Public Pharmaceuticals

State Policy Kit

How states can break Big Pharma monopolies on essential medicines with public manufacturing and distribution of pharmaceuticals



Table of Contents

lr	ntroduction	3
P	Policy Elements	
	Element 1: Establish state-owned enterprises to manufacture generic medications .	6
	Element 2: Create state and/or regional public distribution mechanisms	8
	Element 3: Select a governance model that prioritizes democratic control	12
Precedents1		.15
	California	15
	MassBiologics	15
	Washington	16
	Michigan Biologics	16
	Other State Efforts	17
ln	International and Historic Precedents18	
	Sweden	18
	Cuba	18
	Other International Examples	19

Introduction

Americans pay extremely high prescription drug prices — nearly double that of other wealthy nations. This creates a financial burden, with 83% of Americans agreeing that prescription costs are "unreasonable." What's more, high drug prices impact whether people actually take their medications. 29% of Americans say that in some cases, they can't afford to take their medication as prescribed.

Pharmaceutical companies argue that high prices are a necessary cost for world class research and development (R&D) enterprises. This is not borne out in the data, however — **studies find no correlation** between the price of a drug and the cost of development. Pharmaceutical companies don't set drug prices merely to earn back the costs of drug development — they find the price that will maximize profit, given market conditions, regardless of what it cost to develop the drug.

The enormous investments (both public and private) we make into the pharmaceutical industry accrue <u>almost entirely to private beneficiaries</u>—principally a small group of shareholders and industry executives. This contributes to growing health and economic inequality, as well as rising healthcare costs. In a sector like this with high initial costs and powerful incumbent players, markets are often far from competitive. This market concentration has produced numerous market failures, which can have disastrous consequences. Even beyond skyrocketing prices, a pharmaceutical industry oriented principally around achieving ever-greater returns for shareholders has produced routine shortages of essential medicines, declining innovation in many critical areas, a glut of <u>"metoo" drugs</u> with little clinical benefit, and incentives for misuse and dangerous mislabeling of medications.

Beyond economic issues, the pharmaceutical industry also harms our democracy and political process. With a strong lobbying effort and **massive amounts of money in politics**, some have called Big Pharma the epitome of **regulatory capture**. The public sees this happen and loses faith in our elected officials to make good decisions, instead becoming more susceptible to outrage and disinformation.

There is no shortage of proposals to address these issues. Some think that we should simply strengthen regulations on pharmaceutical companies, while others propose increased transparency or simple price caps on drugs. Still others advocate allowing Medicare to negotiate prescription drug prices, which the **2022 Inflation Reduction Act**

allows in a limited number of cases. Though beneficial, none of these reforms change the design of the pharmaceutical industry, leaving room for pharmaceutical companies to find new ways to evade controls. To fully address these issues, fundamental change is needed.

In this spirit, some states are looking to create elements of a "public option" for generic and biosimilar pharmaceuticals. Recent legislation in <u>California</u>, <u>Washington</u>, and <u>Maine</u> — including leaders from both political parties — are good first steps that other jurisdictions can learn from to pass more comprehensive policies.

Public pharma would increase supply and decrease cost for payers (including patients and public purchasers like Medicare & Medicaid, the Veterans Health Administration, and Departments of Corrections). Beyond the obvious benefits of affordable medicine for patients, these proposals would benefit state economies — healthy people are more able to participate in the workforce, pursue an education, and engage in local economic activity. Public production also returns revenue to public balance sheets and provides good jobs (themselves an upstream determinant of community health outcomes). What's more, such initiatives could be the basis for local and regional industrial strategies, based on good jobs rooted in place in an industry that will continue to be critical to the economy and healthcare needs of the nation — these are the manufacturing jobs of our future.

Another benefit of public pharma is the transparency it can provide in what is currently a very opaque sector. Price transparency in the pharmaceutical supply chain has long been a demand of healthcare advocates, and of government officials who want to spend public dollars wisely. While **over a dozen states** have passed drug price transparency laws, **enforcement has proven difficult** — private pharmaceutical companies view cost information as a trade secret and work hard to keep it private. Public pharma institutions can enshrine transparency in their mission and operations, finally shedding light on pricing in the pharmaceutical supply chain. In many jurisdictions, public sector institutions are already subject to greater transparency measures than private players, and newly-created institutions can choose to set an even higher standard for transparency.

