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AmericaRx

Manufacturing Affordable Drugs in the Public Interest

GROUNDWORK COLLABORATIVE

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Introduction

THE U.S. PHARMACEUTICAL INDUSTRY is a highly profitable, highly extractive industry. While it delivers scientific breakthroughs and develops life-saving treatments for illnesses that were once incurable, the industry fails Americans on numerous fronts: routine and growing shortages of essential medicines, a declining trend in clinically meaningful innovation, and most famously, the world's highest medicine prices.[1]

Brand-name drugs enjoy monopoly rights conferred through patent protection and even the generics market operates with numerous monopolies and oligopolies due to a lack of financial incentives for greater competition. Coupled with decades of industry consolidation[2] and financialization[3], the deployment of one of the country's most powerful lobbies[4], and significant regulatory capture[5], Big Pharma has amassed enormous political and economic power that it successfully wields to block competition, bend the rules, and dodge nearly every attempt to rein in its excesses.

For decades, policymakers and advocates have put forth proposal after proposal to fix high drug prices. But none to date have directly addressed the root of the problem: pharmaceutical manufacturers work to maximize return to shareholders, not to produce the medicines Americans need at a price they can afford.

We lack a business model that can discipline or provide an alternative to the price gouging rampant in both branded and generic drug markets. Further, we lack a system willing to produce low-margin drugs in the interest of public health and wellbeing – even when it isn't profitable.

In this brief, we propose a solution that can fill these gaps: AmericaRx. AmericaRx would be a coordinated, federally backed network of public pharmaceutical factories, developed in partnership with states and localities to produce essential medicines at scale. These facilities would assure a consistent, safe, and affordable supply of medications, break the grip that pharmaceutical monopolies hold on drug pricing, and ensure continued production of low-margin generics that private capital will not sustain.

This brief has three parts. First, we examine the structural challenges in brand and generic drug markets that prevent development of affordable medications. Second, we argue that public drug manufacturing fills the missing middle. Finally, we outline how both traditional and novel industrial policy tools can make AmericaRx public manufacturing feasible, competitive, sustainable, and contribute to thriving local economies.

Part I: Market Failures

PART I: MARKET FAILURES

Brand Drugs: Monopoly Power and Pricing Abuse

DESPITE CONSISTENTLY RANKING among our most profitable industries and pumping out blockbuster after blockbuster, the U.S. pharmaceutical sector fails society on numerous fronts. The industry consistently charges eyewatering prices, even as there are routine shortages in essential medicines. All too often, the industry prioritizes copycat medications that provide little to no clinical benefit over existing medicines on the market. These dynamics stem from the incentives embedded in the industry's structure.

The primary goal of Big Pharma companies is to maximize returns to shareholders, not to deliver the medications people need most.[6] Between 2000 and 2018, large pharmaceutical firms maintained a median gross profit margin of 76.5%, double the 37.4% median for S&P 500 companies.[7] To achieve this, the industry has followed a well-worn path of consolidation and vertical integration that has resulted in far too little competition. Between 1995 and 2015, the number of drug manufacturers dropped from sixty to ten.[8] When it comes to particular drugs, market consolidation is a serious problem as well. An HHS study found that among roughly 1,800 small-molecule drugs on the market in 2022, 43% had only one manufacturer.[9] These drugs made up 65% of total spending on small-molecule medicines. Furthermore, the industry is segmented into small groups of highly specialized producers that focus on a specific subset of the market (e.g., cancer immunotherapies or insulins) to avoid competing with one another. This results in an untenable situation for society: when one company controls a drug, it can set the price as high as the market will bear, and it is vulnerable to supply chain shocks that could leave us all without access to essential medicines.

A second problem is intellectual property (IP) protections that go well beyond their intent. The patent system is intentionally designed to give drug makers time-limited market exclusivity – typically 20 years from the filing date – so they can recoup research and development (R&D) costs before generic competitors enter. But over time, the pharmaceutical industry has learned to exploit this system to block competition and extend monopoly pricing well beyond the window the original patent was meant to provide.

