

On Antitrust Enforcement

The American medical industry offers a case study of how market concentration undermines economic resilience.

Matt Stoller | Jun 11, 2020

ccording to virtually every major figure in Washington, it's time to bring back critical supply chains—including those for medical supplies and medicine—to the United States. Republican Senators Marco Rubio (R-FL) and Josh Hawley (R-MO) have bills, as do Democratic Congressmen Marc Pocan (D-WI) and John Garamendi (D-CA). President Trump has called for reshoring medical production in the wake of the pandemic. "These stupid supply chains that are all over the world," he said in May, "one little piece of the world goes bad, and the whole thing is messed up." [1]

Rubio emphasizes the threat from China, pointing to a threat in Chinese state-run news media to cut off pharmaceutical exports to the United States if America did not show more gratitude for China's help during the pandemic. "If China banned exports," said the article, "the United States will fall into the hell of a new coronavirus pneumonia epidemic." This is not an empty threat; the vast majority of our imports of penicillin, tetraycline, surgical masks, rubber gloves, first aid kits, and liquid-filled thermometers come from China. Beijing does have the ability to induce shortages in America.

What policymakers ignore is that shortages in American hospitals are not new, and have not, until recently, been related to China. These shortages started in the late 1990s and accelerated in the mid-2000s. We've had shortages of hundreds of standard generic medicines for so long that the Food and Drug Administration (FDA) warned that young doctors increasingly do not know how to practice medicine with high standards of care; they just aren't used to having the right medicines available. [3]

Focusing on the foreign threat ignores the real problem, of which Chinese dependence is merely a symptom. The United States' underlying markets for medicine are broken. Shortages should produce higher prices, which should draw in more production. Yet as the FDA noted in a report last year, "Drug shortages persist because they do not appear to resolve according to the 'textbook' pattern of market response." [4] Shortages don't really result in higher prices, and so they don't draw in more producers.

Markets are broken in medicine for the same reason that they are broken in much of the rest of the economy: the rise of monopolies has distorted price signals that used to match supply and demand. This market-rigging has a number of different symptoms, such as high prices for some generic pharmaceuticals, poor quality standards, dependence on foreign imports, and most significantly, shortages. Over the last 25 years, policymakers have allowed the monopolization of drug and medical supply purchasing, which makes it unprofitable to have a diverse and high-quality pharmaceutical production industry. In other words, China is threatening medical shortages that, ironically, we have already inflicted on ourselves.

This essay presents developments in the generic pharmaceutical and medical supply industries as a case study of a broader problem in the American economy: the relationship between consolidation and lost production capacity. Approaching reshoring in other strategic industries, from advanced

materials to semiconductors to telecommunications, will require similar approaches to reform. The industry-specific analysis below can serve as a blueprint for analyzing other industries as well.

The Side Effects of Consolidation

Long before the Chinese entered our market, Americans began to see troubling signs of a fragile drug supply chain. In 1993, the FDA noticed that doctors were running out of off-patent drugs for three unrelated conditions: angina (nitroglycerin), HIV (sulfadiazine), and tuberculous (streptomycin). [5]

Americans had complained about the medical industry for decades. But while politicians like Senator Estes Kefauver (D-TN) had complained about high pharmaceutical costs in the 1960s, they complained about excessive prices to consumers, not about the underlying productive machinery. [6] Supply chains were well-resourced and deep, with a thicket of different producers and distributors making and innovating around chemicals and medicines. Even into the 1980s, the only stories about drug shortages in American newspapers were stories observing problems in the Soviet Union as that system broke down.



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But during the Clinton administration, shortages soon became a regular occurrence. These problems were concentrated among generic pharmaceuticals, ones for which patents had expired, not the more profitable on-patent medicine. Almost inevitably the story was the same. The sole factory that produced the medication would be taken offline by the FDA for some health infraction, and then not restored to production because it was no longer profitable. Such was the case in 1999, when there was a nationwide shortage of penicillin after Marsam Pharmaceuticals shut down production. [7]

By 2001, shortages had become a routine feature of our medical system; one hospital executive observed, "Something strange is going on." What was bizarre about the problem was that they seemed to defy the laws of economics. Unmet demand didn't result in higher prices, but shortages.