Ultimately, private pharmaceutical companies will always prioritize maximizing profit at the expense of all other considerations. Only by fundamentally altering the structure of the pharmaceutical sector will we achieve an equitable system. Public pharma allows us to lower costs, improve access to medicine, increase transparency, and reduce regulatory capture by breaking Big Pharma's monopoly over our medicine supply.

Public production of medicines isn't a silver bullet — it does not solve every problem regarding access to medicine and equitable health outcomes. Patent reform, effective use of compulsory licensing, anti-trust action, and universal health insurance would all contribute to a holistically better system. Nevertheless, state-run public pharmaceutical options in manufacturing and distribution can deliver important gains for patients, return money to public balance sheets, and shore up critical supply chains. Most importantly, they can begin to shift the balance of power from private interests back to the public interest when it comes to the critical and life-saving good of medicine. While waiting for more federal action, states can pursue policies today that start building a more just pharmaceutical system.

Policy Elements

Element 1:

Establish state-owned enterprises to manufacture generic medications

States can bring pharmaceutical prices down and assure a safe and consistent supply of medicines by creating public entities to manufacture generic (off-patent) medications. (Note that in this policy kit, we use the term "generic medicines" broadly to encompass all off-patent medications whether chemical or biological in nature. For regulatory purposes, the terms would be "generic and biosimilar", but for simplicity's sake, we will use generic as a catch-all term.)

The FDA <u>defines a generic</u> as a "medication created to be the same as an already marketed brand-name drug", including in its "dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use." By volume, generics account for <u>80 percent of US pharmaceutical sales</u>, making their manufacturing and sale an impactful avenue for reform.

Many generics sell for substantially lower prices than their brand name counterparts. This generally only happens, however, once there are two or more generics on the market. **The FDA finds** 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." As of **2017**, there were over 500 drugs with only one marketed generic, and **over 180 off-patent drugs with no generic equivalents whatsoever**, due to a lack of market incentives and/or "pay-for-delay" deals struck between private brand-name and generics manufacturers. States can play an important role in boosting the number of affordable generics.

States could either manufacture generics directly, or contract with existing FDA-approved manufacturers. Direct manufacturing will likely be slower and more costly to get started. However, direct manufacturing allows states to retain full public control and promotes the creation of good, local, public sector jobs (which tend to employ more www.women and people of color, and see higher rates of unionization). Contracting will likely be quicker to get started and involve fewer startup costs — hence why nonprofits like CivicaRx and an existing program in California have gone with this model initially (though CivicaRx has plans to manufacture directly in the future, and California's legislation clearly leaves

that as a future possibility). However, contracting has a smaller positive impact on local economies, results in fewer public sector jobs, and forces states to depend on the willingness of private sector manufacturers to continue to enter into favorable contracts.

Regardless of the manufacturing approach states choose, it is vital to implement a governance model that prioritizes democratic control. For more on this, see Element 3.

Operationally, a manufacturer would begin by establishing criteria for the selection of the initial medications it will produce. Criteria 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 regulatory context, and access to suppliers for the active pharmaceutical ingredients involved in manufacturing the particular medication (if manufacturing directly).

States may prefer to sell their publicly-produced medications to patients through insurers (and their pharmacy benefit managers, or PBMs) as this approach would require the least tinkering with the existing system. However, if states find resistance from PBMs in including their low-cost generics on formularies (since the PBM's cut is based on list prices), they can pursue other options. Additionally, the threat of going around insurers and PBMs to set up alternative distribution models may be enough to get them on board with processing and distributing publicly-produced low-cost generics.

An alternative pathway would be for states to sell directly to consumers and health systems, and/or distribute at least some medications for free through existing public and quasi-public entities like the US Postal Service and Federally Qualified Community Health Centers. Some direct purchasing facilities already exist, such as Mark Cuban's Cost Plus Pharmacy, which follows a trend of patients seeking out better prices on medications by paying pharmacies directly, rather than going through their insurance. There are several examples of US states and foreign countries where publicly-produced medications are distributed for free (see MassBiologics and Brazil examples below).