When developing a drug, companies don't just file for one patent, but dozens, increasing the difficulty for competitors to develop their own drugs.[10] Drug companies also use tactics like "evergreening" and "patent thicketing" to keep competitors out even after the original patent should have expired by making small changes to a drug's formula or delivery method, or even changing a pill's appearance, to secure new patents and delay generics. AbbVie, for example, filed over 240 patent applications on Humira, of which 89% were filed after the arthritis drug was already on the market, successfully delaying competition in the U.S. until 2023, nearly two decades after the drug's original approval.[11] Additionally, companies use these treasure troves of IP to intimidate potential competitors by routinely suing generics companies that wish to bring competition to the market, often resulting in "pay-for-delay" agreements that keep low-cost drugs off the market, even when patent protections have expired.[12]

Coupled with decades of industry consolidation and financialization, the deployment of one of the country's most powerful lobbies, and significant regulatory capture, Big Pharma has amassed enormous political and economic power that it successfully wields to block competition, bend the rules, and dodge nearly every attempt to rein in its excesses.

These anti-competitive pressures, combined with a lengthy and costly FDA approval process that imposes significant upfront expenses, leave emerging manufacturers with little runway when entering the market.[13] A 2019 study by the American Economic Liberties Project and the Initiative for Medicines, Access and Knowledge (I-MAK) estimated that these anti-competitive practices cost U.S. patients and payers an extra $40 billion in a single year.[14] That works out to about $120 for every American – money spent not on new cures or better treatments, but on keeping prices high in order to maximize returns to shareholders.[15]

A third problem is consolidation of drug purchasers, particularly Pharmacy Benefit Managers (PBMs), which favor certain brand-name drugs or PBM-owned generics. This limits both revenue and market share for new entrants even when they are able to receive FDA approval.

In addition to lack of competition and barriers to entry in the industry, drug makers are able to raise prices because they have extraordinary political influence and have been able to capture federal regulators. The combination of their vast lobbying efforts and the budgetary structure of the FDA, which relies primarily on income from the industry, all but exempts the industry from strenuous oversight.[16]

The monopoly power Pharma giants have amassed has come at an enormous cost to patients. According to the Institute for Clinical and Economic Review (ICER), the median net launch price for new U.S. drugs rose 51% between 2022 and 2024 (after adjusting for inflation and discounts), with median annual treatment costs for 2024 launches exceeding $308,000.[17] And according to a recent report by the U.S. Department of Health and Human Services (HHS), more than 4,200 drugs saw list price increases between January 2022 and January 2023. Among those drugs, the average increase was 15.2% or the equivalent of $590 per drug, and nearly half of those drug prices rose faster than the overall rate of inflation.[18]

These price trends are not only extreme, they are globally anomalous. A RAND study found that U.S. prescription drug prices are, on average, 2.78 times higher than those in 33 other nations.[19] Among brand-name drugs, the gap is even wider: U.S. prices are an average of 4.22 times those seen around the world. Despite ever-increasing prices, innovation has declined (as defined by the number of new medications approved per U.S. dollars spent on R&D)[20] in recent decades, a trend which is even sharper if you exclude "me-too" drugs.[21]

These price increases, particularly at launch, are detached from research and development costs. One study of 60 new treatments approved by the FDA found no association at all between estimated research and development investments and treatment prices.[22]

Generic Drugs: Fragility and Difficult Economics

Market failures in generic drug manufacturing differ in nature from those in the branded market. When patent protections expire, generic competitors can enter the market. Generic drugs are those that are bioequivalent to the original brand-name drug. That is, they are formulated with the same active pharmaceutical ingredients and at the same dosage and form of administration. They gain access to the U.S. market by submitting data to the FDA that proves this bioequivalence. Generic drugs are intended to offer a much more affordable alternative to branded drugs after patent protections expire, and they often deliver on that promise. As such, generics account for as much as 90% of all prescriptions (by volume) in the U.S.[23]

However, even generics can be unaffordable for many patients and payors. First, many essential generic drugs are produced by only one or two manufacturers – the FDA has found that about 40% of generic drug markets have just a single supplier.[24] Nearly 80% of shortages in the generics market involve drugs with three or fewer manufacturers.[25] Shortages can persist for months, driving up prices and harming patients who depend on treatments.

When there is little to no competition for a generic drug, its price may remain very close to the brand-name price. Evidence shows that the existence of a single generic competitor does little to bring down prices, and there must be a large number of generic manufacturers for prices to be noticeably lower than the brand-name equivalent.[26] In many cases, even when patent protections expire, competitors may choose not to enter the market with generic versions due to a lack of financial incentives.[27] As a result, brand-name manufacturers still exercise monopoly control over the market for many medicines, charging patients whatever they wish.

