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Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

I. Introduction

A. My background

My name is John W.M. Claud, and I am a Counsel at the Washington, D.C. law firm of Hyman, Phelps & McNamara, P.C. HPM is the nation's largest FDA boutique law firm and represents clients across all U.S. Food and Drug Administration (FDA) regulated industries. The opinions I provide here today are my own. Unless otherwise indicated, I do not speak for my firm or its clients.

Before joining HPM in 2022, I served for three years as the Assistant Director for Compliance and Policy of the Consumer Protection Branch at the United States Department of Justice. I had several responsibilities there, including review of all corporate compliance matters before the Branch, and directing the Branch's national coordination of criminal prosecutions under the Food, Drug and Cosmetic Act (FDCA). Before becoming an Assistant Director, I served for 12 years as a Trial Attorney, litigating criminal prosecutions and civil enforcement actions on behalf of FDA. Among my many cases, I served as a member of the prosecution and trial team on DOJ's investigation into the tragedy at the New England Compounding Center (NECC). Lax quality practices and rampant fraud there resulted in adulterated and misbranded sterile injectable drugs contaminated with fungi, which caused the 2012 national outbreak of fungal meningitis. Over 100 deaths resulted, in addition to hundreds of infections in what remains the deadliest occurrence of adulterated drugs in history.

Before joining DOJ, I was an associate in the Business Fraud practice at the law firm of Cadwalader, Wickersham & Taft, LLP. I began my legal career serving as an Assistant District Attorney in Manhattan for five years. I am a 2000 *cum laude* graduate of the Catholic University of America Columbus School of Law, hold a master's degree in criminal justice from the University of Colorado-Denver, and a bachelor's degree from Trinity College in Hartford, Ct.

I am honored to appear today before the Subcommittee.

B. The Vital Role of FDA in Interstate Commerce

Having worked with now-former colleagues at FDA for 15 years, I believe in the Agency's mission, and I also believe that the people there who affect that mission are among the most dedicated and well-intentioned public servants of the American taxpayers. My clients feel the same way. While their respective relationships with FDA can, at times, be adversarial, and while there exist many honest disagreements over some policy decisions, my clients recognize and appreciate FDA's vital role in protecting the flow of goods through interstate commerce. The Agency, as a large organization and despite its important mission, is not perfect. But American consumers can, in vast majority, trust their drugs. That is overwhelmingly due to the people at FDA, who have admirably made public health and safety their chosen careers.

Food and drug regulation is a unique and complex undertaking. Consumers cannot possibly possess the nuanced scientific, medical, and legal knowledge they would need to appropriately protect themselves against the potential perils that they face from poor-quality pharmaceutical products without the regulatory oversight and guidance that FDA provides. One of the complex and nuanced areas that FDA regulates is inspections of foreign drug

manufacturing facilities. I am happy to speak to you today on that topic from the experience I have gained from my 15-year career prosecuting FDA enforcement actions as well as the counseling I currently provide to my firm's clients.

II. Current State of FDA Foreign Inspection Efforts

A. Inspections

FDA has the statutory authority to enter an inspect "any factory, warehouse, or establishment in which [drugs] are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such[drugs] in interstate commerce."[1]

The Agency's public health officers conduct several distinct kinds of inspections at drug facilities. **Surveillance inspections** monitor a facility's adherence to current good manufacturing practices (cGMP) to ensure the quality of FDA regulated products on the market. Domestic drugmakers should expect surveillance inspection bi-annually, although that schedule remains disrupted as the result of the pandemic.[2]

FDA conducts **for-cause inspections** when it has evidence that a facility has quality problems, to investigate complaints, or to evaluate corrections a manufacturer has made to remediate prior deviations from cGMP.[3]

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[1] 21 U.S.C. § 374(a)(1).

[2] *See* U.S. FOOD & DRUG ADMIN., *Types of FDA inspections*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/types-fda-inspections.

[3] *Id*.

Application-based inspections are part of the approval review process drugmakers undergo in order to market a new drug. FDA uses these inspections to determine whether a new drug product is manufactured in compliance with FDA regulations and to ensure the facility where the product is made is capable of consistent quality standards that data submitted to FDA are accurate and complete. According to FDA's website, these inspections occur for approximately twenty percent of the applications it receives.[4]

B. FDA's Risk Based Approach to Inspections

As with most of its enforcement efforts, FDA uses a risk-based approach to select what facilities to inspect.[5] The Agency prioritizes inspections at facilities that present a higher risk due to several varied factors, such as the type of facility, its compliance history, the vintage of its most recent inspection, any evidence of hazards or non-compliance such as product recalls, and the risk level associated with the products made at the facility. [6]

For foreign facilities, FDA considers all these factors and—importantly to the Subcommittee's hearing today—whether a foreign regulatory partner has inspected a facility.[7] However, foreign inspections present several challenges for the Agency. As stated in the 2022 report THE FOOD AND DRUG ADMINISTRATION'S FOREIGN FOR-CAUSE DRUG INSPECTION PROGRAM CAN BE IMPROVED TO PROTECT THE NATION'S DRUG SUPPLY, "[t]he Food and Drug Administration's (FDA's) oversight responsibility has become increasingly complicated because

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[4] *Id*.

