the FDA reports that the US imports around 40 percent of finished pharmaceuticals, though this figure may represent imports by volume, rather than value as per “Report to the Committee on Energy and Commerce: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices,” Government Accountability Office, December 2016, <https://www.gao.gov/assets/690/681689.pdf>.
- 9 Christoph Bieri, “What Drives Mergers & Acquisitions in the Pharmaceutical Industry,” *Contract Pharma*, January 30, 2018, accessed July 16, 2018, https://www.contractpharma.com/issues/2018-01-01/view_features/what-drives-mergers-acquisitions-in-the-pharma-industry.
- 10 Neeraj Sood et al, “Flow of Money Through the Pharmaceutical Distribution System,” USC Schaffer Center for Health Policy and Economics, 2017, accessed July 16, 2019, http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf.



- 11 See: “Generic Drug Savings in the US Seventh Annual Edition:2015,” *The Generic Pharmaceutical Association*, accessed July 16, 2019, http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf, Karen Freifeld, “US states allege broad generic drug price-fixing collusion,” Reuters, October 21, 2017, accessed July 16, 2019, <https://www.reuters.com/article/us-usa-generics/u-s-states-allege-broad-generic-drug-price-fixing-collusion-idUSKBN1D0201> and “Drugmakers Allegedly Inflated Prices Over 1000% and 44 states are now suing,” Reuters, May 11, 2019, accessed May 11, 2019, <https://www.cnbc.com/2019/05/11/us-states-accuse-teva-and-other-drugmakers-of-colluding-to-inflate-prices-over-1000percent.html>.
- 12 Ernst R. Berndt, Rena M. Conti, and Stephen J. Murphy, “The Landscape of US Generic Prescription Drug Markets, 2004-2016,” National Bureau of Economic Research, 2017, accessed July 16, 2019, <http://www.nber.org/papers/w23640>.
- 13 “Follow The Pill: Understanding the US Commercial Pharmaceutical Supply Chain,” Kaiser Family Foundation, 2005, accessed July 16, 2019, <https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/>.
- 14 Neeraj Sood et al, 2017.
- 15 “Everybody’s business: Strengthening health systems to improve health outcomes—WHO’s framework for action.”, *World Health Organization*, 2007, accessed July 16, 2019, http://www.who.int/healthsystems/strategy/everybodys_business.pdf.
- 16 Ashley Kirzinger, Cailey Muñana, Bryan Wu, and Mollyann Brodie, “Data Note: Americans’ Challenges with Health Care Costs,” Kaiser Family Foundation, June 11, 2019, accessed July 16, 2019, <https://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/>.
- 17 See: “Defying Trump, drugmakers hike prescription drug prices for 2019,” Reuters, January 2, 2019, accessed July 16, 2019, <https://www.nbcnews.com/business/business-news/defying-trump-drugmakers-hike-prescription-drug-prices-2019-n953756> and Jared Hopkins, “Drugmakers Raise Prices on Hundreds of Medicines,” *Wall Street Journal*, January 1, 2019, accessed July 16, 2019, <https://www.wsj.com/articles/drugmakers-raise-prices-on-hundreds-of-medicines-11546389293>.
- 18 “BREAKING: Brand-Name Drugs Increasing at 10X Cost of Inflation, McCaskill Report Finds,” Senate Committee on Homeland Security and Governmental Affairs, March 26, 2018, <https://www.hsgac.senate.gov/media/minority-media/breaking-brand-name-drugs-increasing-at-10x-cost-of-inflation-mccaskill-report-finds>.
- 19 Jean Fuglesten Biniek and William Johnson, “Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices,” Healthcare Cost Institute, January 21, 2019, accessed July 16, 2019, <https://www.healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>.
- 20 Herkert D, Vijayakumar P, Luo J, et al. “Cost-Related Insulin Underuse Among Patients With Diabetes,” *JAMA Intern Med.* 2019;179 (1):112-114. doi:10.1001/jamainternmed.2018.5008.



