United States Senate Committee on
Homeland Security & Governmental Affairs
U.S. Senator Gary Peters | Ranking Member

A PRICE TOO HIGH

Cost, Supply, and Security Threats to Affordable Prescription Drugs

A HSGAC MINORITY STAFF REPORT

EXECUTIVE SUMMARY

Hardworking families across the country are struggling to afford the medicine and care they need to live healthy lives. Rising prescription drug costs, a growing number of drug shortages, and mounting concerns about the source and supply of our drugs are creating a threefold public health crisis that puts Americans at risk.

Recent studies have shown that millions of Americans are skipping doses of their medications due to rising costs. Yet over the past 30 years, the pharmaceutical industry has paid more than $35 billion to settle drug pricing related lawsuits alleging violations ranging from "off-label marketing" to deliberately overcharging taxpayer funded health programs through Medicare and Medicaid. In addition, restrictive patent, pricing, and litigation strategies have contributed to delays in the introduction of new and more affordable drugs and have helped maintain high prices for brand name drugs. Average prices for the twelve top selling brand name drugs in the United States increased 68% between 2012 and 2018. The list price in 2017 for a one-year supply of Humira, the top selling drug in the U.S., was over $58,000 – more than the annual median household income in Michigan.

At the same time, active drug shortages in the United States are now at their highest levels in almost five years. An increasing number of essential medications used in hospitals, as well as common prescription medications sold at local pharmacies, have at one time or another been unavailable, in short supply, or in limited circumstances, rationed by hospitals, doctors, and pharmacists. These shortages include drugs as varied as intravenous ("IV") saline solution, lifesaving cancer treatments, and even basic drugs like sodium bicarbonate, which is essentially a sterilized version of the same baking soda that can be found on every supermarket shelf in America. In a 2017 national survey of nearly 300 health care practitioners, 71% indicated that because of drug shortages, they were unable to provide patients with recommended medication or treatment. As a result, shortages are making it harder for hospitals and health care providers to give patients the care they need, when they need it.

Finally, our overdependence on foreign pharmaceutical supply chains is a growing risk to national security. The U.S. is the largest consumer of pharmaceutical products in the world. However, over 80% of the active ingredients in prescription drugs sold throughout the U.S. now come from foreign countries, primarily China and India. China is the largest supplier in the world of the key ingredients in drugs, known as active pharmaceutical ingredients or API. According to Rosemary Gibson, a Senior Advisor at the Hastings Center with an expertise in health care reform and patient safety, "[i]f China shut the door on exports of medicines and their key ingredients and raw materials, U.S. hospitals and military hospitals and clinics would cease to function within months, if not days."

Compounding these concerns, the U.S. is losing the ability to manufacture essential medications at home. Currently, U.S. domestic manufacturing capabilities have declined to the point where the U.S. is largely dependent on other countries to manufacture and supply most antibiotics, other key emergency medications, and even the needles and syringes necessary for administering these medications. Despite the significant amount of pharmaceutical production and manufacturing of both API and finished drug products that has shifted from the U.S. to other

countries over the past two decades, the Food and Drug Administration (FDA) only inspected one in five pharmaceutical manufacturing facilities abroad last year. The FDA is responsible for ensuring the safety, efficacy, and security of our drug products in the United States. Despite its best efforts, however, popular prescription blood pressure medications (manufactured in China) and common over-the-counter heartburn medications (manufactured in India), for example, have recently undergone a series of recalls after a chemical previously used to make rocket fuel was found in the drugs.

To better understand these economic, health, and security risks, U.S. Senator Gary Peters, Ranking Member of the Senate Homeland Security and Governmental Affairs Committee, directed minority staff to examine the causes of rising drug prices, drug shortages, dependence on foreign supply chains, and resulting threats to patients, consumers, and health care systems. While not exhaustive, this focus addresses three key pieces of the larger puzzle contributing to rising health care costs and public health concerns.

This report details the minority staff's findings and provides recommendations to address the threefold crisis of unaffordable prescription drugs, widespread shortages of prescription and hospital-administered drugs, and overreliance on foreign sources and supplies of drugs sold in the United States.

Findings of Fact and Recommendations

Findings of Fact

Drug Pricing

1. **Brand name drug prices continue to increase at record levels:** Of the twelve top selling brand name drugs in the U.S., prices increased 68% from 2012 to 2018. The number one selling brand name drug Humira, a widely prescribed biologic for treatments including rheumatoid arthritis and Crohn's disease, more than tripled in price from 2006 to 2017.