Investors and pharma executives know this and take advantage of these dynamics. Martin Shkreli made himself infamous by acquiring the toxoplasmosis drug, Daraprim (a branded generic with no competition on the market at the time), and immediately hiking its price by over 5,000%. However, Shkreli was far from alone. Valeant Pharmaceuticals hiked the price of two heart medications (Isuprel and Nitropress) by 525% and 212%, respectively, upon acquisition, while Rodelis Therapeutics increased the price of a medication for drug-resistant tuberculosis by 2,100% just after acquiring it.[28]

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Even when there are several generic manufacturers theoretically competing in a drug market, some have even been charged with price-fixing when it was revealed that they colluded with competitors to maintain a certain price. For instance, Teva and Glenmark pharmaceuticals agreed to pay hundreds of millions in fines after the Department of Justice (DOJ) charged them with price-fixing essential generic medications, including widely used cholesterol and infection treatments.[29] According to the DOJ, consumers were overcharged by at least $350 million from Teva's conduct alone.[30] However, such fines are usually no deterrent. Studies have found that penalties paid only amount to 5% of net profits for Big Pharma companies and many companies re-offend even after being slapped with fines for previous misconduct.[31]

The economics of generic drug manufacturing exacerbate the problem. Manufacturers compete primarily on price rather than quality. After all, the whole point is that they're making a copy of what someone else invented. Once a

brand-name drug's patent expires, multiple generic manufacturers often enter, driving prices down by over 50 percent.[32] This rapid price erosion makes it difficult to sustain profitability, especially for older or low-demand drugs. An FDA study found that drugs in shortage were typically older, off-patent generics sold at low prices relative to comparable products – a median of just $8.73 per unit – leaving manufacturers thin margins and little financial incentive to invest in or sustain production.[33] Why take on the complicated job of manufacturing pharmaceuticals when you can make more just putting your money in the S&P 500?

This fragile market structure also leaves hospitals and other health care providers exposed to sudden price spikes. When only one manufacturer supplies a critical drug, even minor supply disruptions can trigger large increases in wholesale prices. For instance, in 2011-2012, norepinephrine, a life-saving drug often used in conjunction with CPR, experienced severe nationwide shortages after manufacturing interruptions. This resulted in increased mortality for patients.[34] Quality concerns compound these risks: limited competition and thin margins reduce incentives for robust quality control, occasionally resulting in recalls or production delays that further disrupt supply. In 2023, for example, quality-control failures at a single plant that supplied roughly half the U.S. market halted production of the chemotherapy drugs cisplatin and carboplatin, triggering a nationwide shortage that forced hospitals to ration cancer treatment.[35]

Ultimately, the generic drug market in the U.S. demonstrates two fundamental failures: insufficient competition for critical drugs and underproduction of low-margin but essential medicines. These failures leave patients vulnerable to both shortages and high prices, revealing a clear gap in the market that cannot be addressed by private incentives alone.

Part II: The Case for Public Drug Manufacturing

PART II: THE CASE FOR PUBLIC DRUG MANUFACTURING

THE CASE FOR PUBLIC MANUFACTURING is a practical and responsive one. Today's drug markets swing between two extremes: brand manufacturers abusing monopoly power to set unaffordable prices, and generic producers abandoning critical drugs when margins collapse. Neither outcome serves public health.

Unlike other consumer goods, medicines are not optional. In fact, some essential medicines are essentially price inelastic – no matter how much the price increases, demand won't waver because people must have medications – which makes them ripe for price gouging. Furthermore, patients cannot substitute away when prices spike or supply dries up. Nor can the market self-correct quickly, since building FDA-approved facilities takes years and shortages often persist long after private firms exit. These dynamics make drug supply less like a conventional market and more like a public utility, essential to daily life and too vital to leave to the volatility of profit cycles.

Public manufacturing is not about replacing private industry. It is about creating a reliable backstop, assuring accessible access to essential medicines, and capturing more public return on public investment. A credible public option could discipline monopoly pricing in brand markets and ensure continued production of low-margin generics that private capital will not sustain, while providing good, public sector manufacturing jobs. Public manufacturing, for example, would give the government the practical capacity to act on legal tools it already has. Under existing law, federal authorities can authorize others to produce a patented drug, or make it themselves, when a patent holder fails to meet the public's needs.[36] But those powers mean little without the means to actually produce the medicine, capacity a public manufacturer would supply.

