Use of Public Research and Manufacturing Enterprises to Lower Prescription Drug Prices and Increase Innovation

Health Policy Portal

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Abstract: This article proposes building on the success of publicly funded drug research and development and expanding the model to include the full cycle development, testing, manufacture and distribution of innovative and affordable new drugs.

Prescription drug prices in the United States exceed those of all other countries, largely driven by brand-name drugs that are protected by monopoly rights which Food and Drug Administration (FDA) approval and patents bestow. Brand-name drugs predominantly drive pharmaceutical spending, accounting for 80% of costs, but only 16% of drugs used.[1] In 2021, the top 10% of drugs by price represented only 1% of prescriptions but accounted for more than 15% of retail and 20–25% of non-retail drug spending.[2]

The brand-name pharmaceutical companies that make these drugs are significantly more profitable than other large publicly traded companies.[3] However, our current dependence on profit-oriented corporations to oversee pharmaceutical development and marketing has resulted in increasing drug prices, diminished innovation in critical areas, disparities in access, persistent drug shortages, and increased offshoring of drug manufacturing. Yet the brand-name drug market, where many problems originate, remains unchallenged.

The US should create public pharmaceutical research, development and manufacturing programs to reduce prices of new drugs, increase innovation, prevent shortages, and drive investment to drugs with the largest social benefits — much like the European Medicines Facility (EMF) proposal currently being debated in the EU.

Public Research and Manufacturing Enterprises (PRMEs)

Expanding and scaling the public sector's role in drug development beyond basic research could be transformative. PRMEs, whether operating within existing or as new public institutions, would do what we currently entrust to private companies — leverage publicly funded research to spearhead the development, testing, manufacture, and distribution of innovative and affordable new drugs. This system of public risk and public reward could have lasting pro-social impacts on the pharmaceutical sector by providing much-needed competition to companies with lagging innovation pipelines and monopolistic pricing practices while spurring investment in crucial areas for public initiatives to manufacture generic drugs.

Around the world — even here in the US — public jurisdictions, from municipalities to federal governments, have successfully advanced biomedical R&D in the public interest. A century ago, a number of public health departments were intimately involved in the development and manufacture of treatments for pressing public health problems. For example, the New York City Public Health Department played a pivotal role in developing and testing diph-

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About This Column

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theria antitoxin, giving the treatment free of charge to state and charitable institutions as well as private patients who could not afford the treatment. Another example includes the state of Michigan, which launched a biologics laboratory as part of its public health department in 1920 and went on to develop and produce a critical rabies vaccine for humans, as well as serve as the only domestic source of anthrax vaccines for a period of time.[4]

Today, public drug development and manufacturing efforts continue to innovate and save lives. Recently, California's Department of Public Health developed a successful treatment for infant botulism which it continues to produce and market today.[5] Then there is Massachusetts, which has been in the business of developing new drugs for over 125 years at MassBiologics, operated by the University of Massachusetts system. In the past few decades, MassBiologics has developed numerous biologics for the prevention of diseases like tetanus, hepatitis B, varicella zoster, and cytomegalovirus.[6] Additionally, the lab has developed monoclonal antibodies for the treatment of SARS, bacterial infections, and rabies.[7]

Public sector labs in other countries have brought the world such breakthroughs as insulin, and the world's first lung cancer and meningitis B vaccines.[8] Against this backdrop, it should come as no surprise that large-scale investment in public R&D infrastructure for the US has been proposed before. For instance, in 2004, legislation introduced in Congress sought to establish the "National Institute for Biomedical Research and Development to provide for the development of drugs, biological products, and devices to: (1) increase the number and medical efficacy of drugs, biological products, and devices on the market; and (2) make the drugs, biological products, and devices available to the public at reasonable prices."[9] PRMEs would meet those same goals through measures tailored to the specifics of today's pharmaceutical market and public health needs.