2. **The United States is the largest market in the world for pharmaceutical company sales:** Pharmaceutical sales in the U.S. exceed $475 billion annually.

3. **Protective business practices are contributing to decreases in market entry for lower priced drugs:** Brand name drug companies have sustained high prices and limited competition, in part, through exploiting certain patent protections and exclusivity periods. From 2005 to 2015, 78% of new drug patents were based on drugs already in existence. One study estimates that an additional two years of market exclusivity for brand name drugs costs the U.S. health care system over $30 billion in potential savings.

4. **Generic drugs have lowered costs but present risks:** In 2018, generic drug competition amounted to $293 billion in overall savings. Generic drugs make up nearly 90% of prescriptions in the U.S., but less than a quarter of all prescription drug costs. From 2001 to 2011 drug recalls increased by over 500%. As one example, in 2018 and 2019, three generic blood pressure medications were recalled after a chemical used to make rocket fuel was discovered in the drug.

Drug Shortages

1. **The number and duration of drug shortages continues to rise:** Drug shortages increased by 300% from 2005 to 2014. The number of active shortages in the second quarter of 2019, 282, exceeded the number of active shortages at any point in 2018 according to the American Society of Health-System Pharmacists. Life-saving drugs formerly required by the Federal Aviation Administration to be carried onboard every U.S. flight are now exempt from being included in medical kits due to shortages. These include epinephrine (used to treat cardiac arrest), atropine (used to treat slow heart rates) and dextrose (used to raise low blood sugar for people with diabetes).

2. **Market consolidation is contributing to drug shortages and price increases:** From 1995 to 2015, sixty pharmaceutical companies merged into ten. A 2017 GAO report found that less competition was associated with higher drug prices, particularly for generic drugs. Less competition in the branded marketplace can impact innovation, new drug approvals, and prices throughout the industry. In some instances, sole-source suppliers have led to higher prices and market fragility that make certain drug products susceptible to shortages.

3. **U.S. drug manufacturers have increasingly declined to invest in new equipment:** Over half of the companies surveyed in a 2017 Pew Charitable Trust report stated that they chose not to upgrade manufacturing equipment – a critical component in resilient manufacturing of sterile injectables – for low margin, low volume products because of cost.

4. **Drug manufacturers are not required to provide critical manufacturing details to the FDA:** The FDA has no timely insight into the volume of drug products produced by each manufacturer and other critical information that could help address shortages. Currently, manufacturers only provide volume information retrospectively and are not required by law to provide information on inventory on hand, percentage of market controlled, or drug shortage risk management plans.

National Security Implications and Supply Chain Vulnerability

1. **U.S. dependence on foreign sources of prescription drugs increases security risks:** Currently, for prescription drugs sold in the U.S., over 80% of the active pharmaceutical ingredients (API) – the key ingredients used in the production of drugs – come from overseas, primarily China and India. Experts including the former Department of Homeland Security Under Secretary for Science and Technology have testified before Congress that the United States has failed to assess its growing dependence on foreign sources of drugs as a national security threat.

2. **The U.S. is losing its ability to independently manufacture generic antibiotics:** In 2004, the last U.S. plant that manufactured active ingredients for antibiotics like penicillin closed. The FDA has found that the majority of facilities that manufacture API for most critical medical countermeasures against biological, chemical, influenza, and radiation threats, now originate in foreign countries. For example, 96% of facilities that manufacture API for ciprofloxacin and 82% of those for doxycycline, two critical antibiotics used to counteract anthrax and other biological threats, are now located in foreign countries.

3. **The FDA lacks adequate oversight of foreign manufacturing facilities:** The FDA inspects or samples less than 1% of all regulated products before allowing them into the U.S. While surveillance inspections in the U.S. are unannounced, the FDA provides notice before conducting the majority of inspections at foreign facilities.

4. **U.S. based pharmaceutical manufacturing is declining:** Within the past two decades, pharmaceutical manufacturing has shifted overseas due to lower labor, construction, regulatory, and environmental costs. According to the FDA, approximately 80% of the manufacturing facilities that produce API are now located outside of the United States.

