HEALTH JUSTICE

Healing a Sick System

From Big Pharma to Our Pharma

by Dana Brown

Creating a robust public pharmaceutical sector can help break Big Pharma's monopoly on the nation's medicine supply and shift the balance of power, offering a systemic solution to exorbitant prices, recurring shortages, and declining innovation.

Imagine a world in which insulin and PrEP—the revolutionary one-a-day preventative HIV pill—were available to all who needed them at prices they could easily afford. Imagine that the effective Lyme disease vaccine once available was still on the market, and that new drugs consistently provided new clinical benefits, not just new prices.

In this world, there would be no artificial scarcity of COVID-19 vaccines, therapeutics, or tests needlessly prolonging the pandemic and upping the body count. Pharmaceutical manufacturing plants would be considered critical infrastructure, and retail pharmacies would be run for the benefit of their workers and local communities.

That world is eminently possible, and it could be built from a foundation of democratic, public ownership in the pharmaceutical sector. In fact, from Massachusetts, in the United States, to India, Thailand, and Great Britain, regions and whole countries have turned to public ownership in the sector to combat high prices, drug shortages, and political interference by multinational corporations, or to strengthen local economies and focus biomedical innovation on socially important goals.[1] Historically, much of the world—including the United States—relies on public sector labs for the development of vaccines.

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PUBLIC OWNERSHIP OF PHARMACEUTICAL COMPANIES CAN BE A VEHICLE FOR THE DESIGNS WE NEED TO PRODUCE SUPERIOR OUTCOMES.

But today, drug production is dominated by large, for-profit companies—"Big Pharma"—whose political power and market share allow them to dictate terms to patients, payers, and entire swaths of the globe. Big Pharma does whatever it takes to maintain its power: suing governments,[2] buying off competitors,[3] and keeping life-saving medications off markets if not given total freedom to set prices.[4] Despite comprising the most profitable large companies on the Standard and Poor's 500,[5] Big Pharma has delivered recurring shortages, increasing regulatory capture, rising post-market safety issues, and a decline in clinically meaningful innovation in recent decades.[6] As highly financialized corporations, they favor downsizing, outsourcing, and paying out extraordinary dividends to shareholders (often accounting for more than 100 percent of profits) over reinvesting in the business of making medicines.[7]

These trends are harmful to our health, our economy, and our democracy, and they disproportionately impact the least powerful groups in our society, including immigrants, people of color, LGBTI people, and people with disabilities. They are also the natural outcomes of an industry oriented around the singular goal of maximizing profit. To get different outcomes, we need a different design.

A PUBLIC PHARMA

Public ownership of pharmaceutical companies can be a vehicle for the designs we need to produce superior outcomes. Because they are not beholden to market imperatives, publicly owned pharmaceuticals are free from the constraints of profit maximization and rent seeking. Instead, they can define their bottom line on the basis of their contributions to public health, scientific advancement, and local economic benefit. With such goals, they would find it in their interest to reinvest earnings for socially productive purposes, such as researching new therapies, improving existing ones, and making essential medicines broadly available and affordable.

"Public pharma" institutions may exist at any or all points in the supply chain. Since 1960, Cuba's entire pharmaceutical sector has been public. It produces both low-cost generics and first-in-class therapies, manufactures a majority share of the domestic supply of medicine, provides thousands of good jobs, and contributes significantly to the national economy.[8] Known for its innovations, like the world's first lung cancer and meningitis B vaccines, Cuba's public pharmaceutical industry also engages in active technology transfer with numerous low- and middle-income countries, diminishing reliance on Big Pharma to meet healthcare needs.[9]

Several other countries employ public ownership in one or more nodes of the supply chain to meet local public health goals, support the economy, and assure sufficient supply of essential medicines. Sweden's public APL is the largest specialty drug manufacturer in Europe.[10] South Korea provides public contract manufacturing facilities to support small and medium biopharmaceutical enterprises as part of its industrial strategy.[11]

Properly designed publicly owned pharmaceuticals can have significant positive social benefits. Assuring that high-quality medications are available and affordable for all means that more people can stay active in their communities, remain in the workforce, pursue educational opportunities, and contribute to the local economy. Publicly owned pharmaceuticals can also foster resilient supply chains by building in surge capacity for emergencies in ways that actors in competitive markets do not.