Moreover, by building public power in this critical sector, we can erode Big Pharma's political influence and open up space for further policy reforms. Currently, many attempts to discipline the sector fall short, in part because holding the industry to account is difficult when they are our only option to secure life saving remedies for our populace. For example, while numerous states have passed drug price transparency laws, they've proven difficult to implement due to industry's instinct to protect nearly all information as trade secrets.[37] Public pharmaceutical manufacturers could and should operate with complete transparency on pricing and contracting which would shed light on the flow of money through the pharmaceutical supply chain and give policymakers more data to work with when seeking to rein-in prices on out-of-reach medications. Just as we accept

public intervention in electricity, water, or defense procurement, medicines, no less critical, demand the same.

Finally, public domestic manufacturing capacity would also strengthen supply chain security for essential medicines. Today, the U.S. relies heavily on a concentrated global supply chain – China produces an estimated 80% of the world's active pharmaceutical ingredients, and India is the largest exporter of finished generic drugs.[38] During the early months of the COVID-19 pandemic, India temporarily banned the export of 26 key drugs and formulations, exposing just how vulnerable the U.S. drug supply is to disruptions abroad.[39] A domestic public manufacturing network would provide a critical buffer against these vulnerabilities, ensuring that supply of essential finished medicines is not subject to the risks of geopolitical conflict, pandemics, or trade disputes.

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We don't have to start from a blank canvas. Public manufacturing of essential medicines has a long and storied history in the U.S. and around the world.[40] For example, MassBiologics, the Massachusetts state-owned and operated biopharmaceutical production lab has successfully developed, manufactured, and distributed a wide variety of medications since 1894.[41] The Department of Defense owns and operates the Walter Reed Pilot Bioproduction Facility where it manufactures vaccines and other medicines as part of its research and development undertaking.[42] And the California Department of Public Health produces and sells (at cost) a lifesaving treatment for infant botulism.[43]

Historically, the U.S. had even more public sector manufacturing capacity, including the Michigan Biologics Laboratory, which was the only U.S.-based producer of anthrax and rabies vaccines for a time.[44] Additionally, other public health departments were more active in the manufacture and distribution of medicines last century. For example, The New York State Public Health Department developed and manufactured diphtheria antitoxin critical for controlling the outbreak the state was undergoing in the early 1900s.[45]

Around the world, examples of successful public production abound. In the 1920s, Canada's Connaught Laboratories became the first in the world to manufacture and distribute insulin, which it sold at cost for decades.[46] Brazil[47] and Thailand[48] have significant, longstanding public pharmaceutical production

capacity, which they successfully leveraged to negotiate a steep discount on antiretroviral drugs early in the AIDS pandemic (with the threat of simply manufacturing the drugs themselves for domestic distribution).[49] China produces much of the world's primary pharmaceutical inputs (API) in public labs[50], and India, the largest exporter of generics in the world, has a long history of publicly-owned pharmaceutical manufacturers.[51] Cuba produces the majority of the domestic medicines supply (plus specialty drugs for export) in its fully public facilities.[52] Additionally, Sweden, South Korea, the UK, Australia, Argentina, and numerous other countries have or have had significant public manufacturing capacity for generic and innovator drugs.

Support for public manufacturing of essential medicines is seeing a resurgence in the U.S. California recently set up a program (CalRx) to bring insulins, naloxone, and eventually other medications to market via the public sector through a partnership with non-profit manufacturer, CivicaRx.[53] Several other states (including NY[54], IL[55] and MI[56]) have seen bills introduced or proposals debated in the governors' office to support public manufacturing of insulins and other drugs, while a federal public manufacturing bill has been introduced by Senator Elizabeth Warren and Representative Jan Schakowsky in several congressional sessions.[57]

Collectively, these examples provide a framework for a federal drug manufacturing project – one that leverages contract manufacturing, strategic procurement, and government oversight to supply essential drugs, stabilize prices, and protect public health.

Part III: A Framework for Implementing Public Manufacturing

PART III: A FRAMEWORK FOR IMPLEMENTING PUBLIC MANUFACTURING

IN PROPOSING PUBLIC MANUFACTURING, we are not making an appeal to altruism or social benefit. A nationwide network of public manufacturing sites would not have to be a charity or an experiment on the margins of the market. In our proposal, a public manufacturing initiative would be a competitive, scaled alternative designed to fill the gaps that private industry cannot or will not address.

Just as we have historical precedent to guide us, we also have a set of industrial policy tools and purchasing power that can de-risk and accelerate implementation – tools that federal and state governments have refined and expanded over the past decade. This is not just another call for an extra line item in HHS's budget to fund a grant program and hope it somehow results in cheaper drugs.

