House Energy and Commerce Committee

Oversight and Investigations Subcommittee Hearing: "Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains"

May 11, 2023

Witnesses

- Alex Oshmyansky, MD, PhD, CEO/Founder, Mark Cuban Cost Plus Drug Company
- Anthony Sardella, Chair, API Innovation Center, Adjunct Lecturer & Senior Research Advisor, Center for Analytics & Business Insights, Washington University in St. Louis
- Laura Bray, Founder, Angels for Change
- Fernando Muzzio, PhD, Distinguished Professor of Chemical & Biochemical Engineering, Rutgers University

Key Takeaways

- Members on the subcommittee and witnesses strongly emphasized how drug shortages are complex and create intense danger to patients.
- Subcommittee and Committee leadership commented on the inefficiencies at the Food and Drug Administration (FDA) and their inability to combat drug shortages.
- Witnesses provided recommendations to better predict drug shortages, enhance manufacturing in the US, and improve the quality and safety of drugs, including the need to invest in advanced technologies, provide incentives, improve inspections and monitoring of manufacturers, foster a multistakeholder approach, and others.

Summary of Comments

- House Energy and Commerce (E&C) Committee Chair Cathy McMorris Rodgers (R-WA) said that the FDA has not been an effective partner in combatting drug shortages.
    - The FDA testified recently that around 80 percent of active pharmaceutical ingredients (API) facilities and 60 percent of finished dosage facilities are overseas, including India and adversarial countries, like China. The COVID-19 pandemic revealed the countries' overreliance on foreign production of essential drugs.
- E&C Committee Ranking Member Frank Pallone (D-NJ) said that the FDA's current reporting requirements make it difficult to predict how a disruption with one supplier would affect the manufacturers' ability to produce their drugs. The FDA's tools are even more limited when it comes to forecasting and anticipating changes in demand. Manufacturers aren't required to report demand surges to the FDA, which means the FDA agency lacks the information it needs to foresee a shortage.
- Anthony Sardella was asked about pharmacy group purchasing organizations (GPOs) – the price setters for generic drugs. Sardella said GPOs create market inefficiencies, contribute to the aggregation of profits, and are putting manufacturers out of business. As Congress develops policies to address GPOs, Sardella said they must recognize that any redistribution of profits will go to foreign manufacturers not US manufacturers because that's where GPOs are getting their

supply. To create a sustainable, strong economic US-based supply, incentives for US manufacturers need to be established before addressing the GPO's concentration of profits.

- Sardella and Fernando Muzzio talked about the need for innovation and advanced technology. During COVID-19, we had an overreliance on foreign manufacturers. Moving forward, the strategy should not be to just move the same type of manufacturing to the US to produce drugs. Instead, they recommended leveraging advanced technologies, such as continuous flow, that allows for significant cost reductions.
    - The API Innovation Center has been focused on a series of oncology drugs. For one crisis oncology drug, Lomustine, the center built a consortium of innovators to develop new novel techniques to produce the drug using continuous flow, existing manufacturers with capacity to produce the drug in the US and engaged with entities to make the control systems. This took a multistakeholder effort, but there was a 90 percent cost reduction on the drug that now is feasible for manufacturers in the US.
- Sardella said advanced technology will be required for long term improvements. This will require incentivizing US based manufacturers and changes in formularies/preferred drug lists to allow manufacturers with advanced technology that are more environmentally and economically favorable to be chosen for formularies.
    - We don't need legislation to provide designations on formularies for the requirements for preferred drugs. For examples, requirements may include US made, made from a facility that has no warning letter, facility using advanced technologies to allow for higher quality drugs and those that are economic and environmentally favorable.
- Muzzio emphasized the need for systems that are nimble and more flexible for manufacturing. Generic manufacturers are having trouble implementing newer technologies because they cost a lot of money, take a long time to produce, and don't have access in house to people with the required knowledge. He said this is the perfect opportunity to create centers of excellence, or places where we have knowledge, people and equipment, working closely with manufacturers.
- Sardella also commented on how important timely and effective inspections of both domestic and foreign manufacturing facilities are for ensuring security of the drug supply chain. This is essential for ensuring the quality and safety of medicine and the stability of the market. Inspections tell us which manufacturers are complying and we should award those who don't have warning letters, but to do this we need a robust inspection auditing process.
- Sardella said we must modernize monitoring systems. New emerging advanced manufacturing technology control systems monitor productions every second. This will allow inspection and observation without being at the facility and allow for data transport in real time. Congress should enable FDA to utilize and leverage these technologies.
- Representative Gary Palmer (R-AL) commented that in 1996, the Clinton administration repealed Section 936 of the Internal Revenue Code which provided tax incentives for drug manufacturers and that change had a devastating impact on the pharmaceutical industry in Puerto Rico. Sardella said he is not familiar with this provision, but he believes a tax incentive would be a strong instrument to re-incentivize manufacturers in US.
- Lauren Bray outlined her recommendation to lead to a redundant supply chain, one that can recover during a disruption and remove the impact of shortages from patients and hospitals:
    - Step 1: Align Incentives and Motives through Partnerships.
    - Step 2: Prediction and Forecasting must be employed.

    - Step 3: We must be ready to supply patients.
    - Step 4: Collaboration.
    - Step 5: Patient advocacy at the center of the conversation.
    - Step 6: An Entrance and Exit Ramp for Generic Manufacturers.
- Bray said that 90 percent of oncologists say that shortages have led to patient harm including death in some instances. These shortages are adding emotional trauma to families in a medical crisis.
- Bray reiterated previous comments about the problem with not knowing when there is a spike in demand. She said we need data that leads to prediction so that we don't have disruption. Bray said there is good work being done at the United States Pharmacopeia with their medicine supply map – they are mapping the entire global supply chain.
- All the witnesses agreed that in order to address drug shortages, there needs to be a multistakeholder approach with public and private partnerships, including the FDA, supply chain manufacturers, hospitals, patients, etc.