SHIFTING THE BALANCE OF POWER

Establishing a publicly owned full-cycle pharmaceutical research and development (R&D) institute in the United States would be the most impactful public intervention in the sector. Because R&D is associated with the ability to claim and monetize intellectual property rights (IPR) on the new medicines that result, it is the point of greatest extraction and distortion in the current system. Industry-friendly regulations

PUBLIC OWNERSHIP OF PHARMACEUTICAL R&D CAN ALSO ASSURE THAT THE MEDICATIONS MOST ESSENTIAL TO PUBLIC HEALTH ARE PRIORITIZED FOR DEVELOPMENT—A SHARP CONTRAST TO BIG PHARMA COMPANIES THAT PRIORITIZE THE MOST PROFITABLE MEDICATIONS.

and IPR not only allow companies to charge whatever they please for the drugs they produce (regardless of clinical efficacy or production cost) but also slow down innovation, provide incentives to develop some drugs but not others, and keep competing products off the market—often for well beyond the original twenty years granted for any single patent.[12]

Companies also charge exorbitant prices to a public that has essentially already paid for its products through decades of publicly funded research, tax breaks, subsidies, and government purchasing through Medicare, Medicaid, and the Veterans Administration. Funding from a single public lab, the National Institutes of Health (NIH), already accounts for more than half of the R&D spend reported by major pharmaceutical companies each year.[13] In one striking example, this funding was linked at some level to the development of every single one of the 210 novel drugs approved for the U.S. market between 2010 and 2016.[14] Directing more of these funds into a public, not-for-profit institute would increase the efficiency of these investments.

Public ownership of pharmaceutical R&D can also assure that the medications most essential to public health are prioritized for development—a sharp contrast to Big Pharma companies that prioritize the most profitable medications, often copies of existing products, or "me-too drugs." These drugs not only offer little if any clinical benefit over existing drugs on the market, but their centrality to drugmakers' profit margins can even lead to what is called "negative innovation," with drugs coming to market that are "affirmatively harmful to patients."[15] Authors of a recent article in *Nature Biotechnology* highlight a cancer drug sold at a dose that provokes severe side effects because safer doses would not have earned the company the coveted patent it sought.[16]

While these duplicative and sometimes harmful drugs *are* being developed by the industry, many medications critical to health are *not*. Drugs like antibiotics and therapies for central nervous system diseases are chronically neglected by Big Pharma due to their low profit potential. Publicly owned labs can be explicitly tasked to prioritize R&D in these areas (as they already are in Brazil and Cuba) because it is valuable to the national healthcare system. A focus on therapies "overlooked" by the market would contribute to more equitable biomedical innovation, since diseases that predominantly affect less privileged groups (e.g., sickle cell anemia, multidrug-resistant tuberculosis, and many tropical diseases) are often eschewed by the market because the affected patient population is seen as too small or too poor to constitute a lucrative market.

A PUBLIC PHARMACEUTICAL R&D INSTITUTE

As an article I coauthored in 2020 details, a natural place to house a public pharmaceutical R&D institute would be at the National Institutes of Health, effectively closing the loop on the majority of existing public investment in pharmaceutical innovation.[17] There, the institute would also benefit from "close collaboration with existing institutes and their increasing involvement in early-phase clinical trials."[18] Nothing prohibits states or regions from also investing in public pharmaceutical R&D; but building on existing federal public investment in biomedical research and leveraging research already occurring at the NIH is likely the most direct route to achieving public return on public investment in the sector at scale.

Freed from market constraints, the institute could embrace explicit mandates to develop a safe, adequate, and accessible supply of essential medicines for the public; adhere to the highest standards of clinical trial and data transparency; and manage the intellectual property resulting from its discoveries in the public interest.

OVER TIME, A NETWORK OF STATE, LOCAL, AND REGIONAL PUBLIC PHARMACEUTICAL MANUFACTURERS, RETAILERS, AND DRUG DEVELOPERS COULD GROW TO DISPLACE EXTRACTIVE FOR-PROFIT COMPANIES AND RECLAIM MEDICINE AS A PUBLIC GOOD.

Initial R&D priorities could include products neglected by the market, medications to combat emerging pathogens, and promising areas of science that could lead to breakthrough technologies. Priorities could be updated over time in a similar process already used by the NIH to determine internal research priorities that balance "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."[19]

The institute's clinical trial and data transparency practices would help speed innovation by reducing duplication and waste.[20] Additionally, it would put pressure on private sector pharmaceuticals to manage their data more transparently—something advocates have long demanded—which, in turn, would further scientific advancement, ensure patient safety, and promote fairer pricing.