- 21 “Patients vs. Pharma: Hagens Berman files complaint against ‘Big Three’ insulin producers,” *TlInternational Statements*, January 30, 2017, <https://www.tlinternational.com/blog/2017/01/30/patients-vs-pharma-hagens-berman-files-complaint-against-eli-lilly-novo-nordisk-and-sanofi/>, and Nate Raymond, “Minnesota accuses insulin makers of deceptive drug pricing,” *Reuters*, October 16, 2018, <https://uk.reuters.com/article/us-minnesota-lawsuit-insulin/minnesota-accuses-insulin-makers-of-deceptive-drug-pricing-idUKKCN1MQ2OA>.
- 22 “New Report Shows Impact of Rising Drug Prices and Drug Shortages on Patients and Hospitals,” *American Society of Hospital Pharmacists*, January 15, 2019, <https://www.ashp.org/news/2019/01/16/new-report-shows-impact-of-rising-drug-prices-and-drug-shortages-on-patients-and-hospitals>.
- 23 C. Lee Ventola, “The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies,” *P & T : a peer-reviewed journal for formulary management*, 36(11), 2011, accessed July 16, 2019, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/>, Christopher Stomberg, “Drug Shortages, Pricing, and Regulatory Activity,” NBER Working Paper No. 22912, 2016, accessed July 16, 2019, <https://www.nber.org/papers/w22912>.
- 24 Katie Thomas and Sheila Kaplan, “Hurricane Damage in Puerto Rico Leads to Fears of Drug Shortages Nationwide,” *New York Times*, October 4, 2017, <https://www.nytimes.com/2017/10/04/health/puerto-rico-hurricane-maria-pharmaceutical-manufacturers.html>.
- 25 Lauren Weber, “Hurricane Maria’s Effect On The Health Care Industry Is Threatening Lives Across The US,” *Huffington Post*, September 20, 2018, accessed July 16, 2019, https://www.huffingtonpost.com/entry/iv-bag-drug-shortage-puerto-rico-hurricane-maria_us_5ba1ca16e4b046313fc07a8b.
- 26 Ventola, 2011.
- 27 Dana Brown, “Before Big Pharma Kills Us, Maybe Public Pharma Can Save Us,” *The American Prospect*, August 27, 2018, <https://prospect.org/article/big-pharma-kills-us-maybe-public-pharma-can-save-us>.
- 28 This is why it was no surprise that the US’s first nonprofit pharmaceutical venture, CivicaRx chose two antibiotics as the first medications they would produce, beginning in 2019.
- 29 Belen Pedrique, Nathalie Strub-Wourgaft, Claudette Some, Piero Olliaro, Patrice Trouiller, Nathan Ford, Bernard Pécoul, Jean-Hervé Bradol, “The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment,” *The Lancet*, October 24, 2013, [http://dx.doi.org/10.1016/S2214-109X\(13\)70078-0](http://dx.doi.org/10.1016/S2214-109X(13)70078-0).
- 30 Downing NS, Shah ND, Aminawung JA, et al. “Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010.” *JAMA*. 2017; 317(18):1854–1863. doi:10.1001/jama.2017.5150.
- 31 Data from “Recalls, Market Withdrawals, & Safety Alerts,” *Food and Drug Administration*, <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>. Ken Alltucker, “Three more blood pressure drugs recalled over cancer concern: Here’s what you need to know,”



- USA Today, December 6, 2018, accessed July 16, 2019, <https://www.usatoday.com/story/news/health/2018/12/06/mylan-pharmaceuticals-blood-pressure-medicine-recall-valsartan-amlodipine-hydrochlorothiazide-fda/2230721002/>.
- 32 Ben Goldacre, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*, Faber and Faber, 2012.
- 33 “Understanding the Epidemic,” *Centers for Disease Control and Prevention*, December 19, 2018, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.
- 34 Jackie Wattles, “Purdue Pharma says it will stop promoting opioids to doctors,” *CNN Business*, February 11, 2018, accessed July 16, 2019, <http://money.cnn.com/2018/02/11/news/companies/purdue-opioid-marketing-oxycotin/index.html>, and Lev Facher and David Armstrong, “End of an era: Purdue to stop marketing opioids to doctors,” *Stat News*, February 10, 2018, accessed July 16, 2019, <https://www.statnews.com/2018/02/10/purdue-stop-marketing-opioids/>.
