On June 2, 2020, the Senate Committee on Finance hosted a full Committee hearing entitled “COVID-19 and Beyond: Oversight of the FDA’s Foreign Drug Manufacturing Inspection Process.” Witnesses represented the U.S. Food and Drug Administration (FDA), U.S. Government Accountability Office (GAO), and private sector companies. The hearing sought to examine the accountability of FDA’s vetting process, especially in regard to drugs necessitated by the COVID-19 pandemic. Lawmakers and witnesses in the public and private sector discussed FDA’s current policy and future measures to increase onshoring and prevent the influx of drugs from unsafe supply chains.

Committee Chairman Senator Chuck Grassley (R-IA) opened the hearing by...
commenting on the Committee's obligation to ensure that drugs supported by taxpayers are effective and enter the United States from a safe supply chain. Grassley was foremost concerned with the manufacture of Active Pharmaceutical Ingredients (API) and the overseas inspection process. He noted that internationally, FDA gives a 12-week notice in advance of inspections, yet facilities still fail to pass inspections. Grassley characterized the inability to pass inspection after a 12-week notice as a sign of a safety failure in the global market. Grassley cited that the majority of facilities making APIs are overseas, indicating a lack of self-sufficiency for U.S. industry. Grassley asserted the need for oversight and an “aggressive inspections regime” of foreign manufacturers to ensure consumer safety. Grassley discussed the former India Pilot Program, which allowed unannounced inspections into foreign facilities.

Ranking Member Senator Ron Wyden (D-OR) commented on racial disparities in health care, citing majority black counties experiencing higher COVID-19 morbidity and mortality. Wyden discussed U.S. market proliferation of hydroxychloroquine, which whistleblower Dr. Rick Bright claimed had been imported from uninspected foreign markets. Wyden remarked on the absence of Dr. Stephen Hahn, FDA Commissioner, whose testimony he argued was pertinent to fact-finding and accountability. He introduced an article from The New England Journal of Medicine on the impact of ineffective and unsafe drugs during the pandemic.

The Committee heard from the following witnesses (written testimony is hyperlinked, with the first three Panel 1 witnesses under McMeekin):

Panel 1

- Judith A. McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, FDA;
- Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, FDA;
- Mark Abdoo, Associate Commissioner for Global Policy and Strategy, FDA; and
- Mary Denigan-Macauley, Ph.D., Director, Health Care, GAO.

Panel 2

- Martin VanTrieste, President and Chief Executive Officer (CEO), Civica Rx, and;
- David Light, Founder and CEO, Valisure.

Dr. McMeekin’s testimony urged that American consumers should have confidence in the U.S. supply chain being “among the safest in the world.” McMeekin agreed that broadening domestic sourcing was important in responding to a question from Senator John Cornyn (R-TX) about potential vulnerabilities in foreign reliance on APIs. In response to questioning from Chairman Grassley on whether advance inspection notice gave “bad actors time to hide the true nature of the problems at
their facilities,” McMeekin highlighted the distinctions of domestic and international inspections. Advance notice enables FDA to confirm the international facility’s registration. Outside of the United States, due to jurisdictional differences, FDA cannot use a warrant to compel firms to grant inspectors entry. FDA can only stop unchecked supplies from crossing the border. McMeekin clarified that unannounced for-cause inspections could occur, and while there is no database of facilities that refuse inspection, she expects efforts to collect that data are under way.

In Dr. Throckmorton’s testimony, he agreed that policies such as supporting advanced manufacturing policies in U.S. firms would improve security, assuage environmental concerns, and increase product onshoring. Throckmorton elaborated that FDA’s typical responses to drug shortages are to contact API manufacturers to discover new product sources. Senator Pat Toomey (R-PA) questioned Throckmorton on qualifying the extent that the United States was reliant on China to source COVID-19 related drugs. Throckmorton clarified that the United States was not solely dependent on China for drugs necessitated by COVID-19, but for certain non-pandemic drugs. Throckmorton was unaware of any action by an overseas manufacturer to withhold medicine that Americans need. He testified that data supported the authorization of emergency use of hydroxychloroquine early in the pandemic. The FDA does not have mandatory recall powers in the drug market, most companies follow the recall.

Mr. Abdoo, responding to questioning from Chairman Grassley on the India Pilot Program, defended the Obama Administration’s termination of the program. He testified that there were “no metrics by which we could evaluate whether it was a success ... and it was collecting data with an inherent bias.”

Dr. Denigan-Macaulay elaborated on the challenges posed by understanding foreign supply chains, where APIs can come from many sources. She agreed that there might have been imports from uninspected facilities. As there is no country of origin labeling, consumers cannot know if the drug comes from inspected or uninspected facilities. She testified that GAO is re-examining criteria for drug safety.

Martin VanTrieste suggested private sector solutions for the non-profit industry. VanTrieste emphasized the business incentive, especially for non-profits, which are unable to raise the same capital. VanTrieste suggested that instituting grants and low-interest loans would be productive policy measures to increase onshoring. The Trump Administration has contracted with Civica Rx to manufacture COVID 19 drugs. Civica Rx’s focus is not on making drugs or APIs but rather on putting infrastructure in place to do so. Civica Rx has provided 1.6 million vials of pandemic drugs at the government’s request, including sedatives, antibiotics, heart medication, and anesthetics.

David Light described his company’s process in testing various factors, including dissolution rate and carcinogenic rate. The cost of independent analysis adds minimal cost toward patient and pharmacy distribution. He argued that this low-cost assessment is a reward for high-quality manufacturers. Through an evidence-based approach of independent study, Light stated that risk assessment increased transparency for patients and buyers.
Commentary

The hearing emphasized the necessity of ensuring drug accountability and strengthening the domestic production of pharmaceuticals. FDA faced criticism for faulty COVID-19 tests entering the market and its decision to allow unvetted hydroxychloroquine into the market. Dr. Hahn’s absence meant that FDA was unable to answer some lines of questioning. FDA suspended in-person inspections due to COVID-19. Additionally, the hearing illustrated a lack of data on the frequency of inspections at foreign facilities and the rate of facility refusal. Witnesses noted efforts on behalf of FDA to collect information. GAO has increased its involvement, with FDA oversight. The recently enacted Coronavirus Aid, Relief, and Economic Security Act enables FDA to access more information about supply chain disruptions. FDA signaled that it is better prepared for strategic stockpiles and is in talks with the Federal Emergency Management Agency about distribution. Senator Sherrod Brown (D-OH) criticized that this was the Committee’s first hearing since the onset of COVID-19, amid a time of deep unrest in the United States. In closing, Wyden called for a future hearing addressing racial health care disparities.

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