

TESTIMONY
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
U.S.-CHINA ECONOMIC & SECURITY REVIEW COMMISSION

“EXPLORING THE GROWING U.S. RELIANCE ON CHINA'S
BIOTECH AND PHARMACEUTICAL PRODUCTS”

JULY 31, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Chairman Bartholomew, Vice Chairman Cleveland, and distinguished Members of the Commission, thank you for the opportunity to submit written testimony to the Commission. We appreciate the Commission's thoughtful consideration of the national security implications and the opportunities that arise from the trade of products regulated by the Food and Drug Administration (FDA) between the United States and the People's Republic of China.

FDA is responsible for protecting public health by ensuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The Agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that emit electronic radiation; and for regulating tobacco products. Imported products generally must meet the same standards as those produced domestically.

Sweeping economic and technological changes have revolutionized international trade over the last several decades creating a truly global marketplace for goods and services. Many of the challenges associated with globalization are observed in China and mirror the challenges we see in other countries. FDA has engaged in a variety of efforts to help address these challenges.

For example, in China, FDA conducts risk-based regulatory inspectional activities; capacity-building and confidence-building activities with Chinese regulatory authorities; and focused engagements with key in-country stakeholders, including regulatory counterparts, regulated industry, U.S. government agencies, multilateral organizations and academia. FDA monitors and reports regulatory trends, conditions, and emerging public health events/incidents that have the potential to impact the safety of FDA-regulated products produced in China intended for U.S. consumption. FDA also coordinates with other agencies to support U.S. interests, including national security interests.

Scope of medical product & supplement manufacturing taking place in China

As of 2018, China ranks second among countries that export drugs and biologics to the United States by import line (13.4 percent). An import line is a distinct regulated product within a shipment through customs. A single shipment may include multiple lines of varying sizes. Approximately 83 percent of these Chinese import lines for drugs and biologics were human finished dosage forms (finished drugs) and 7.5 percent were active pharmaceutical ingredients (APIs), the remaining 10 percent were animal drugs and medicated animal feed. In addition to these import lines, APIs manufactured by China also come to the U.S. as part of finished drug products manufactured in other countries, for example, India. Therefore, the percentage of APIs produced by China for the United States marketplace is likely underrepresented by our numbers

as China is a major supplier of APIs for other countries. It is important to note, FDA’s Drug Shortages Staff continuously monitor drug supply chains for potential shortage issues, including for drugs and APIs sourced from China. With respect to registered foreign human drug manufacturing facilities that are subject to CGMP (current good manufacturing practices) surveillance inspections, approximately 22 percent of the API manufacturing facilities and 14 percent of finished dosage form manufacturing facilities are located in China.

China provides 39.3 percent of the medical device import lines, and ranks first among countries that export devices to the United States by import line. It is imperative FDA continues to ensure the quality and availability of FDA regulated medical products.

Risk-based Oversight

The Agency electronically screens imports using an automated risk-based system to determine if shipments meet identified criteria for physical examination or other review. To enhance our ability to target high-risk products, FDA developed the *Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting* application, or PREDICT. This is a sophisticated screening application that uses information from many sources—such as intrinsic product risks, past inspection results, intelligence data, and even information about threats such as extreme weather that could spoil a shipment—to provide FDA entry reviewers with risk scores on every import line.

FDA maintains global vigilance of manufacturing facilities through a risk-based inspection strategy to focus inspectional resources on higher risk facilities and works closely with our international regulatory partners in Europe to avoid duplication of inspections. Among other things, the number of inspections in any given country reflects our risk-based prioritization of our inspections and improvements in our targeting; our increasing ability to leverage inspectional work done by trusted partners, especially in Europe; and a higher number of foreign pre-approval inspections.

Our policy for prioritizing drug manufacturing surveillance inspections is based on factors such as a facility’s compliance history, recall trends, time since last inspection, inherent risks associated with the drug being manufactured, processing complexity, and other factors, which are all carefully weighed and considered. FDA is maintaining global vigilance by concentrating inspections on higher risk facilities, both for routine surveillance and in evaluating new drug applications. As global compliance trends change – and standards in some sectors improve – we should expect to see an evolution in our inspection priorities.

In regard to food products, FDA recently published its *Strategy for the Safety of Imported Food*. FDA applies the same U.S. food safety requirements to all food consumed in the United States, regardless of whether the facility or farm that produces the food is located within the United States or half way across the globe. Because FDA's enforcement tools abroad differ from the Agency's tools domestically, Congress directed FDA to develop certain programs to ensure the safety of imported food. As with domestic oversight, FDA's strategy for overseeing the safety of imported food is to maximize agency public health impact by aligning resource allocation to risk level, tailoring the use of new and existing regulatory tools accordingly. FDA will work to optimize oversight of foreign firms and the portion of imported foods that receives FDA oversight, including leveraging the work of partners with strong regulatory systems or responsible parties in the food supply chain. However, based on our experience, the process of negotiating arrangements is time- and resource-intensive, requiring funding over a long period, and could potentially detract from resources for other inspection approaches and activities.