- 35 Lena Groeger, “Big Pharma’s Big Fines,” *ProPublica*, February 24, 2014, <https://projects.propublica.org/graphics/bigpharma>.
- 36 See: Ken-Hou Lin and Donald Tomaskovic-Devey, “How Financialization Leads To Income Inequality,” Institute for New Economic Thinking, October 14, 2014, <https://www.ineteconomics.org/perspectives/blog/how-financialization-leads-to-income-inequality>; “Inequality and Health,” Inequality.org, <https://inequality.org/facts/inequality-and-health/>; and C.J. Polychroniou, “Financialization Has Turned the Global Economy Into a House of Cards: An Interview With Gerald Epstein,” *Truthout*, July 23, 2017, <https://truthout.org/articles/financialization-has-turned-the-global-economy-into-a-house-of-cards-an-interview-with-gerald-epstein/>.
- 37 “Health, United States, 2017: With Special Feature on Mortality,” National Center for Health Statistics, 2018, <https://www.ncbi.nlm.nih.gov/books/NBK532684/table/ch4.tab63/>.
- 38 Economic Costs of Diabetes in the U.S. in 2017,” *American Diabetes Association*, *Diabetes Care* 2018 Mar; dci180007. <https://doi.org/10.2337/dci18-0007>.
- 39 Katrin Weigmann, “The ethics of global clinical trials: In developing countries, participation in clinical trials is sometimes the only way to access medical treatment. What should be done to avoid exploitation of disadvantaged populations?,” *EMBO reports* vol. 16,5 (2015): 566-70. doi:10.15252/embr.201540398.
- 40 Waseem Noor and Saule Serikova, “Diversity and Inclusion: A Pharma 50 Perspective,” *PharmaExec.com*, June 23, 2016, accessed July 16, 2019, <http://www.pharmexec.com/diversity-and-inclusion-pharma-50-perspective>.
- 41 “Pharmaceutical and Medicine Manufacturing,” *Data USA*, accessed July 19, 2019, <https://datausa.io/profile/naics/3254/#demographics>.
- 42 Jonathan Fielding, “We Can Make Medicine Affordable,” *US News*, October 5, 2016, accessed July 16, 2019, <https://www.usnews.com/opinion/articles/2016-10-05/the-us-can-make-prescription-drugs-more-affordable>.



- 43 Mariana Mazzucato, "How taxpayers prop up Big Pharma, and how to cap that," *LA Times*, October 27, 2015, <https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html>.
- 44 Alexander Zaitchik, "Beyond the Planet of the Pharma Bros," *The American Prospect*, November 28, 2017, <https://prospect.org/article/beyond-planet-pharma-bros>.
- 45 Bhaven N. Sampat and Frank R. Lichtenberg, "What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?," *Health Affairs* 2011 30:2, 332-339, <https://doi.org/10.1377/hlthaff.2009.0917>.
- 46 Ekaterina Galkina Cleary, Jennifer M. Beierlein, Navleen Surjit Khanuja, Laura M. McNamee, Fred D. Ledley, "Contribution of NIH funding to new drug approvals," *Proceedings of the National Academy of Sciences* Mar 2018, DOI:10.1073/pnas.1715368115.
- 47 Carolyn Y. Johnson, "Taxpayers helped fund this \$129,000 cancer drug. Should the government help cut the price?," *Washington Post*, January 14, 2016, https://www.washingtonpost.com/news/wonk/wp/2016/01/14/taxpayers-helped-fund-this-129000-cancer-drug-should-the-government-help-cut-the-price/?utm_term=.de140dba2aee.
- 48 "Current Model for Financing Drug Development: From Concept Through Approval," in *Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies: Workshop Summary*, Institute of Medicine Forum on Drug Discovery, Development, and Translation, 2009, <https://www.ncbi.nlm.nih.gov/books/NBK50972/>.
- 49 "Aggregate Pharmaceutical Company Drug Sales, R&D outlays, and selected government R&D outlays," *Drug Databases*, Knowledge Ecology International, <http://drugdatabase.info/databases/>.