[5] *See* U.S. FOOD & DRUG ADMIN., *FDA's Risk-Based Approach to Inspections*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/fdas-risk-based-approach-inspections#:~:text=The%20FDA%20uses%20a%20risk,manufacturer%2C%20control%20laboratory%2C%20etc.

[6] *Id.*

[7] *Id*.

many drugs used in the United States are manufactured overseas."[8] Estimates vary from source to source, but evidence indicates that an increasing amount of API that go into the finished drugs that American consumers use have some international source.[9] More recent, post-pandemic numbers on this topic are elusive, and may bear more investigation from the Subcommittee's respective staff. Statistics notwithstanding, the Subcommittee can doubtlessly imagine how logistical hurdles, the recovery from the pandemic, and the subsequent need to ramp up training and professional education for inspectors impacts this part of the Agency's mission.[10] Of note are inspections for drug manufacturing facilities in China and India, which have their own complex regulatory systems that may not always align with FDA's. Increasing reliance on foreign products combined with open questions about foreign quality standards emphasize the need for FDA to use its enforcement arm wisely.

III. How Foreign Inspections Affect Drug Shortages

A. Use of Foreign-Made Drugs to Resolve Shortages

Given the vastness of the policy and practical problems addressing foreign inspections, I will not try to comprehensively address them here. At least two reports external to FDA have done so. To understand these complexities, I offer one example of how FDA's decisions relating

[8] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved to Protect the Nation's Drug Supply, 2022. https://oig.hhs.gov/oas/reports/region1/11901500.asp.; U.S. GOVERNMENT ACCOUNTABILITY OFFICE, Drug Safety—FDA Should Take Additional Steps to Improve Its Foreign Inspection Program ["GAO Report"], https://www.gao.gov/products/gao-22-103611.

[9] *See, e.g.,* Graham, Neils (April 20, 2023). The US is relying more on China for pharmaceuticals — and vice versa. The Atlantic Council. https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/.

[10] *See, e.g.,* GAO Report at 31.

to foreign inspections intersects with another crucial issue facing FDA: how foreign inspections affect domestic drug shortages.

In addition to inspections, FDA is charged with resolving drug shortages. The Agency has some statutory tools to deal with crucial shortages,[11] but it has also exercised enforcement discretion and allows foreign drugs to supply the market.[12] In situations such as this, FDA determines that the needs for medicines of America consumers outweighs the risk that can be associated with drugs from foreign facilities.

But as both GAO and the HHS-OIG have noted in their recent reports, the extent to which FDA has been able to successfully conduct foreign inspections is in doubt. Thus, to resolve drug shortages, the Agency is left with a Hobson's choice of allowing a shortage to continue or allowing drugs that may lack a preferred quality pedigree that domestic manufacturers ought to be able to provide. These issues can place a great strain on the Agency as a whole, and on the small office at FDA charged with addressing shortages.[13]

B. International Inspectional Issues Can Lead to Domestic Problems

These international issues and the difficult decisions that accompany them can lead—and have led—to domestic problems, the resolution of which might amount to low-hanging fruit that in some circumstances FDA is not picking. One example is that faced by my firm's client, Nexus Pharmaceuticals. Nexus is a domestic manufacturer of sterile injectable generic drugs, the highest-risk class of drugs. Nexus has established a domestic manufacturing facility, heavily

[11] *See, e.g.*, 21 U.S.C. § 356c(a)(2).

[12] *See* U.S. FOOD & DRUG ADMIN., Report to Congress—Drug Shortages CY 2022, at 13.

[13] *See* U.S. FOOD & DRUG ADMIN., Drug Shortage Staff, https://www.fda.gov/drugs/drug-shortage-staff.

funding and validating its quality and cGMP compliance. To help address a recent drug shortage, Nexus made a significant investment to obtain approval of an ANDA for a generic version of the drug at issue, called fluorescein. However, after approving the Nexus drug, FDA de-valued Nexus' approved and validated quality system and allowed another company to market the same drug that was 1) previously manufactured by a now-bankrupt manufacturer and 2) under unclear quality surveillance.[14] Compounding this problem, after the shortage was recently resolved, FDA allowed the competitor to stay on the market, even though it remains uncertain how the question of adherence to cGMP has been resolved. If the drug were to be manufactured internationally in the future, one can hardly be confident that FDA will prioritize an international inspection if the Agency has allowed the drug to enter the market here under these circumstances, and under the duress of the recent shortage. Adding to the irony and unfairness in this situation is that Nexus followed FDA's stated policies[15] and obtained an approval while investing in its quality facilities and culture.