What we are proposing is a deliberate, policy-driven investment, designed to adapt, scale, and serve public health just as a private company is structured to serve its shareholders. Like any serious enterprise, we cannot simply raise funding and walk away. This public manufacturing initiative needs a clear roadmap to achieve its goals and the industrial policy tools to make progress real: strategic procurement to guarantee steady demand for essential drugs; subsidies to offset the thin margins that drive private firms out of the generic market; permitting exemptions and coordinated regulatory support to allow rapid entry into production when shortages emerge and integration with local economies to tap into underutilized talent and resources. Together, these tools make public manufacturing sustainable rather than symbolic.

Critically, this proposal does not aim to displace private firms across the board. Instead, this approach to public manufacturing would seek to build a credible competitor that disciplines monopoly pricing in brand markets and ensures stable production of low-margin generics. In doing so, it reframes public manufacturing as a practical mechanism for building resilience and affordability into the drug supply system.

Strategic Procurement

For any startup entering a capital-intensive, low-margin market, consistent volume is essential for survival. In the generic drug market, this has been nearly impossible. The combination of low-margins, limited volume, and long regulatory timelines are often lethal for healthy competition in pharmaceutical markets. But

governments do have tools to alter these dynamics.

The first and most direct tool is strategic procurement. By committing in advance to purchase certain volumes of essential drugs, particularly those that face chronic shortages or persistently thin margins, governments can create the stable demand signal that private markets often fail to provide.[58] This approach transforms public procurement from a passive purchasing function into an active tool of market shaping, allowing governments to support mission-aligned manufacturers, lower entry barriers, and ensure supply continuity and safety.

Strategic procurement has been used successfully in other sectors to catalyze industrial development. In the defense sector, strategic procurement has long been foundational to U.S. military readiness. The Pentagon does not simply purchase weapons off the shelf; it enters into multi-year, guaranteed contracts with a wide range of suppliers, often well in advance of production. For example, the U.S. Department of Defense's munitions industrial base is supported by long-term agreements with manufacturers that ensure continuous production even for low-demand, low-profit items like specialty ammunition or niche components.[59] Without these contracts, private firms would have little reason to maintain production capacity for such goods.

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In the clean energy sector, the federal government has used procurement tools to jump-start entire industries. The Biden administration's Federal Buy Clean Initiative required federal agencies to prioritize purchasing construction materials, like low-carbon steel and concrete, that meet specific emissions standards.[60] By guaranteeing demand for cleaner products, Buy Clean gave manufacturers the market signal they needed to invest in retooling production lines, lowering costs over time.

During the COVID-19 pandemic, Operation Warp Speed demonstrated perhaps the most relevant example of strategic pharmaceutical procurement. The federal government entered into advance purchase agreements with vaccine developers like Moderna and Pfizer, committing billions of dollars before any product was FDA approved. These commitments absorbed early-stage risk, allowed companies to scale manufacturing in parallel with clinical trials, and ensured

a rapid nationwide rollout once vaccines were authorized. Operation Warp Speed also funded manufacturing retrofits, raw material stockpiling, and workforce expansion, showing that procurement can go far beyond purchasing finished goods.[61]

Even in public infrastructure, strategic procurement has been used to revitalize supply chains. Under the Buy America provisions of federal infrastructure laws, agencies are required to source materials like steel, cement, and glass from domestic producers.[62] This demand guarantee supports American manufacturers in industries often undercut by foreign competitors, and allows for long-term capital planning.

Unlike clean energy or COVID vaccines, we wouldn't need to create a net new purchasing program to support a nascent public manufacturing initiative. The federal government is already the largest single purchaser of all prescription drugs, through programs like Medicare, Medicaid, and the Department of Veterans Affairs.[63] To support initial demand for AmericaRx production, federal and state health care agencies providers – such as community health centers, Federally Qualified Health centers, public health departments, and departments of corrections – could enter into multi-year purchasing agreements with American Rx manufacturing sites, including:

- The VA and Department of Defense
- State Medicaid programs
- 340B-covered entities like community health centers and safety-net hospitals
- Departments of Corrections
- Public Health Departments
- Public hospitals

Regulatory Waivers

Similarly, our approach envisions government as a catalyst, not a constraint, in public drug manufacturing. Rather than adding bureaucratic hurdles, the public sector should focus on removing barriers and accelerating timelines. Long delays for permitting, facility construction, and FDA approval add significant costs that threaten the financial viability of new entrants. For example, an HHS-commissioned analysis found that slow FDA approval processes can add roughly 13 months and $3.5 million to a generic developer's costs.[64]