- 50 "Offshore Shell Games 2017: The Use of Offshore Tax Havens by Fortune 500 Companies," *Institute on Taxation and Economic Policy*, October 17, 2017, <https://itep.org/offshoreshellgames2017/>.
- 51 Max Nisen, "Big Pharma Murdered Tax Inversions," *Bloomberg*, April 6, 2016, accessed July 16, 2019, <https://www.bloomberg.com/opinion/articles/2016-04-06/big-pharma-ruined-tax-inversions-for-everybody>.
- 52 Matthew Gardner, Steve Wamhoff, Mary Martellotta, Lorena Roque, "60 Profitable Fortune 500 Companies Avoided All Federal Income Taxes in 2018," *Institute on Taxation and Economic Policy*, April 11, 2019, <https://itep.org/notadime/>.
- 53 Ana Swanson, "Big pharmaceutical companies are spending far more on marketing than research," *Washington Post*, February 11, 2015, <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research>.
- 54 William T. Cefalu, Daniel E. Dawes, Gina Gavlak, Dana Goldman, William H. Herman, Karen Van Nuys, Alvin C. Powers, Simeon I. Taylor, Alan L. Yatvin, "Insulin Access and



- Affordability Working Group: Conclusions and Recommendations,” *Diabetes Care* Jun 2018, 41 (6) 1299-1311; DOI: 10.2337/dci18-0019.
- 55 Drug Databases, Knowledge Ecology International.
- 56 William Lazonick, Matt Hopkins, Ken Jacobson, Mustafa Erdem Sakiñ, and Öner Tulum, “US Pharma’s Business Model: Why It Is Broken, and How It Can Be Fixed: Submission to the United Nations Secretary-General’s High-Level Panel on Access to Medicines,” *The Academic-Industry Research Network*, February 28, 2016, <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56d53506e32140fc7fd2a915/1456813318775/theAIR-net+US+Pharma+Broken+Business+Model+SUBMITTED+20160228.pdf>.
- 57 William Lazonick, Matt Hopkins, Ken Jacobson, Mustafa Erdem Sakiñ and Öner Tulum, “US Pharma’s Financialized Business Model,” Working Paper No. 60, *Institute for New Economic Thinking*, July 13, 2017, https://www.ineteconomics.org/uploads/papers/Final-WP_60-Lazonick-et-al.-US-Pharma-Business-Model-sept-8.pdf.
- 58 Gretchen Morgenson, “Big Pharma Spends on Share Buybacks, but R&D? Not So Much,” *New York Times*, July 14, 2017, <https://www.nytimes.com/2017/07/14/business/big-pharma-spends-on-share-buybacks-but-rd-not-so-much.html>.
- 59 Alexander Zaitchik, “How Big Pharma Was Captured by the One Percent,” *New Republic*, June 28, 2018, <https://newrepublic.com/article/149438/big-pharma-captured-one-percent>.
- 60 “Price Fixing,” *Federal Trade Commission*, accessed July 16, 2019, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/price-fixing>.
- 61 Friefeld, *Reuters*, 2017.
- 62 Christopher Rowland, “Investigation of generic ‘cartel’ expands to 300 drugs,” *Washington Post*, December 9, 2018, https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7_story.html.
- 63 CNBC, 2019.
- 64 Katie Thomas, “Drug Makers Accused of Fixing Prices on Insulin,” *New York Times*, January 30, 2017, <https://www.nytimes.com/2017/01/30/health/drugmakers-lawsuit-insulin-drugs.html>.
- 65 Jordan Canedy, “Pay-for-Delay: A Costly Practice in the Pharmaceutical Industry,” *Harvard Health Policy Review*, January 12, 2014, accessed July 16, 2019, <http://www.hhpronline.org/articles/2016/11/12/pay-for-delay-a-costly-practice-in-the-pharmaceutical-industry>.
- 66 Beth Mole, “Drug companies are sitting on generics—43% of recently approved aren’t for sale,” *ARSTechnica*, February 8, 2019, <https://arstechnica.com/science/2019/02/drug-companies-are-sitting-on-generics-43-of-recently-approved-arent-for-sale/>.