Recommendations

1. **Improve price transparency:** Pharmaceutical manufacturers, middlemen responsible for negotiating drug prices, and other actors behind the financial engineering of drug prices do not share the net price (the actual cost of the drug after any rebates, discounts, or incentives) with the public, who can only see the list price. Congress should require disclosure of the net price of drug products to improve transparency and accountability. Congress should also evaluate the effectiveness of rebates and whether elements of those rebates should be passed on to the consumer.

2. **Increase approvals for an affordable supply of drugs in shortage:** Congress should require the FDA to prioritize approvals for critical drugs currently in shortage and waive certain fees in if manufacturers agree to bring those drugs to market at pre-shortage levels to stabilize the market and ensure an affordable supply. Congress should also create incentives for negotiating better long-term affordable prices through contracting practices that ensure high-volume, sustainable production of safe, accessible, quality medication.

3. **Reward quality in manufacturing and sufficiently resource and authorize unannounced inspections worldwide:** The FDA should revise its pharmaceutical manufacturing evaluation system from a pass/fail rubric to a sliding scale (e.g., one through five stars) to reward quality. The results should be public so consumers, patients, and health care systems can access the information and use it when making decisions about what drugs to buy. All FDA inspections, regardless of location, should be unannounced, and the FDA should be resourced to ensure it can deploy a sufficient number of trained and qualified inspectors abroad.

4. **Prohibit unjustified price increases by pharmaceutical companies:** Congress should pass the Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act and the Forcing Limits on Abusive and Tumultuous Prices (FLAT) Act, both co-sponsored by Senator Peters, which would require pharmaceutical companies to submit justification for their price increases above a certain threshold and shorten market exclusivity periods for prescription drugs that engage in price hikes.

5. **Level the playing field for generics:** Congress should encourage new and affordable generic competition by prohibiting unfair and manipulative patent and regulatory exclusivity practices. Congress should also pass the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, which would prevent unfair drug company practices by allowing innovators to purchase drug samples for a commercially reasonable price and bring civil actions if a sample is withheld. It would also broaden FDA authority to approve generics and biosimiliars.

6. **Allow Medicare to negotiate drug prices:** Congress should pass the Empowering Medicare Seniors to Negotiate Drug Prices Act, which would strike the "noninterference clause" that prohibits the government from negotiating drug prices under Medicare Part D.

7. **Allow for personal use importation where safe and viable:** Americans have resorted to traveling outside of the U.S. to obtain prescription medications at an affordable cost. Congress should consider passing the Safe and Affordable Drugs from Canada Act, a bipartisan bill that would allow individuals to safely import prescription drugs from Canada into the United States.

8. **Require pharmaceutical companies and manufacturers to report needed data to the FDA and list key information on drug labels:** The Food and Drug Administration Safety and Innovation Act (FDASIA) should be amended to require manufacturers to report the percentage of the market currently held by the manufacturer, inventory on hand and in distribution channels, and interruptions or discontinuances of manufacturing for certain key ingredients. Congress should expand FDA authority to impose fines for noncompliance. In addition, information about active ingredients and manufacturing facilities, including the country of origin, should be listed on prescription labels.

9. **Require pharmaceutical manufacturers to submit annual redundancy and contingency plans to the FDA:** Pharmaceutical companies should be required to submit annual redundancy and contingency plans for critical lifesaving and emergency medications to help reduce the impacts of drug shortages.

10. **Require pharmaceutical manufacturers to provide key quarterly data:** The government does not have insight into the real-time manufacturing capacity of pharmaceutical companies bringing drugs to the U.S., creating gaps in information necessary to assess safety and security risks. Pharmaceutical companies should be required, on a quarterly basis, to provide to the Department of Homeland Security and the Department of Health and Human Services with information on the location, volume, and production capacity for each drug produced at a company's manufacturing facilities.

11. **Require DHS and HHS to conduct an annual risk assessment:** DHS and HHS should be required to publish an annual risk assessment of the national security implications regarding the diversification of the pharmaceutical industry's supply chain, relevant market intelligence, and potential threats. The risk assessment should classify severity of risks and propose specific solutions.

12. **Help bring pharmaceutical manufacturing for critical drugs back to the U.S.:** The FDA should be given authority to provide incentives for pharmaceutical companies that bring manufacturing for certain critical drugs back to the U.S. Congress should also provide incentives for pharmaceutical companies to partner with academic institutions to further advancements in continuous pharmaceutical manufacturing in the United States.