But federal and state governments have shown they can shorten these timelines when they choose to. During the COVID-19 pandemic, Operation Warp

Speed demonstrated how government coordination, expedited FDA reviews, and parallel investments in manufacturing could bring new drugs to market in under a year. Emergency Use Authorizations and targeted regulatory waivers allowed safe but rapid deployment of vaccines and treatments.[65] Likewise, the Defense Production Act has been used to fast-track critical infrastructure and procurement, while the Building Chips in America Act enabled permitting reforms and environmental streamlining for semiconductor plants.[66]

States have taken similar steps. California's CalRx initiative has begun laying the groundwork for bringing insulins and other generics to market via the public sector, with an emphasis on flexible procurement and simplified facility approvals. Other states could follow suit by designating fast-track permitting zones for essential medicine production or offering regulatory concierge services for public-sector manufacturers.

Public manufacturing can benefit from the same accelerated treatment we already apply to other strategic sectors. The FDA for example, could reduce the approval timeline for publicly manufactured drugs by extending Priority Review and Competitive Gene Therapy Designations to Abbreviated New Drug Applications (ANDAs) filed by public manufacturers for drugs on the FDA's shortage list or with three or fewer competitors. The FDA could also establish a dedicated regulatory concierge office within the Center for Drug Evaluation and Research (CDER) to provide pre-submission guidance and a single point of contact for public manufacturers.

On siting and construction, retrofits of existing FDA-approved facilities and new public pharmaceutical plants could qualify for NEPA categorical exclusions, mirroring precedents under the CHIPS Act and broadband expansion, and states should establish fast-track permitting zones with consolidated state environmental review for essential medicine production. Finally, Congress could designate public pharmaceutical manufacturing as critical infrastructure, unlocking Defense Production Act authorities to accelerate facility financing (Title III) and secure priority access to active pharmaceutical ingredients and other inputs (Title I). Taken together, these reforms can cut years off production timelines and make public drug manufacturing a viable, scalable solution to chronic shortages and unaffordable prices.

Inclusive economic development

Finally, we see public pharmaceutical manufacturers are well-placed to form part of a larger inclusive economic development strategy, ensuring access to stable, good manufacturing jobs across the country by serving as local economic engines that can materially improve conditions in the local economy through their mission, relationships and investments. As enterprises managing

significant economic, human, and institutional resources, they can generate significant benefits for local communities through the creation of good jobs and directed procurement pipelines.

In order to achieve this vision, public pharmaceutical manufacturers should commit to practices like prioritizing hiring from local communities, particularly those most historically underresourced and/or those that face barriers to entry in the job market. Such strategic hiring practices, coupled with training and career advancement can assure that more of these good, public sector jobs go to those that need them most, improving economic and health outcomes in the community.[67] The public sector in general tends to employ more women and people of color than the private sector, and with higher rates of unionization.[68] Thus, creating more public sector jobs in pharmaceutical manufacturing stands to continue this trend providing good, stable, pro-labor jobs that strengthen worker's rights and counterbalance corporate dominance in the sector.

Just as a company like Pfizer builds a global network of facilities to meet demand across markets, AmericaRx would build a nimble, responsive, and regionally anchored manufacturing network – but with a public mandate and public accountability at its core.

Public pharmaceuticals should also employ strategic procurement – or impact purchasing – programs that positively affect local economic outcomes (and reduce harmful environmental impacts).[69] By prioritizing procurement from small and medium-sized local businesses, worker-owned cooperatives, and minority-owned producers, purchasers create a more resilient supply chain and keep more money circulating within the local economy.

Many health systems and universities around the nation are already engaged in similar strategies and report significant positive impact on local economies. For example, Rush University System for Health has been increasing the amount of goods and services it sources directly from local vendors in Chicago's West Side as an upstream investment in community health.[70] In 2024, it contracted a local vendor for laundry services, which is projected to save Rush around $500,000 while also supporting the creation of 175 new local jobs. Kaiser Permanente has supported two worker-cooperative ownership conversions in recent years, giving 194 local employees access to jobs with higher wages and better working conditions, including ownership opportunities.