- 67 “Pay for Delay,” *Federal Trade Commission*, accessed July 16, 2019, <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>.



- 68 Erin Fox, “How Pharma Companies Game the System to Keep Drugs Expensive,” *Harvard Business Review*, April 6, 2017, <https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive>.
- 69 Erik Sherman, “Big Pharma Companies Use Loophole on Old Drugs for New Profits,” *Fortune*, February 19, 2019, <http://fortune.com/2019/02/19/orphan-drug-loopholes/>.
- 70 US House of Representatives, Energy and Commerce Committee, “Examining FDA’s Generic Drug and Biosimilar User Fee Programs Hearing,” Question to Dr. Janet Woodcock, March 2017, <https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fdas-generic-drug-and-biosimilar-user-fee-programs>.
- 71 Nadia Whitehead, “Why A Pill That’s 4 Cents In Tanzania Costs Up To \$400 In The US,” NPR, December 11, 2017, <https://www.npr.org/sections/goatsandsoda/2017/12/11/567753423/why-a-pill-thats-4-cents-in-tanzania-costs-up-to-400-in-the-u-s>; and Thyrotropin Alpha, *GoodRx*, last accessed July 19, 2019, <https://www.goodrx.com/thyrotropin-alfa>.
- 72 “Top Industries: 2018”, *Open Secrets*, <https://www.opensecrets.org/lobby/top.php?show-Year=2018&indexType=i> and “Pharmaceutical Health Products: Industry Profile Summary 2018,” *Open Secrets*, <https://www.opensecrets.org/lobby/indusclient.php?id=H04&year=2018>.
- 73 Sydney Lupkin, “Big Pharma Greets Hundreds Of Ex-Federal Workers At The ‘Revolving Door’,” January 25, 2018, <https://khn.org/news/big-pharma-greets-hundreds-of-ex-federal-workers-at-the-revolving-door/>.
- 74 “Pharmaceutical Health Products: Industry Profile Summary 2018,” *Open Secrets*.
- 75 Zaitchik, *The American Prospect*, 2017.
- 76 Eric Pianin, “How Big Pharma Lobbyists Keep Medicare Drug Prices High,” *Fiscal Times*, October 20, 2016, <http://www.thefiscaltimes.com/2016/10/20/How-Big-Pharma-Lobbyists-Keep-Medicare-Drug-Prices-High>.
- 77 Richard G. Frank and Richard J. Zeckhauser, “High-Priced Drugs in Medicare Part D: Diagnosis and Potential Prescription,” NBER Working Paper No. 24240, 2018, <https://www.nber.org/papers/w24240.pdf>
- 78 Carpenter, Daniel, and David A. Moss, eds. “Corrosive Capture? The Dueling Forces of Autonomy and Industry Influence in FDA Pharmaceutical Regulation.” Chapter in *Preventing Regulatory Capture: Special Interest Influence and How to Limit It*, 152–72. Cambridge: Cambridge University Press, 2013, doi:10.1017/CBO9781139565875.011.
- 79 DS Egilman, AH Presler AH, and CS Valentin, “Avoiding the Regulatory Capture of the Food and Drug Administration,” *Arch Intern Med*. 2007, doi:10.1001/archinte.167.7.732-b.
- 80 David Hilzenrath, “FDA Depends on Industry Funding; Money Comes with ‘Strings Attached’,” *Project on Government Oversight*, December 1, 2016, <https://www.pogo.org/investigation/2016/12/fda-depends-on-industry-funding-money-comes-with-strings-attached/>.



- 81 Mostaghim Sana R, Gagne Joshua J, Kesselheim Aaron S., "Safety related label changes for new drugs after approval in the US through expedited regulatory pathways: retrospective cohort study", *BMJ* 2017; 358 :j3837.
- 82 "Which firms profit most from America's health-care system," *The Economist*, March 15, 2018, <https://www.economist.com/business/2018/03/15/which-firms-profit-most-from-americas-health-care-system>.