Additionally, if some states or regional compacts begin to play the role of wholesale distributors (as discussed in the following section) these can allow for public-public partnerships between manufacturers and distributors that can further decrease end-user prices and help assure consistent supply. As more states begin to explore their unique role in an evolving landscape of public pharma initiatives, they might find it beneficial for states to specialize in different things—like chemical vs biologic generic drug manufacturing, medical device manufacturing, or wholesale distribution. With different jurisdictions

taking different roles, the opportunities for cooperation and collaboration grow, and the possibilities of developing a whole public-interest market for essential medicines is much greater.

Public manufacturers could be capitalized in a variety of different ways, including but not limited to general obligation bonds, state loans, and possible equity financing. Existing research institutes like the **California Institute for Regenerative Medicine** 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 may require voter approval via a ballot measure, and may be seen as a more politically risky or controversial form of financing, especially for an institution that should be able to produce the revenue needed to meet revenue bond obligations.

Unlike private manufacturers, public manufacturers (not motivated by shareholders demands for ever-increasing quarterly returns) could and should charge unitary prices (offering no rebates or other "kickbacks" to purchasers or distributors) and make those prices public. This would help assure that essential medications are distributed at accessible prices, ensuring broad access to life-saving medications and eliminating an unnecessary source of inefficiency and obscurity from pharmaceutical sales. Furthermore, having public producers publish their prices would shine a light on the percentage that intermediaries like private distributors are taking, providing the public and their elected representatives more information about where further savings are possible.

Element 2:

Create state and/or regional public distribution mechanisms

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. Wholesale distributors 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. Wholesale distribution is among the most highly concentrated parts of the current pharmaceutical market, with just three firms controlling as much as **92% of the market**, creating inefficiencies and driving up prices. This means there is ample opportunity for states to help drive down drug prices at the point of purchase by setting up public sector wholesale distributors.

States may choose to do their own distribution, but could also work together to form regional distribution mechanisms, which would be mutually beneficial for participating states, reach more patients, and have a greater impact on the pharmaceutical market as a whole. These could provide a low-cost, more efficient and transparent alternative to the existing for-profit players in this sector. 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. (Note that as with manufacturing, states should carefully consider implementing governance models that prioritize democratic control. For more on this, see Element 3.)

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 reasons of efficiency and scale. Additionally, regional organization would allow for smaller states to band together, reaping the benefits of democratic public ownership even if they can't support their own pharmaceutical manufacturing enterprises. Furthermore, as states begin to enter the pharmaceutical manufacturing market, they may choose to specialize in different types of medications and medical devices. But working through regional public distributors, all those goods could be exchanged and the full range of publicly-produced medicines would be available to more purchasers.

Existing regional compacts and partnerships in the healthcare or pharmaceutical sector might be leveraged to help get such initiatives off the ground. For instance, the <u>ArrayRx</u> <u>program</u> (formerly the Northwest Prescription Drug Consortium) which currently includes WA, OR, and NV, could act as, or help create, a regional public distributor for both publicly and privately-produced medicines.

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. 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 which provides electricity, flood control, navigation and other services to the region while also serving as a regional economic 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 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, understanding the factors responsible for its success and enduring political support, as well as its limitations regarding participatory processes.

Other existing regional public entities like the <u>Appalachian Regional Commission (ARC)</u> and the <u>Delta Regional Authority (DRA)</u> might be leveraged for their expertise, or even become implementing partners for new public wholesale distributors. 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.

While not always organized regionally, a number of jurisdictions in the US already have experience with distribution, both of pharmaceuticals and other products. The state of Massachusetts distributes vaccines and other biologics produced by their state-owned laboratory, MassBiologics, both in-state and nationally. The state of Michigan also used to distribute publicly-produced vaccines and other medicines for many decades before the 1998 privatization of their state-owned lab.

Additionally, 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.

On the national level, the Veterans Health Administration (VHA) operated all of its pharmaceutical distribution in-house prior to the early 1990s, with a <u>network of warehouses for the acquisition and storage of medicines and other medical products</u>. 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 the operations of regional public wholesale distributors.

Together, existing public institutions like the VHA and public hospitals, or quasi-public institutions (like community health centers), could be leveraged as part of a future public pharmaceutical distribution network. 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 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 list price, as is the practice with private wholesalers). 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.

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 serves every community in the United States. 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. Furthermore, increased utilization of the USPS for this service could shore up this critical public institution as the demand for letter delivery declines.

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**.