Public funding already drives drug research and development, with 99.4% of new drugs receiving public support before biopharmaceutical companies commercialize them.[10]

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Last December, the Biden administration proposed a framework by which the government can assert the Bayh-Dole Act "march-in" rights on publicly-funded drugs. March-in rights allow the government to manufacture or transfer patent rights to generic firms, if brand drugs become too inaccessible domestically.[11] Other legal provisions allow the government to manufacture and use any patented invention in exchange for reasonable compensation.[12] Additionally, some US states and non-governmental organizations have already entered the generic drug manufacturing business to increase supplies and reduce prices of existing drugs, and federal legislation to produce generic drugs in the public sector at scale was reintroduced in both the House and Senate at the end of 2023.[13]

PRMEs would simply marry government-funded drug development with drug manufacturing/distribution, creating a full-service drug supply chain dedicated to both developing and manufacturing new drugs for the public's benefit. Creating new domestic manufacturing capacity would also help achieve Bayh-Dole's original goal of commercializing federally-funded innovation and the Biden administration's current priority to reduce drug costs. Although the primary goals of PRMEs are to increase drug innovation and reduce drug prices, PRMEs should also have additional benefits. Specifically, PRMEs could help to reduce drug shortages, supporting underinvested drugs (such as antibiotics and vaccines), and enhancing domestic drug manufacturing capacity.

Furthermore, PRMEs may soon become essential to maintaining US competitiveness in the pharmaceutical sector. Europe is already considering large-scale investments in public pharmaceutical R&D infrastructure because "the existing EU system of direct and indirect support to R&D health projects has intrinsic limits, which cannot be solved with a mix of regulatory and marginal policy adjustments."[14] The most ambitious policy solution involves creating a large public R&D infrastructure, comparable to the NIH, "but going beyond it in terms of ownership and delivery mechanisms of innovative medicines … [placing] Europe as the top global player in the field of R&D for medicines, with direct benefits for patients and public-health systems, early career researchers."[15] This European Medicines Facility would be tasked to develop therapeutics in *at least* the following three areas: unmet medical needs, therapeutic areas where private pharmaceuticals charge excessive prices, and priority antimicrobials according to the WHO priority pathogens list for R&D of new antibiotics, ultimately producing a wide variety of therapeutics across drug classes.[16]

Opportunities

First, PRMEs could reduce drug prices, both directly and indirectly.

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Because they would be accountable to the public, PRMEs would have to prioritize affordability and eschew monopolistic pricing practices that make new drugs so expensive in the US. While many Big Pharma firms downsize productive assets to free up cash to pay dividends to stockholders or finance stock buybacks,[17] PRMEs could utilize all such funds as long-term investments in R&D. Without the need for bloated marketing budgets either, ultimately significantly greater investments in PRMEs would be productively deployed than at for-profit firms. Thus, even if PRMEs achieved no greater rate of innovation than private firms, the total costs to the public would be lower and the savings could be passed on to consumers and other payers.

Patients would benefit directly from more affordable PRME-produced drugs and indirectly from pressure exerted on private companies to lower prices for similar drugs. PRMEs would have the added benefit of revealing the true costs of drug production, manufacturing and distribution, helping the government better negotiate non-PRME drug prices, including for Medicare and all other public programs, such as Medicaid, the Veterans Administration, and the Department of Defense.

PRMEs could maximize public welfare by investing in drugs such as antibiotics, vaccines, and drugs for cardiovascular disease and diabetes. Typically, these drugs produce smaller profits for companies but bigger benefits for public health. Additionally, PRMEs could invest in oncology and gene therapy drugs, thereby lowering costs by increasing competition for these high-priced drugs responsible for a significant portion of current drug spending. By prioritizing drug development based on societal needs instead of profit margins, PRMEs could focus on developing drugs that are truly beneficial and innovative, maximizing the welfare returns on public investment.

PRMEs could also drive greater investment in early-stage research by private companies. Currently, drug companies spend less than a fifth of their revenue on research and development, with substantially more going to marketing and stock buybacks.[18] If companies could no longer exclusively capture government basic research, they would have to invest a greater share of their profits on their own research to remain competitive.

PRMEs could strengthen incentives for innovation by giving greater shares of revenues from scientific breakthroughs to the government-sponsored researchers who make them. The EMF proposal recognizes particular benefits to early career researchers. This would incorporate the benefits of prize-based incentives for innovation, which leading economists have long supported.

PRMEs could also manage intellectual property such as patents and "know how" in a way that more effectively accelerates innovation and efficiency. For example, PRMEs could spur innovation by openly licensing patents to enable researchers to develop new treatments in related fields, manufacturers outside the US to produce affordable drugs, particularly in the Global South, and to authorize generic drug manufacturers to begin production long before a patent's twenty-year term expires. Much like NIH did in providing non-exclusive licenses for COVID-19 vaccine technology, PRMEs could work with industry to boost manufacturing and distribution of drugs in urgent need or short supply.