University Hospitals (a health system in Ohio) developed career pathway programs that have helped hundreds of employees advance into higher-paying

roles. Other health systems and universities have focused on underserved populations: Advocate Health has hired dozens of formerly incarcerated citizens, while Baystate Health and others partner with community organizations to train local residents and connect them to quality healthcare jobs.[71] In 2015, Johns Hopkins University launched a comprehensive anchor strategy, Hopkins Local[72], which resulted in over $1 billion in investments in local Baltimore-based businesses and over 2,100 individuals hired from high-need areas in its first 10 years.[73]

Policy Design and Implementation Strategy

We envision the construction of AmericaRx – a coordinated, federally backed public manufacturing system composed of multiple facilities across the country.[74] These sites would be fully publicly owned, seeded through a mix of grants and loans from the Department of Health and Human Services as well as supplemental state subsidies, and developed in partnership with states to address regional drug needs and support local economic development. AmericaRx would be a strategically structured public enterprise, with the capacity to adapt to changing public health needs and scale production of essential medicines over time.

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INVESTMENT

To make a meaningful impact on the U.S. drug supply system, AmericaRx would operate at a scale comparable to major private pharmaceutical manufacturers. Rather than a small pilot or one-off factory, we envision a network of 10 manufacturing sites in 10 states, with each focused on different classes of drugs such as sterile injectables, small-molecule generics, or biosimilars.

Although AmericaRx would be designed to become self-sustaining, it would nonetheless require a significant upfront public investment to reach scale and meet early demand. Federal and state funds would be used to build or acquire facilities, purchase equipment, support regulatory approvals, and hire skilled staff. Initial production, whether through in-house capacity or contracted partners, will also require operational support until the program breaks-even through sales to public and private payers.

Here again, we approach ownership differently than traditional policymakers. Instead of choosing between two options – subsidizing private construction and handing over operations, or pursuing full federal ownership and control – we see

value in blended ownership structures, much like those used in the private sector. We envision the federal government owning and operating the initial "seed" sites, while state governments that help fund and expand local manufacturing within the network take on ownership shares proportional to their investment and eventually assume operational control. With their local knowledge and proximity to community needs, states are well positioned to guide the long-term growth of these facilities. Over time, as the network matures, other mission-aligned partners, such as hospitals and health systems with a direct interest in access and affordability, could also invest in American Rx, following a model similar to Civica Rx.

Per-facility construction costs will likely vary significantly by product type, from roughly $150 million for small-molecule generic plants to over $1 billion for biosimilar facilities.[75] Beyond construction, each site will require sustained operating investment – staffing, raw materials, quality systems, technology transfer, and validation – through the multi-year period from construction completion to FDA approval and into production ramp-up, before revenue can cover ongoing costs.[76] Taken together, a representative AmericaRx manufacturing network – roughly three to four small-molecule generic plants, three to four sterile injectable plants, and two to three biosimilar facilities, with a mix of retrofits and new builds – could require all-in startup investment in the range of $6 to $10 billion, with the total sum varying depending on the type of drugs prioritized and the speed of implementation.[77] This back of the envelope figure covers construction, technology transfer, workforce and validation costs, operating runway through FDA approval and production ramp-up across the full network.

The investment would give the federal government majority ownership over American Rx, but would allow for additional investment from states or private investors. Initial capital would be deployed over five to seven years through a combination of federal appropriations and state contributions. And because federal and state governments would take bold, transparent action to streamline the regulatory path for American Rx, capital expenditures should be significantly lower than those typically required for private-sector manufacturing projects. This is not intended as a permanent, flat subsidy from the federal government. While American Rx would provide some drugs to some buyers at a steep discount (e.g. insulin to community health centers), it would recover costs through cost-plus pricing to private buyers. Any surplus would be reinvested into capacity expansion, infrastructure upgrades, or manufacturing of additional drugs in the public interest.

ORGANIZATIONAL STRUCTURE

We propose establishing a quasi-public national institution to oversee and coordinate the initiative. This entity would combine public ownership and accountability with operational independence and agility, allowing it to move at the pace required to compete in pharmaceutical markets while remaining focused on public health outcomes.

There is precedent for this model. One relevant example is the National Semiconductor Technology Center (NSTC), created under the CHIPS and Science Act of 2022.[78] The NSTC was structured as a public-private consortium with federal oversight but is operated by an independent nonprofit. It managed government funding, worked directly with industry, oversaw R&D, and could respond quickly to technological shifts and supply chain disruptions. This hybrid governance model ensures democratic accountability while avoiding the bureaucratic constraints that can slow innovation and responsiveness.