Element 3:

Select a governance model that prioritizes democratic control

Public pharmaceuticals need not reflect the highly centralized, top-down and often bureaucratic forms of past public ownership (nor those of the for-profit pharmaceutical industry whose market failures they seek to remedy). 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.

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;
- 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.

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 any potential 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. Surplus, if there is any, could be reinvested into manufacturing in order to help manufacturers expand and produce more essential medicines. Or it could be used to subsidize the end-user purchase price of certain medicines. Lastly, states could choose to utilize any surplus for 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.

Precedents

California

California is currently the leading example of a state effort to manufacture generic drugs in the public sector. In January 2019, California Governor Gavin Newsom signed an **Executive Order on State Prescription Drug Spending**, making it clear that reigning in prescription costs is a political priority for the state, and that there is sufficient evidence that public sector intervention 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**). As the largest state pharmaceutical market by volume, California's foray into public production is expected to create ripples around the country and open up opportunities for other states to get involved in public pharma initiatives

In 2020, California passed legislation that requires the "California Health and Human Services Agency (CHHSA) to enter into partnerships to produce or distribute generic prescription drugs and at least one form of insulin." This act created a public generic label, called CalRx, which has since begun a process of contract-manufacturing generic medicines to sell to Californians, with the goal of reducing overall prescription spending for the state and its residents. In 2022, a second bill was passed which requires the "development of a California-based manufacturing facility for insulin" and mandates that CHHSA prioritize for selection generic drugs that "have the greatest impact on lowering drug costs to patients, increasing competition and addressing shortages in the prescription drug market, improving public health, or reducing the cost of prescription drugs to public and private purchasers." The state also appropriated an initial \$100 million to bring public insulin to the California market and create local manufacturing capacity for it.

MassBiologics

MassBiologics is a public biopharmaceutical R&D and manufacturing enterprise associated with the University of Massachusetts (formerly operated by the Department of Public Health) and is the "only non-profit, FDA-licensed manufacturer of vaccines" in the United States. For over 100 years, MassBiologics has worked to improve public health through applied research, development and production of biologic products including vaccines, plasma derivatives and, most recently, monoclonal antibodies. MassBiologics currently manufactures Tetanus and Diphtheria Toxoids, Adsorbed (Td) vaccine and distributes products nationwide." MassBiologics engages in R&D, but also manufactures

and distributes its products. Additionally, they maintain manufacturing capacity that is often used as contract-manufacturing space, bringing revenue into the public sector by leasing that manufacturing capacity to private entities.

MassBiologics receives ongoing appropriations from the state legislature, but these are complemented by other sources of income. **Recent annual reports** show that appropriations partially cover staff and provide the supplies and equipment used in the production of the Td vaccine (which is distributed to Massachusetts residents without charge). Other revenue comes in the form of licensing royalties (e.g. for their rabies, RSV and c diff monoclonal antibodies) and grants (both from public entities and from private philanthropy).

Washington

In 2021, Washington State passed SB 5203, building on the example set by California. Washington's program gives the state increased flexibility, allowing partnerships with California and other states. Implementation is led by the Washington State Health Care Authority. Nevertheless, the initiative has been woefully under-resourced to date. While the state has made great strides to reduce out-of-pocket spending at the retail pharmacies through an innovative discount card program, ArrayRx, developed together with the states of Oregon and Nevada, efforts to make deeper change in the pharmaceutical supply chain by engaging in public production or distribution are on hold due to resource constraints. However, having the enabling legislation on the books could empower a new generation of activity in Washington state to ensure the public interest is centered in state pharmaceutical spending, but legislators will have to appropriate the funds necessary to make such efforts successful.

Michigan Biologics

Until 1998, Michigan produced vaccines through its Public Health Department and the Michigan Biologics Laboratories. The program was started in the 1920s following a diphtheria outbreak, and initially operated under the Public Health Department. The lab made typhoid vaccines, silver nitrate (once used to prevent gonorrheal infection in the eyes of newborn infants), DPT (diphtheria-pertussis-tetanus) vaccine, tetanus toxoid, diphtheria-tetanus toxoids, rabies vaccine, anthrax vaccine, botulinum toxoid, pertussis vaccine, human albumin (a blood product), immune serum globulin, and anti-hemophilic factor, amongst other products. These products were distributed for free to Michigan residents, and some were sold at-cost to other states and through contracts with NGOs.