In addition, PRMEs could increase the transparency of information that is critical for patients, researchers, and drug manufacturers by freely sharing clinical trial data and manufacturing "know how." Making this information available would enable patients to make more informed choices, researchers to make new advances, and generic drug manufacturers to produce a wider range of medications, particularly biologics.[19] Indeed, the EMF proposal recognizes the benefits of open science and open data while concurrently obtaining and asserting ownership of intellectual property rights for the public interest.

Similarly, PMREs could also publish the costs of their clinical trials to help reveal the true costs associated with R&D costs for new drug development. Pharmaceutical companies have long argued that elevated drug prices are necessary to recuperate high R&D expenditures. However, estimates of these R&D costs have varied from $43.4 million[20] to $4.2 billion.[21] Recently, Doctors Without Borders published the $36 million clinical trial costs[22] associated with its tuberculosis treatment.[23] Understanding the true cost of drug development would have numerous downstream benefits. First, it would enable the government to negotiate drug prices more effectively under the Inflation Reduction Act (IRA). Second, understanding these costs would allow the government to properly allocate necessary funding for optimal investment in R&D, translational research, and manufacturing and distribution of the drug.

Finally, by manufacturing drugs domestically, PRMEs would support local businesses and generate jobs, strengthening the domestic drug manufacturing industry, protecting patients from shortages, and bolstering the economy as a whole. As a 2021 White House review of supply chain vulnerabilities found, the current US pharmaceutical supply chain has "insufficient manufacturing capacity," and "misaligned incentives and short-termism in private markets."[24] PRMEs could provide much-needed supply chain resilience while also being a source of public-sector jobs where women and people of color enjoy higher employment rates, making these jobs an upstream investment in community health.

Challenges

While PRMEs have immense promise, it's crucial to acknowledge potential challenges.

Chief among them is the large capital investment needed to launch domestic drug research and manufacturing enterprises. The European plan also recognizes this issue and calls for an annual budget of €6.5 billion. However, these initial costs should be viewed against the high costs of the status quo and increased public benefits from investment in capital and workforce rather

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than corporate dividends or drug marketing.

The initial costs should be offset if PRMEs become financially sustainable by selecting research projects wisely, focusing on drugs that offer societal benefits and economic viability. A mechanism such as a right of first refusal would allow PRMEs to choose whether (or not) to develop promising candidates from publicly funded research before allowing private companies to cherry-pick the most lucrative prospects. This would enable PRMEs to utilize robust early-stage research capabilities that public funds already support while leaving ample development opportunities for private companies.

Another challenge is the anticipated backlash from the pharmaceutical industry, which hardly welcomes competition from for-profit firms (as decades of consolidation in the sector demonstrate), much less publicly-owned institutions. However, competing with PRMEs should rebalance anticompetitive behaviors such as patent abuse and regulatory gamesmanship, and compel companies to invest more in research and/or charge lower prices, benefiting us all.

Supporters of the status quo may argue that the public sector is not as innovative as the private sector, and thus should not receive such a large share of resources the country intends to invest in drug development. However, we must recall that the US public sector has a long tradition of breakthrough innovation in science and technology above and beyond the pharmaceutical examples above. For example, the Department of Defense's Defense Advanced Research Projects Agency (DARPA) played an instrumental role in the research and development of such innovations as Global Positioning System, microchips and the internet.[25] NASA sent astronauts to the moon and built the International Space Station together with other nations' space agencies. And of course, the Manhattan Project allowed the US to win the race to develop nuclear technology, leaving behind a legacy of national laboratories that continue to produce cutting edge research and development in areas such as clean energy, supercomputing, and nanotechnology. This impressive track record of public sector scientific achievement gives us an idea of what would be possible if public funds for pharmaceutical R&D were redirected to PRMEs designed to deliver high-quality medications accessible to all.

However, while these benefits are clear, they will not be instantaneous. The time lag between PRMEs' costs and benefits is another obstacle as their benefits will likely take time to materialize. Specifically, it may take 5-10 years before a drug moves from the laboratory bench to the bedside. It is critical that policymakers and their constituents understand that the program's advantages will be cumulative and long-term. Nevertheless, improvements in drug prices, hospitalization costs, and the overall wellness of our society should more than offset the high initial cost of capital.

PRMEs represent a transformative solution to the drug pricing crisis and concomitant problems of inadequate and inequitable access to medicine. Creating them will require effort, investment, and political will, but they could deliver what we urgently need: enhanced pharmaceutical innovation and manufacturing capacity, more affordable, effective, and equitable health care, and a stronger domestic economy.

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