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Committee Hearing Memorandum

Tuesday, June 2, 2020
Senate Committee on Finance: "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process"

Witnesses

Panel One:

Judith A. McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, Food and Drug Administration

Douglas Throckmorton M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration

Mark Abdoo, Associate Commissioner for Global Policy and Strategy, Food and Drug Administration

Mary Denigan-Macauley, Ph.D., Director, Health Care, Government Accountability Office

Panel Two:

Martin VanTrieste, President & Chief Executive Officer, Civica Rx

David Light, Founder and CEO, Valisure

Executive Summary

On Tuesday, June 2, the Senate Committee on Finance held a hearing to hear from public officials and private sector representatives on foreign drug manufacturing and supply chain issues. In his opening statement, Chairman Chuck Grassley (R-IA) discussed the U.S.' overreliance on the foreign facilities for Active Pharmaceutical Ingredients (API) and other drug products. Grassley expressed frustration that foreign facilities are forewarned of FDA inspections. Ranking Member Ron Wyden (D-OR) criticized the FDA's issuance of an Emergency Use Authorization (EUA) for hydroxychloroquine. During the first panel, committee members heard from Food and Drug Administration (FDA) and Government Accountability Office (GAO) officials on the FDA's foreign inspection program and drug evaluation processes. Witnesses on the second panel explained their companies' work to test the safety of pharmaceuticals and ensure the U.S. has adequate supply of necessary pharmaceutical products.

Sen. Debbie Stabenow (D-MI) and other committee Democrats brought up hydroxychloroquine as an example of the FDA's failure to ensure safe foreign manufacturing. Republican lines of questioning, on the other hand, revolved around ways to reduce reliance on China and bring pharmaceutical manufacturing back to U.S.

Committee Democrats spent much of their time criticizing Grassley for holding this hearing despite the protests spreading throughout the country, and urged the Chairman to hold a separate hearing on racial disparities in healthcare. The Ranking Member, along with Sens. Bob Casey (D-PA) and Sherrod Brown (D-OH), were particularly vocal on this point.

Member Statements

Chairman Chuck Grassley (R-IA): This committee has the responsibility to ensure medications paid for by the taxpayers, whether Medicaid or Medicare, satisfy quality standards and are safe and effective for patients. We also must guarantee that only quality pharmaceuticals enter the U.S. Whether we are in the middle of a pandemic or not, we must ensure supply chain issues are under control. I have asked about foreign inspection management and Active Pharmaceutical Ingredients (API). I have questions about the amount of time the FDA provides to facilities to prepare facilities for instruction.

Over 50 percent of the sites manufacturing the final product are outside of the country. We need to understand where APIs are coming from. Over 70 percent of facilities making API are located overseas. The COVID-19 pandemic has highlighted the national security and public health issues that come with this.

We need to have a robust foreign inspection process to ensure patient safety. Inspections should be unannounced, so that facilities do not have the ability to clean up their facilities prior to FDA visits. We need a strong enforcement mechanism to discourage bad actors.

Today we have witnesses from FDA that can speak to these issues and how the COVID-19 crisis has impacted their work. We will hold another hearing examining the increase in trade of fake and faulty Personal Protective Equipment (PPE).

To view Grassley's full opening statement, click here.

Ranking Member Ron Wyden (D-OR): The Finance Committee is holding this hearing to investigate the FDA's failure to adequately inspect foreign drug manufacturers. The FDA Commissioner should be here to answer questions, but the Trump Administration blocked him from appearing.

While the committee meets for this hearing, COVID-19 is killing thousands of Americans, unemployment is at near Depression levels, and racial tensions are boiling across the country following the murder of George Floyd. I want to bring to the committee's attention the disparity of which COVID-19 is affecting Black communities. The health care system has failed the African American community.

Relative to today's hearing, I would like to speak on the administration and the FDA's push of the unsafe use of hydroxychloroquine. The FDA issued an Emergency Use Authorization (EUA) for this medicine for COVID-19. This led to stocks of this medication coming from unsafe and uninspected facilities overseas. In addition, this medication is used for other health conditions, and the administration's actions have limited the ability of patients to access it. This is the starkest example of FDA failure, but there are many others.