While in operation in the public sector, the lab was considered highly successful at

building resilience to national market conditions. In the mid-1980s, for example, there was a national shortage of the Tdap vaccine. **Michigan and Massachusetts were the only states not affected**, because of their in-house production capabilities.

In 1998, the lab was privatized and the facilities were sold to the newly-formed company Bioport. At the time of the sale, the lab was the sole US producer of the **anthrax** and **rabies** vaccines.

After the state sold the lab to Bioport (now Emergent BioSolutions), Bioport <u>struggled</u> to produce the anthrax vaccine and failed to secure FDA certification for its manufacturing facility, meaning that the anthrax vaccine they produced could not be routinely distributed **from 1998-2002**.

Michigan's history of public sector biologics' production is now <u>being hailed</u> by lawmakers and constituents who suggest the state look into public production of insulin to drive down prices.

Other State Efforts

In 2022, the Maine legislature passed <u>legislation</u> to assess the feasibility of public production of insulin and created a formal commission to study possibilities for their state.

York and Illinois, and have been discussed in several other states. Nevertheless, while several of these current efforts allow for state health authorities to produce or procure generic medicines in the public sector, few require state agencies to do so, and even fewer have been resourced to actually allow for successful implementation of such efforts. Thus far, only California's efforts have included appropriations commensurate with the stated goal of actually bringing at least one generic essential medicine (insulin) to market in the coming years.

As with any new program, public pharmaceutical initiatives will be most successful when they can rely on consistent budgets and clear priorities over time. Additionally, if not established with a clear mission and sufficient democratic governance and accountability mechanisms, public pharmaceuticals could be vulnerable to politicization or revert to market-based measures of success. States considering public pharmaceutical initiatives should seek to learn from existing and past examples, but also work with local partners and patient advocates to assure that their initiatives best meet local needs and take advantage of local resources to achieve their goals.

International and Historic Precedents

in Public Pharma R&D, Manufacturing, and Distribution

Sweden

Much of the Swedish pharmaceutical sector—including retail and specialty drug development and manufacturing—was <u>nationalized in 1970</u>. Apoteket, a state-owned company, 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 <u>nearly 900 retail sites</u>. 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 <u>among the lowest in Europe</u>. 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, the retail and production entities were divided in 2009-10, during a period of deregulation. Since then, 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 catalog 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.

Cuba

Since 1960, Cuba's entire pharmaceutical sector has been public. It produces both low-cost generic drugs and first-in-class discoveries, while providing thousands of good jobs and educational opportunities in the local economy. Known principally for its

innovations, like the world's first <u>lung cancer and meningitis B vaccines</u>, the industry also manufactures the majority of the domestic supply of medicine and shares its technology with numerous low and middle-income countries, diminishing those countries' reliance on Big Pharma to meet healthcare needs.

The industry's success in Cuba can be measured by its <u>numerous technology transfer</u> 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 over **1,200** international patents, and has garnered a number of UN World Intellectual Property Organization innovation awards. 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.

Other International Examples

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.

The UK has **over two dozen public manufacturers** of medicines and medical devices that make hundreds of products which they sell to hospitals in the UK and purchasers abroad. China and India's state-owned pharmaceutical companies produce a large number of active pharmaceutical ingredients, chemical and biologic drugs purchased worldwide. 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.

About Democracy Policy Network:

The Democracy Policy Network (DPN) empowers state leaders, policy experts, and volunteer researchers across America to gather, develop, and spread a transformative state policy agenda for deepening American democracy.

Learn more at **DemocracyPolicy.network**

About Democracy Collaborative:

The Democracy Collaborative is a research and change-agent organization building a people-powered vision for a new, democratic economy run on shared prosperity and inclusion, not exploitation. We develop and advance bold policy frameworks, like community wealth building, to aid policy-makers, academics, researchers, and legislators in the United States and across the world working to realize a more just and equitable world for all.

Learn more at: **DemocracyCollaborative.org**

About T1International:

T1international is a non-profit led by people with and impacted by type 1 diabetes for people with type 1 diabetes. They support local communities by giving them the tools they need to stand up for their rights so that access to insulin and diabetes supplies becomes a reality for all.

Learn more at **T1International.com**

To get in touch, visit DemocracyPolicy.network/PublicPharma



 $This work is licensed under a {\color{red} \underline{\textbf{Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License}}.$