Regarding intellectual property rights on its innovations, the institute could be directed to maintain its patents in a pool subject to a "copyleft"-type license,[21] but to seek no trade secrets or data protections, as these forms of IPR present significant impediments to scientific collaboration and slow down innovation.[22] Managed in this way, new publicly developed medications would be broadly available and could be priced to ensure equitable access. Brazil provides a compelling example in which a network of its public labs and retail pharmacies were leveraged to help establish the country's Popular Pharmacies program, which provides low-income patients with over one hundred medications used to treat the most prevalent diseases for free or at deeply reduced prices.[23]

A PATH FORWARD

To be sure, a federal public pharmaceutical R&D institute in the United States would face many challenges. Political pressure from Big Pharma could easily undercut attempts to adequately fund the institute and constrain its mandate. Start-up costs would be significant, while achieving lower drug prices and innovation would take time. As short-termism dominates American politics, the institute could suffer a backlash in its early years before it is able to produce many easily recognizable returns. (This is not merely a theoretical concern; a similar pattern was evident in the initial U.S. public response to the Affordable Care Act.) For these reasons, it might be strategic to start with a limited mandate focused on developing drugs neglected or abandoned by the industry for their lack of profitability. If Big Pharma's bottom line is not threatened, the institute might enjoy broader political and financial support, enabling a successful start.

Notwithstanding the promise of public R&D at scale, experiments in public manufacturing, wholesale, or distribution may be easier to set in motion first. In fact, some of the groundwork for such initiatives has already been laid. In 2018, Senator Elizabeth Warren (D-MA) and Representative Jan Schakowsky (D-IL) introduced a bill for federal public drug manufacturing for the first time.[24] In 2020, California passed legislation that created a public generic drug label and established a pathway for future public manufacturing.[25] Since then, other states have introduced public drug manufacturing bills, largely at the behest of type 1 diabetes patient advocates aiming to break the insulin cartel's stronghold on the medicine that keeps them alive (which, ironically, was developed in a public lab in Canada a century ago).[26]

While one state-owned pharmaceutical manufacturer or retailer alone will not transform the economics of the industry, it could provide a powerful model and inspire others to experiment with interventions that prioritize residents' health. Over time, a network of state, local, and regional public pharmaceutical manufacturers, retailers, and drug developers could grow to displace extractive for-profit companies and reclaim medicine as a public good.

In recent years, much attention has rightly been focused on achieving swift and equitable access to COVID-19 vaccines and treatments globally. Strategies advanced include sharing intellectual property rights, engaging in active tech transfer, and helping scale manufacturing efforts worldwide. These steps can and should be taken. But most of these efforts do not address the root causes of artificial scarcity and high prices in the drug market. Ultimately, the main structural impediment to broad access to medicines must be addressed: the system of profit-based drug production.

Creating a robust public pharmaceutical sector can help break Big Pharma's monopoly on the nation's medicine supply and shift the balance of power, offering a systemic solution to exorbitant prices, recurring shortages, and declining innovation. As a leading funder of pharmaceutical R&D globally, the U.S. public sector is uniquely positioned to contribute to a new global paradigm of medicine provision as a public good. It would be a big step away from Big Pharma toward Our Pharma.

NOTES

1. See, for example: Violaine S. Mitchell, Nalini M. Philipose, and Jay P. Sanford, eds., *The Children's Vaccine Initiative: Achieving the Vision*, Institute of Medicine [US] Committee on the Children's Vaccine Initiative (Washington, DC: The National Academy Press, 1993); in Great Britain, the NHS trusts own and operate thirty-two drug manufacturers, listed here: www.pro-file.nhs.uk /Manufacturerinfo/NHSManufacturerList.aspx; "About Us," The Government Pharmaceutical Organization, www.gpo.or.th /about?lang=en; Thomas Fuller, "Thailand takes on drug industry, and may be winning," *New York Times,* April 11, 2007, www .nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html; "Central Public Sector Enterprises," Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, accessed December 14, 2021, pharmaceuticals .gov.in/central-public-sector-enterprises; and *Indian policies to promote local production of pharmaceutical products and protect public health* (Geneva: World Health Organization, 2017).
2. Helene Cooper, Rachel Zimmerman, and Laurie McGinley, "AIDS Epidemic Puts Drug Firms In a Vise: Treatment vs. Profits," *Wall Street Journal*, March 2, 2001, www.wsj.com/articles/SB983487988418159849.
3. Jordan Canedy, "Pay-for-Delay: A Costly Practice in the Pharmaceutical Industry," *Harvard Health Policy Review*, January 12, 2014, www.hhpronline.org/articles/2016/11/12/pay-for-delay-a-costly-practice-in-the-pharmaceutical-industry.
4. Sarah Boseley, "Drug maker 'will make $21bn from treating cystic fibrosis,'" *The Guardian*, August 12, 2019, www.theguardian .com/society/2019/aug/12/drug-maker-will-make-21bn-from-treating-cystic-fibrosis.
5. Fred D. Ledley et al., "Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies," *JAMA* 323, no. 9 (March 3, 2020): 834–43.
6. Dana Brown, *Medicine For All: The Case for a Public Option in the Pharmaceutical Industry* (The Democracy Collaborative, September 10, 2019).
7. William Lazonick et al. "US Pharma's Financialized Business Model," Working Paper No. 60, Institute for New Economic Thinking, July 13, 2017, www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf.
8. Cuba's biopharmaceutical industry is 100 percent publicly owned and operated. Cuba's public health infrastructure and healthcare infrastructure (provision of health services) are separate from the biopharmaceutical industry (although they interact, of course). All three experience challenges, in particular due to the embargo and limitations on imports of certain inputs, as well as other economic and political issues on the island. Nevertheless, the Cuban biopharmaceutical industry is still broadly seen as very successful (in terms of output, number of patents, innovation, and coverage of domestic demand, as well as an important amount of exports). See Andrés Cárdenas O'Farrill, "How Cuba Became a Biopharma Juggernaut," Institute for New Economic Thinking blog, March 5, 2018, www.ineteconomics.org/perspectives/blog/how-cuba-became-a-biopharma -juggernaut; and Andrés Cárdenas O'Farrill, *Cooperation Networks and Economic Development: Cuba's High-Tech Potential* (London: Routledge, 2021).
9. Dana Brown and Isaiah J. Poole, "The Case for a Public Option for the Drug Industry," *New Republic*, September 16, 2019, newrepublic.com/article/155071/case-public-option-drug-industry-purdue-pharma-settlement-bankruptcy.
10. Ibid.