What had shifted was the market structure by which hospitals buy supplies, including pharmaceuticals, medical devices, and generic products like cotton balls. Traditionally, hospitals bought supplies through large purchasing co-ops known as Group Purchasing Organizations (GPOs), a bit like Costco for medicine. GPOs used to be membership organizations, with hospitals paying dues. But in 1987, Congress exempted GPOs from anti-kickback rules, allowing GPOs to take money from suppliers. [9]

This change, finalized in regulations in 1991, shifted competition in the marketplace for devices and drugs. ^[10] Prior to this shift, suppliers and buyers matched through open competitive bidding, facilitated by a GPO. Afterwards, suppliers competed with each other to pay off the GPO and get an exclusive or near-exclusive contract to supply hospitals. The price that mattered was what vendors were willing to pay to the GPO. Moreover, GPOs now had an incentive to inflate prices, because they were paid fees by vendors based on the total amount sold.

GPOs maintained control of the hospital market through a number of mechanisms. For one thing, several large GPOs were owned by hospitals. In addition, GPOs offered rebates to hospitals who purchased from them, or penalized hospitals who bought elsewhere by removing discounts. The industry also began consolidating; in 1995, Premier Health Alliance, American Healthcare Systems, and SunHealth Alliance merged into the nation's largest GPO, Premier. [11] By 1998, six GPOs controlled 80% of medical supply buying for acute care hospitals. Today, four GPOs manage 90% of hospital purchasing. [12] According to experts, four of these corporations – Vizient, Premier, HealthTrust, and Intaler — control purchasing of more

than \$300 billion annually of drugs, devices, and supplies for 5,000 health systems. [13]

GPOs gradually evolved into the business of selling access to the hospital buying market. Pharmaceutical manufacturers who weren't closely tied to GPOs could no longer make money; fees charged by GPOs could exceed 50% of the cost of the drug. [14] It was impossible to stay in the market for commodity products unless you were connected to a GPO. In 2002, the *New York Times* did a groundbreaking series of stories on GPOs, finding that Premier had, in the late 1990s, helped set up a pharmaceutical company called American Pharmaceuticals, which then had a successful IPO on Wall Street. [15] American Pharmaceuticals sourced from China, and its drugs were routinely recalled for poor quality. Yet Premier sold its drugs to hospitals because Premier had taken an undisclosed stake in the drug company.

Such self-dealing has eliminated the price signals that make markets work. Last year, the FDA noted that large GPOs do not really care about shortages of low-priced generic pharmaceuticals. A high-volume buyer "bears only a small portion of the costs of a shortage while other parties (health care providers, third-party payers, and patients) bear larger portions." [16] Since GPOs often contract with just one or two drug makers for any particular generic pharmaceutical, and any particular product is a small part of their business, it's just not particularly important to the people who control the market if there is a shortage of low-cost, but highly important drugs or devices.

Merger Mania

GPOs are the most obvious culprit in terms of breaking our medical markets, but consolidation was happening across multiple healthcare sectors, from hospitals to drugs to distribution. As pharmacy specialist Erin Fox put it, "drug shortages exploded in 2001," pointing to mergers as the culprit. [17] In a frenzy of mergers in the late 1990s and early 2000s, Pfizer had bought Warner-Lambert in 1999, in the biggest pharmaceutical merger of all time, and in 2000, Glaxo bought Smithkline in the second biggest. [18]

Size in production led to a relentless focus on the most profitable drugs. For instance, in 2001, at the same time as GlaxoSmithKline's medicine Beclovent, an inhaled corticosteroid for asthma patients, lost its patent protection, there were production problems in the rest of the inhaled corticosteroid market. The corporation stopped production of Beclovent and shifted to making a more expensive treatment, Flovent. [19]



Yet few connected consolidation to the shortages. Even as the drug supply chain fell into crisis, business school case studies celebrated the growth of consolidated healthcare distributors and GPOs as earnings-per-share bonanzas.



This consolidation happened largely because policymakers had changed their philosophy around monopoly power. Prior to the 1980s, policymakers followed the thinking of Louis Brandeis, who saw the control of markets through size as a threat to social stability. Enforcers were generally skeptical of attempts to roll up industries and tried to protect small and mid-sized businesses as resilient and responsive to public needs.

In the early 1980s, the Reagan administration and Congress adopted a new philosophical underpinning for industrial organization. Encouraged by law and economics scholars at the University of Chicago, as well as the consumer rights movement on the Left, lawmakers focused on efficiency, not resiliency, as the lodestar of commercial politics. They radically relaxed merger law and antitrust enforcement in the early 1980s. Big was no longer bad, and corporate consolidation no longer mattered.