- 83 Alison Kodjak, "It Will Take More Than Transparency To Reduce Drug Prices, Economists Say," *NPR*, <https://www.npr.org/sections/health-shots/2019/03/22/705469296/it-will-take-more-than-transparency-to-reduce-drug-prices-economists-say>.
- 84 Alex Lawson and Stephanie Taylor, "We Need a Public Option for Prescription Drugs," *The American Prospect*, July 27, 2018, <https://prospect.org/article/we-need-public-option-prescription-drugs>.
- 85 Andrew Cumbers and Thomas Hanna, "Constructing the Democratic Public Enterprise", *The Democracy Collaborative and Glasgow University*, 2019, <https://thenextsystem.org/learn/stories/constructing-democratic-public-enterprise>.
- 86 "NIH-Wide Strategic Plan: Fiscal Years 2016-2020," *National Institutes of Health*, <https://www.nih.gov/about-nih/nih-wide-strategic-plan>.
- 87 Dean Baker, "The Future of the Pharmaceutical Industry: Beyond Government-Granted Monopolies," *CEPR*, March 2019, <http://cepr.net/images//stories/reports/pharma-industry-2019-03.pdf>.
- 88 D. Gotham, MJ Barber MJ, and A Hill, "Production costs and potential prices for biosimilars of human insulin and insulin analogues," *BMJ Global Health* 2018 <https://gh.bmj.com/content/3/5/e000850>.
- 89 Jean Fuglesten Biniek and William Johnson, "Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices," *Health Care Cost Institute*, 2019, https://healthcostinstitute.org/images/easyblog_articles/267/HCCI-Insulin-Use-and-Spending-Trends-Brief-01.22.19.pdf.
- 90 Michael Alkire, "Unpacking Drug Price Spikes: Generics," *Health Affairs Blog*, March 21, 2016, DOI: 10.1377/hblog20160321.054028.
- 91 Henry Waxman, Bill Corr, Kristi Martin, and Sophia Duong, "Getting to the Root of High Prescription Drug Prices: Drivers and potential solutions," *The Commonwealth Fund*, July 2017, http://www.commonwealthfund.org/-/media/files/publications/fund-report/2017/jul/waxman_high_drug_prices_drivers_solutions_report.pdf , and "Generic Competition and Drug Prices," *Food and Drug Administration*, November 20, 2017, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.
- 92 Selena Simmons-Duffin, "To Combat Generic Drugs' High Prices, Civica RX To Make 2 Antibiotics," *NPR*, May 15, 2019, <https://www.npr.org/2019/05/15/723466508/to-combat-generic-drugs-high-prices-civica-rx-to-make-2-antibiotics>.



- 93 “Number of Retail Prescription Drugs Filled at Pharmacies by Payer,” *Kaiser Family Foundation*, 2018, <https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs>.
- 94 Gina Chereus, “New York City launches \$100 million universal health insurance program,” *Reuters*, January 8, 2019, <https://www.reuters.com/article/us-new-york-healthcare/new-york-city-launches-100-million-universal-health-insurance-program-idUSKCN1P21WF>.
- 95 Roni Caryn Rabin, “Consumers Struggle to Find EpiPens,” *New York Times*, March 10, 2018, <https://www.nytimes.com/2018/05/10/well/live/epipen-shortage-allergies.html>.
- 96 Kelly Tunney, “How Many People Use EpiPens In America? Mylan’s Price Increase Is Taking Advantage Of Its User,” *Bustle*, August 26, 2016, <https://www.bustle.com/articles/180800-how-many-people-use-epipens-in-america-mylans-price-increase-is-taking-advantage-of-its-users>.
- 97 Dan Mangan, “EpiPens cost just several dollars to make. Customers pay more than \$600 for them,” *CNBC Markets*, August 25, 2016, <https://www.cnbc.com/2016/08/25/epipens-cost-just-several-dollars-to-make-customers-pay-more-than-600-dollars-for-them.html>.
- 98 Tracy Seipel, “EpiPen outrage: Silicon Valley engineers figure real cost to make lifesaving auto-injector two-pack—about \$8,” *The Mercury News*, October 1, 2016, <https://www.mercurynews.com/2016/10/01/epipen-outrage-silicon-valley-engineers-figure-true-cost-to-make-lifesaving-auto-injector-about-10/>.