To view Wyden's full opening statement, click here.

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Witness Statements

To view the joint written testimony of Abdoo, McMeekin, and Throckmarten, click here.

Mark Abdoo: My office provides oversight and policy for the FDA's trade practices. Drug manufacturing has increasingly been moved overseas, which has created significant oversight issues for the FDA. The agency responded by increasing foreign inspections, developing new enforcement and regulatory tools, increasing collaboration with foreign regulators, developing global standards, educating foreign manufacturers about FDA standards, and increasing transparency in the supply chain.

We have made progress in increasing staffing levels at foreign offices. Our foreign offices conduct inspections, particularly unannounced for-cause inspections. They also engage in outreach and training to promote good practices and provide data to inform decision funds.

In recent years, we established the Mutual Recognition Agreement (MRA), which allows EU and U.S. regulation authorities to rely on information from routine drug inspection information conducted within another's borders. This will lower inspection costs and permit us to devote resources to other parts of the world.

Judith A. McMeekin: The FDA's strategy for overseeing the safety of imported products is to maximize the agency's public health impact by aligning resource allocations to risk levels and tailoring regulatory mechanisms accordingly. In the foreign arena, the FDA does not have a comparable level of infrastructure. To supplement our overseas inspections, we use border surveillance and import screening, foreign inspections, etc.

During the pandemic, the agency continues to utilize alternative inspection tools while postponing foreign and domestic facility inspections. This approach will continue as conditions warrant with the exception of mission critical inspections, including for-cause and pre-approval assignments. Importantly, we are evaluating additional ways to conduct our work while ensuring the safety of FDA staff and partners.

Hiring and retention of foreign inspection workers is challenges. We are committed to looking at the foreign inspection process and making improvements.

Douglas Throckmorton: Inspections are one important part of a robust multi-pronged process of ensuring FDA compliance. Firms manufacturing products are required to adhere to quality and safety standards. We provide guidance on best manufacturing practices. We also partner with ORA to maximize the value of inspections. Additionally, other safety initiatives include proactive testing of API and finished dosage form drugs. Only a small percentage of drugs tested fail to meet the quality standards. We collect data on the safety of drugs once they are on the market as well. We hope to spur the industry to modernize and improve safety. We believe advanced manufacturing techniques can provide a safer and more secure drug supply chain and may provide a shift to more American manufacturing.

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Mary Denigan-Macauley: The pandemic has highlighted the U.S.' overreliance on foreign manufacturing of important drugs. We have long been concerned about the FDA's ability to conduct effective inspection of foreign manufacturing facilities.

The FDA has been increasing the number of foreign inspections it conducts, but still faces significant challenges. As the Chairman pointed out, the agency often gives up to three months' notice prior to an inspection, giving the facility much time to improve conditions for the inspection. The FDA also often relies on English-speaking facility employees to translate documents noting FDA compliance. Inspectors often have short timelines to inspect large facilities. While the FDA has made strides over the years, these challenges call into question the ability of the agency to conduct foreign inspections.

With the COVID crisis, the halt of foreign inspections removes a source of critical information about the quality of drugs produced overseas. It is also unclear that the FDA will be able to combat staffing issues.

To view Denigan-Macauley's written testimony, click here.

David Light: Valisure, our mission is to help ensure the safety, quality, and transparency of medications, and we do this with a very simple but novel approach: we check. Valisure is an online pharmacy attached to an analytical laboratory. We are the first and only pharmacy in America that chemically batch-validates every medication we sell, and we do it at no additional cost to consumers.

Valisure conducts batch-testing of every product dispensed to our customers before it leaves the pharmacy, and we do so without adding any cost to patients. We believe this could be replicated on a larger scale, creating "certified drugs" that are independently chemically analyzed and certified before being sold to a patient, pharmacy, wholesaler, or health care system.

Data is available today that provides valuable insights on practically all drug products in the U.S. Independent quality rating systems should be developed through a process that includes robust stakeholder feedback, including patients, providers, academic institutions, and health systems. Results from independent chemical analysis of drug products could be combined with publicly available regulatory data and turned into drug quality scores that could be as simple as a "red/yellow/green" rating for each drug made by each manufacturer. Any buyer or payer could simply strive to buy green, occasionally yellow, and just avoid red.