Drug distributors, GPOs, hospitals, pharmaceutical makers, and pharmacy benefits managers consolidated throughout the 1980s and 1990s. "Shortages are now a fact of life," said an FDA official in 2001. [20] "We have to find ways to deal with them." Yet few connected consolidation to the shortages. Even as the drug supply chain fell into crisis, business school case studies celebrated the growth of consolidated healthcare distributors and

GPOs as earnings-per-share bonanzas. [21]

A Dose of Reality

The problem is far worse today. Wave after wave of consolidation in purchasing and distribution has created massive fragility in the supply chain. Along with concentration among the pharmaceutical benefit managers, drug distributors, hospitals, and pharmaceutical corporations, there is now a complex thicket of oligopolies, joint ventures, and resulting coercive contractual arrangements that make it extremely hard to sell things into healthcare markets unless you are an incumbent player.

Selling to what is known as a "power buyer" is much like selling to Walmart or Amazon in retail; you have to be able to supply large amounts at extremely low prices, putting relentless pressure on suppliers to cut corners. [22] There's virtually no profit margin for a small player because the ability to compete is solely based on bargaining power among middlemen and not on patients' needs.

And that's where China comes in. In the 1990s, foreign suppliers in India began exporting active pharmaceutical ingredients into the U.S., but without dominating the still-fragmented market. China followed and used its state power to build up an increasingly sophisticated pharmaceutical industry and to become a manufacturing powerhouse in other medical supplies.



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Some of China's pricing advantage was due to state subsidies and lighter regulation of pollution. But these sources of supply also plugged directly into an increasingly concentrated American production and distribution system. By the 2000s, Chinese pharmaceutical companies were buying American players; Wuhan-based Humanwell purchased Risedose, PuraCap Pharma, and Epic Pharma, bragging in an investor presentation about how it had become a monopoly provider of five separate products. [23]

For the same reason that it was not sufficiently profitable to make penicillin in 1999, it isn't worth it for today's domestic players to challenge Chinese dominance in supply. After all, even if you are able to level the cost advantage, you're still up against power buyers.

That's why putting up tariffs hasn't really brought production back to the U.S.; the price signals have broken down. Without open and flexible markets, it's hard to get into the business of making medicine. By and large, this dynamic is true across much of the medical supply industry, not just pharmaceuticals.

In fact, the more you take a step back, the more this story of consolidation represents the American economy writ large. Everything from outdoor grills to construction cranes to consumer electronics is sold through a consolidated retail and distribution apparatus and made in China. Even our own ability to make weapons is increasingly controlled by a few giant defense contractors who thwart new entrants, leaving our military dependent on production in China.

Policymakers largely missed this massive consolidation for the same reason they missed the elevated power of China. As monopolization was occurring in the early 2000s, the philosophy of the law and economics movement posited market structure as an innate force of nature rather than a political choice. In 2001, Mark J. Goldberger, the FDA official responsible for monitoring drug shortages, adopted the learned helplessness of this

philosophy, telling *The New York Times* why there was little he could do about shortages: "We can't control who is making drugs." After all, "that," he continued, "is determined by the marketplace." [24]



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We must ensure that American producers are no longer at a disadvantage versus their Chinese competitors. To do this, there are various levers, like raising tariffs and providing financial incentives for domestic producers. But failing to recognize the underlying market dynamics leads to the wrong —or at best, to an incomplete—policy response. The Trump administration's tariffs haven't helped. [25] It's had tariffs up for years, but they haven't restructured the market because its price signals no longer work. More recently, the Trump administration has tried direct financing. The Biomedical Advanced Research and Development Authority offered nearly a billion-dollar contract to a new corporation, Phlow, to create active pharmaceutical ingredient chemicals and finished medicines for federal stockpiles. [26] But Phlow is backed by the hospital consortium CivicRX, which is heavily tied into the existing concentrated GPO system. [28] We aren't going to create a resilient and flexible pharmaceutical supply chain with an industrial policy focused entirely on financing appendages of existing monopolies.

The solution here is conceptually simple. Congress should remove the safe harbor to anti-kickback statutes it granted to GPOs in 1987 and then break up GPOs into smaller companies. These actions would force GPOs to return to their roots, as co-ops helping hospitals buy supplies through open and competitive bidding and thus restoring the market's price signals. Tariffs could then work because pricing would bring in new domestic producers. There are a host of other policy choices to restore price signals, all of which involve removing conflicts of interest among middlemen and breaking them up so that there is competition within the market—instead of over the market.

There is an emerging consensus that we must stand up to the Chinese threat. The question is whether we can muster the capacity to stand up to the American domestic corporate monopolies that serve as China's unwitting allies. We once had a vibrant and diverse supply chain in the United States. Reshoring the production of generic pharmaceuticals and medical supplies will require not only changing the relative cost of production, but ensuring that American entrants can actually sell into functional markets.