- 99 Martha White, “It’s Jaw-Dropping How Little It Costs to Make an EpiPen,” *Money*, September 7, 2016, <http://money.com/money/4481786/how-much-epipen-costs-to-make/>.
- 100 Ben Popkin, “Mylan’s Upgraded EpiPen Torn Apart By Experts,” *NBC News*, September 30, 2016, <https://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-inside-n652651>.
- 101 TThomas M. Hanna, *Our Common Wealth: The Return of Public Ownership in the United States*, Manchester University Press, 2018.
- 102 “Prime Vendor Division - Pharmaceutical Prime Vendor (PPV) Program,” *US Department of Veterans Affairs*, <https://www.va.gov/opal/nac/ncs/ppv.asp>.
- 103 “Postal Facts,” *USPS*, <https://facts.usps.com/>.
- 104 “Postal Facts,” *USPS*, <https://facts.usps.com/>.
- 105 “Joint Action,” *Northern California Power Agency*, <http://www.ncpa.com/about/mission/joint-action/>, and “How joint action agencies and state associations help power strong communities,” *American Public Power Association*, <https://www.publicpower.org/periodical/article/public-power-wholesale-savings-and-quality>.
- 106 According to WHO, “The social determinants of health are the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels. The social determinants of health are mostly responsible for health inequities - the unfair and avoidable differences in



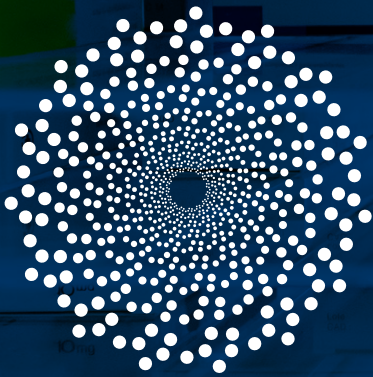
health status seen within and between countries.” https://www.who.int/social_determinants/sdh_definition/en/.

- 107 Cingano, F., “Trends in Income Inequality and its Impact on Economic Growth”, *OECD Social, Employment and Migration Working Papers*, No. 163, OECD Publishing, Paris 2014, <https://doi.org/10.1787/5jxrjncwxv6j-en>.
- 108 Era Dabla-Norris, Kalpana Kochhar, Frantisek Ricka, Nujin Suphaphiphat, and Evridiki Tsounta, *Causes and Consequences of Income Inequality: A Global Perspective*, International Monetary Fund, 2015, <https://www.imf.org/external/pubs/ft/sdn/2015/sdn1513.pdf>.
- 109 Randy Oostra, *Embracing an Anchor Mission: ProMedica's All-In Strategy*, Democracy Collaborative Press, 2018, <https://democracycollaborative.org/content/embracing-anchor-mission-promedica-s-all-strategy>.
- 110 “Research Portfolio Online Reporting Tools,” *National Institutes of Health*, <https://report.nih.gov/>.
- 111 See Kim S, Kim CY, You MS. “Civic participation and self-rated health: a cross-national multi-level analysis using the world value survey.” *J Prev Med Public Health*. 2015;48(1):18–27 and Marquez B, Gonzalez P, Gallo L, Ji M. “Latino Civic Group Participation, Social Networks, and Physical Activity.” *Am J Health Behav*. 2016.
- 112 “Putting ‘health’ in the electronic health record: A call for collective action,” *Nursing Outlook*, Volume 63, Issue 5, 614 - 616 <https://doi.org/10.1016/j.outlook.2015.08.003>.
- 113 Tyler Norris and Ted Howard, “Can Hospitals Heal America’s Communities?”, *The Democracy Collaborative*, December, 2015, [CanHospitalsHealAmericasCommunities.pdf](#).
- 114 Peter Bach and Mark Trusheim, “The US Government Should Buy Gilead For \$156 Billion To Save Money On Hepatitis C,” *Forbes*, January 17, 2017, <https://www.forbes.com/sites/sciencebiz/2017/01/17/the-u-s-government-should-buy-gilead-for-156-billion-to-save-money-on-hepatitis-c>.

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