In addition, FDA also recently published the *Plant and Animal Biotechnology Innovation Action Plan* to implement and clarify risk-based policies with the goals of ensuring that developers know what they need to do to efficiently bring a plant or animal biotechnology product to market, and that consumers and the public understand how FDA's regulatory system helps ensure the safety of such products. FDA has already evaluated a genetically engineered crop (a rice variety) developed in China. The Agency anticipates other Chinese developers will engage FDA as part of the Agency's voluntary consultation process for biotechnology-derived plant varieties. FDA is well prepared to support a global marketplace focused on innovation in plant and animal biotechnology and to advance the Agency's public health mission.

On-going challenges

Substantial improvements have been made in the inventory of registered pharmaceutical manufacturing firms in recent years. However, there are remaining gaps in this inventory that should be addressed to ensure visibility of all Chinese manufacturers that produce drugs or active pharmaceutical ingredients of drugs that are ultimately shipped to the United States. The President's FY2020 budget includes a legislative proposal to address information gaps relating to foreign drug manufacturers. This full information on the drug supply chain, while available domestically, can be enhanced for foreign sites. Closing this gap will help ensure FDA has the information needed for effective shortage mitigation, provide more complete data for risk-based surveillance inspection planning, and help ensure prompt detection and intervention of unsafe drugs in the marketplace.

Coordination with other agencies

In addition to these efforts, FDA is also actively engaged in a number of collaborative efforts with other agencies. In general, for complicated issues that involve trade or scientific dispute, interagency (e.g., the Department of Homeland Security, the Office of the United States Trade Representative, the Department of Agriculture, and others as appropriate) coordination is pivotal in ensuring FDA's overall mission is advanced. While FDA depends on the major national security agencies and the Department of Health and Human Services' (HHS) broad national security efforts to protect our national security interests, FDA and the regulated industry at large have a vested interest in preventing unacceptable breaches of trust and confidentiality that can undermine the integrity of U.S. biomedical innovation and research. To that end, FDA has safeguards to prevent diversion of intellectual property in product applications to other entities, including other countries, and restricts the sharing of confidential information by FDA staff with others, including in some instances with foreign entities.

Foreign acquisitions, or investments by a foreign entity involving over 10 percent, of a U.S. company triggers a review of the transaction by the Committee on Foreign Investment in the United States (CFIUS) under 31 CFR § 800-806. While normally voluntary in nature, notices to CFIUS may be mandated (or even unilaterally filed by CFIUS) in the event a transaction not submitted to CFIUS but involving national security risk is identified. FDA provides input to the larger HHS response to CFIUS cases involving the Healthcare and Public Health, and Food and Agriculture, critical infrastructure sectors where FDA has a potential interest involved or may be impacted by the transaction. This includes, but is not limited to, acquisitions by Chinese entities. When applicable, CFIUS has the ability to refer the matter to the President, certify to Congress that the transaction does not present an unmitigated national security concern, or negotiate a risk mitigation agreement with the company that can require up to and including the complete, total, and permanent divestiture of the U.S. portions of the acquired or invested company. In the event of a mitigation agreement, CFIUS can also institute a mitigation monitoring agreement wherein compliance with the mitigation agreement is monitored by involved Federal agencies, generally with severe monetary damages imposed in the event of a breach of the mitigation agreement. CFIUS cases are not limited to any particular sector or industry; any transaction potentially involving national security risk and foreign control can be pulled into the process. CFIUS controls are sufficient to address merger and acquisition risks when identified and applicable; they cannot cover transactions or company creation efforts that fall outside CFIUS' purview.

For dietary supplements, there are no formal agreements. For biotechnology, there are no formal agreements. However, the U.S. and China have a Biotechnology Working Group and a Technical Working Group that foster bilateral dialogue and are focused on trade and information sharing.

Another item of note is the Department of Defense's (DoD) access to FDA's *Compliance Status Information System* (COMSTAT) to evaluate a facility's ability to produce medical products in accordance with FDA's regulatory requirements. COMSTAT displays the status of medical product firm profiles using profile class codes based on categories of products produced by a firm. Profile class codes and statuses indicating if they are in accordance with FDA's regulatory requirements are determined during FDA inspections. Although COMSTAT requires an account for access and DoD personnel have accounts, COMSTAT does not have a reporting mechanism to determine when DoD accesses the system or what records are viewed.

Conclusion

Thank you for giving FDA the opportunity to describe the Agency's efforts to address the challenges of our globalized marketplace and to discuss our work in China. FDA is implementing a comprehensive strategy to enhance the safety of imported products and to establish an effective global safety net.

Our priorities in China are consistent with our priorities everywhere. The best way to ensure food safety and the integrity of medical products is to make sure firms consistently follow appropriate processes for safeguarding safety and quality in production. Manufacturers are best situated to ensure these processes, and regulatory bodies should hold companies accountable for lapses in the production process and not simply rely on testing after the fact to detect flaws. Inspections and testing play an important role in that process, but they need to be used as part of a larger system that emphasizes a systematic, proactive, preventive approach to strengthen the production of safe food and safe and effective medical products produced in China for export to the United States. And in our globalized world, it is increasingly important that regulatory partners work together to ensure the safety of products as they move across borders. While many future challenges remain as we engage Chinese regulators and industry on these key issues, we will continue to expand on successes attained in recent years.