To view Light's full written testimony, click here.

Martin VanTrieste: Civica was created to ensure medications are always available and affordable. The Civica model can provide insight into the supply chain. We try to avoid Chinese ingredients, and Buy American where we can. We create our products based on need. As Congress considers methods of securing the supply chain, we urge you to keep these principles in mind: define and focus on specific drugs, ensure redundancy in supplies and stockpiles, and purchase from companies with robust quality controls.

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To view VanTrieste's full written testimony, click here.

Key Exchanges

Grassley: You indicated that while domestic inspections are unannounced, foreign facilities are given advanced notice of inspections. Does this impact the accuracy of the information collected at these facilities?

McMeekin: Most foreign inspections are announced to avoid a potential refusal and waste of ORA resources. There are jurisdictional differences between domestic and foreign facilities. When a foreign firm refuses inspection, the FDA must seek different inspection methods (i.e. refuse products at the border), whereas the FDA can seek an inspection warrant for domestic facilities.

Grassley: Would unannounced inspections improve the FDA's ability to secure the drug supply chain?

Denigan-Macauley: Yes.

Wyden: The U.S. has been short on PPE for months. How does it make sense the FDA has been issuing EUA for uninspected respirator manufacturers in China, when U.S. companies cannot receive this authorization?

Denigan-Macauley: They have full authority to make that call without oversight. I do not have an answer for you.

Sen. Tom Carper (D-DE): Does GAO have work on racial disparities in levels of health care?

Denigan-Macauley: Yes. We have started work on exploring racial disparities specific to the COVID-19 pandemic.

Sen. Ben Cardin (D-MD): There are situations where we have had drug shortages on domestic supply. Does the FDA have a strategy to make sure we don't have drug shortages in this country, even when there is adequate supply chain but it is more the economics of a private drug manufacturer deciding not to make enough of the drug?

Throckmorton: We have put out a drug shortage report that laid out the solutions to prevent drug shortages. One critically important one is the quality management maturity. If we could find a way to improve the transparency of the quality of the drug supply chain, purchasers could make better choices about what products to pay a bit more for. This would allow us to set up a rating system.

Sen. Maggie Hassan (D-NH): What is FDA doing to stop illegal fentanyl from crossing the border?

McMeekin: Our enforcement mechanisms are primarily at points of entry: borders, mail, and online sales.

Sen. John Thune (R-SD): What updates can FDA provide to CARES Act provisions related to supply chain disruptions?

Throckmorton: We are very grateful for the provisions we received in CARES. We are in the process of implementing it and I will be happy to provide an update in the Fall.

Sen. Steve Daines (R-MT): What are the most challenging aspects of maintaining quality control of Chinese pharmaceutical products in the United States?

Abdoo: Through the Beijing office, we work closely with the National Medical Products Administration to raise their ability to regulate products in their jurisdiction. We promote adherence to international standards and more.

McMeekin: Our jurisdiction of foreign products begins when a product enters the country's border. FDA uses tools to help compliment foreign inspections. We have an import screening tool, called Predict, and product test at the borders. We can also request records from facilities to ensure they are complying. We are ramping these processes up during COVID in lieu of foreign inspections.

Daines: What are the impediments of domestic drug manufacturing? What would be the benefits of having a domestic supply for our most critical drugs?

Throckmorton: The three main factors that prevent domestic manufacturing are labor costs, environmental standards, and the economics of drug manufacturing. If you look at the drug shortage report, we believe there is a fundamental disconnect between the incentivizes of creating high quality products and the reimbursements of those products. We believe we could fix this is we could grade products based on quality standards.

Grassley: Based on your experience, how can Congress encourage manufacturers to return to the U.S.?

VanTrieste: Non-profit pharma has great potential, not as an alternative to pharma, but as a compliment. There are things Congress can do to help this emerging industry. Non-profits cannot raise capital, therefore grants and low-interest loans would help this industry. There are also a number of bills working to re-shore drug products which we support.