11. I've seen presentations by Korean pharmacists about the public sector contract manufacturing facilities (there are two—one owned by the Korean Institute of Industrial Technology, a part of the Ministry of Industry, and another owned by a part of the Ministry of Health dedicated to vaccine development)—but currently there doesn't appear to be anything published in English on the topic.

12. *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, I-MAK, August 2018.

13. Drug Database, "Pharmaceutical Company Drug Sales as Compared to R&D Outlays," drugdatabase.info/pharmaceutical-company-drug-sales-as-compared-to-rd-outlays/.

14. Ekaterina Galkina Cleary et al., "Contribution of NIH funding to new drug approvals 2010–2016," *PNAS* 115, no. 10 (March 6, 2018): 2329–34.

15. Robin C. Feldman et al., "Negative innovation: when patents are bad for patients," *Nature Biotechnology* 39, no. 8 (August 2021): 914–16.

16. Ibid.

17. Ameet Sarpatwari, Dana Brown, and Aaron S. Kesselheim, "Development of a National Public Pharmaceutical Research and Development Institute," *Journal of Law, Medicine and Ethics* 48, no. 1 (2020): 225–27.

18. Ibid.

19. National Institutes of Health, *NIH-Wide Strategic Plan: Fiscal Years 2016–2020: Turning Discovery Into Health*, 2015.

20. Christopher J. Morten et al., "To Help Develop The Safest, Most Effective Coronavirus Tests, Treatments, And Vaccines, Ensure Public Access To Clinical Research Data," Health Affairs blog, March 26, 2020, www.healthaffairs.org/do/10.1377/hblog20200326.869114/full/.

21. Patent pools are agreements between two or more patent owners to license their patents to one another or to third parties, reducing transaction costs and accelerating scientific innovation. The fully public Cuban biopharmaceutical industry maintains all its patents in a similar pooled arrangement to facilitate shared learning.

22. If and until U.S. patent law is overhauled, taking out patents on publicly developed drugs might be necessary to protect against still powerful private companies seeking to profit off of those public inventions (or small tweaks on them) and control access to the resulting products. Some have argued, however, that if public inventions are put in the public domain—published freely and without patents—no company could patent them as they could not prove novelty. Nevertheless, such a strategy has never been tried at scale in the context of a large and powerful opposition well-versed in patent law, and thus other advocates contend that the current legal and cultural context would necessitate a form of defensive patenting on behalf of public institutions to maintain the public's interest.

23. Vera L. Luiza et al., "Applying a health system perspective to the evolving Farmácia Popular medicines access programme in Brazil," *BMJ Global Health* 2, Suppl. 3 (December 2017).

24. Affordable Drug Manufacturing Act of 2018, S. 3775, 115th Cong. (2018), www.congress.gov/115/bills/s3775/BILLS-115s3775is.pdf.

25. Office of Governor Gavin Newsom, "Governor Newsom Signs Legislation Advancing California's Fight to Lower Prescription Drug Prices," press release, September 28, 2020, www.gov.ca.gov/2020/09/28/governor-newsom-signs-legislation-advancing-californias-fight-to-lower-prescription-drug-prices/.

26. Dana Brown and Elizabeth Pfiester, "Insulin: a case study for why we need a public option in the pharmaceutical industry," STAT News, September 10, 2019, www.statnews.com/2019/09/10/insulin-public-option-pharmaceutical-industry/.

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