The public pharmaceutical manufacturing system we propose would follow a similar structure. It would be authorized and initially capitalized by Congress, governed by a federal board that ensures transparency and public alignment, but operated independently to manage procurement, contracting, and production. This model allows for the coordination of multiple subsidiary plants, each of which could specialize in different classes of drugs (e.g., sterile injectables, small-molecule generics, biosimilars) and respond to regional health needs or market shortages. It also allows for interoperability and consistent standards amongst the factories, both of which are critical to addressing surge requirements in time of emergencies.

STARTUP PHASE AND CONTRACTING STRATEGY

In its early phase, the initiative could rely heavily on contract manufacturing – as many pharmaceutical companies do – to rapidly begin producing key drugs without waiting for new facilities to be built. Contracting would allow the public entity to establish market presence, begin securing supply, and generate operational learnings while building out permanent infrastructure.

However, unlike typical private-sector outsourcing, contracting would be guided by mission-aligned criteria. The initiative would prioritize contracts with public, nonprofit, or low-cost manufacturers, such as MassBiologics and Civica Rx, that share a commitment to affordability, transparency, and resilience. Additionally, contracts would include price transparency provisions and provisions to ensure the public interest is maintained by keeping intellectual property rights and regulatory filings. These partnerships would not only help expand production quickly but would also reinforce a broader ecosystem of public and nonprofit pharmaceutical manufacturing already emerging in the United States.

Over time, the public entity would acquire or build its own manufacturing sites, particularly in regions with underutilized industrial capacity, critical supply chain vulnerabilities, or high unmet public health needs. Facilities could be located in collaboration with state governments and local partners to maximize impact, both in terms of healthcare access and economic development. Specifically, we envision American Rx eventually purchasing and repurposing existing, idle factories to manufacture essential drugs. This could include former defense factories, unused industrial facilities, or even existing private drug manufacturing facilities.

PRIORITIZATION OF DRUGS

To ensure the greatest impact, public manufacturing should begin with a focused set of high-need, high-impact drugs. It would build or contract based on the following criteria:

Cost to Patients and Public Payers: Drugs with high out-of-pocket costs or those that drive significant spending in public programs (Medicare, Medicaid, VA, correctional health systems) should be prioritized. This includes treatments like insulin or HIV medications, where public manufacturing could both improve access and reduce public expenditure.

Public Health Impact: Priority should be given to drugs with high clinical and population-level value, especially those treating widespread or life-threatening conditions such as diabetes, hypertension, infectious diseases, and cancer. Medicines critical for emergency preparedness, like antibiotics or antitoxins, also warrant early attention.

Health Equity: The framework should consider the ability of a drug to address health disparities. This includes treatments needed disproportionately by underserved communities or conditions that receive limited market attention, such as sickle cell disease or reproductive health products.

Lack of Market Competition: Drugs with limited competition or a history of price spikes, especially those with a single manufacturer, are prime candidates. Public entry can help discipline pricing and stabilize markets where private actors have failed to deliver affordability or supply continuity.

Risk of or Ongoing Shortage: Drugs prone to supply disruptions, particularly sterile injectables, oncology medications, and older antibiotics, should be prioritized to ensure resilient supply chains and uninterrupted patient care.

Conclusion

IN SUM, THE U.S. PHARMACEUTICAL MARKET is structurally incapable of delivering affordable, reliable access to essential medicines. Brand-name manufacturers exploit monopoly protections to set prices as high as the market will bear, while generic manufacturers routinely exit production of critical drugs when profits are too thin to justify staying. The result is a system marked by shortages, price spikes, and declining public trust. Prior reform efforts – focused largely on transparency or modest subsidy programs – have failed to confront the deeper problem: there is no durable, mission-aligned alternative to the profit-maximizing logic that dominates the market.

Our proposal fills that gap. We envision *America Rx*, a federally backed, publicly owned manufacturing network designed to produce high-need drugs the private market cannot or will not provide. Unlike past proposals that rely solely on regulation or fragmented state efforts, this is a national-scale, public option for pharmaceutical manufacturing that is built to be competitive, transparent, and sustainable. With coordinated public purchasing, targeted subsidies, and regional manufacturing strategies, American Rx would provide a stable supply of essential medicines, discipline prices, and create good jobs in underserved communities. This is not a symbolic gesture or a parallel system. It is a practical restructuring of market power that restores public leverage, improves health outcomes, and reclaims pharmaceutical production as a tool of public purpose.

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