All Nexus and its domestic peers ask for is a level playing field, where—as may be appropriate and possible—FDA does not choose to rely on foreign manufacturers that may fall within the gaps of FDA's inspections to resolve drug shortages. On the occasions when FDA fails to resolve shortages with a strategy that emphasizes domestic drugs with validated quality systems, it potentially discourages generic drug makers from seeking approvals in the first instance. Said another way, addressing drug shortages does not mean allowing shortcuts that may

[14] *See* U.S. FOOD & DRUG ADMIN., UPDATE - Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown, 2023, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry.

[15] *See* U.S. FOOD & DRUG ADMIN., Abbreviated New Drug Application (ANDA) Forms and Submission Requirements, https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/abbreviated-new-drug-application-anda-forms-and-submission-requirements.

be caused by a dearth of foreign inspections—especially on drug quality—because those shortcuts will inevitably result in more drug shortages as manufacturers of quality drugs decide not to enter the market.

IV. Possible Solutions to FDA's Open Questions About Foreign Inspections

FDA devotes resources to implement changes in these areas, including ongoing assessments as to how grave the presented risk-level is.[16] However, there are some big-picture ideas that the Subcommittee might find useful as it considers the need for oversight.

A. Relationships with Foreign Inspectors

FDA must continue to expand its reliance on international regulatory bodies. The Agency touts this in its approach to shortages.[17] This expansion holds promise as a way in which FDA may potentially improve its ability to identify high-risk facilities overseas, and, as importantly, gain assurances about those that present a minimal risk. Here again, FDA is asked to follow through on what are hopefully less nuanced assessments and pick low-hanging fruit. I can offer a specific example, in a matter involving another firm client. There, FDA conducted an inspection of a European manufacturing facility that then embarked on a thorough and well-intentioned program of remediations. A subsequent inspection from European authorities have resulted in the

[16] *See* U.S. FOOD & DRUG ADMIN., *FDA's Risk-Based Approach to Inspections*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/fdas-risk-based-approach-inspections#:~:text=The%20FDA%20uses%20a%20risk,manufacturer%2C%20control%

[17] *See* U.S. FOOD & DRUG ADMIN., Report to Congress—Drug Shortages CY 2022, at 16.

issuance of a certificate of full cGMP compliance. Alas, FDA has yet to resolve its initial inspection while the facility waits to move forward.

B. Leveraging Data

Most regulated companies have numerous reporting requirements in place. For example, the Federal Food, Drug and Cosmetic Act already has provisions that require drug manufacturers to report anticipated shortages six months in advance.[18] And though FDA has improved its data relating to foreign inspections, it remains unclear what kind of impact additional reporting might have. Additionally, providing FDA with what has been called "total visibility in the supply chain" through mandatory reporting of API raise serious questions about how generic manufacturers such as Nexus can protect their intellectual property questions as to how the data collected is actionable. Thus, regulated industry already has some duty to provide relevant data to FDA. Expanding this internationally, or requiring additional supply-chain reporting requirements, would require a large expansion to some key offices. For example, as I noted above, FDA's Drug Shortage Staff is only about twelve people strong. I know them to be a small, dedicated group that faces a large task and many difficult decisions. But limited or unfocused resources at FDA can result in unsatisfying resolutions of situations, like the one that faces Nexus. Thus, giving more information to FDA isn't a cure-all if it is not accompanied by a corresponding plan of use and protection.

[18] 21 U.S.C. § 356c(a)(2).

C. Remote Inspections

FDA has made some inroads into utilizing remote inspections through document collection and teleconferencing. However, the Agency still lags other countries.[19] The existing current draft guidance limits remote inspectional efforts to information that come from a marketing application such a new or abbreviated new drug application or a biologics license, or a supplement to any of these types of applications.[20] FDA has not yet determined that it can rely on remote inspections for post-approval, surveillance, or for-cause compliance inspections, but not due to any statutory or regulatory restrictions. [21] It merely seems to not fit into FDA's risk-based assessments.

Expanding this program where appropriate might help alleviate some of the foreign backlog, especially as a tool to make those risk assessments in the first instance. Doing so would naturally rely on an increase in how the Agency relies on the inspectional capabilities of other international bodies. Using remote inspectional tools in places that align more closely with FDA's regulatory viewpoint could potentially eliminate the need for in-person inspections. Those inspectors, in theory, could then make in-person visits to higher risk facilities.

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[19] *See, e.g.,* Farquhar, Douglas B. (August 15, 2023). Enforcement Trends: CDER Presentation Confirms Fewer Warning Letters Are Issued by FDA for OAI Inspections. FDA Law Blog. https://www.thefdalawblog.com/2023/08/enforcement-trends-cder-presentation-confirms-fewer-warning-letters-are-issued-by-fda-for-oai-inspections/.; Schwartz, Mark I. (December 7, 2020). FDA Fiddles with Remote Drug Inspections While Pharma Burns. Bloomberg Law. https://news.bloomberglaw.com/health-law-and-business/fda-fiddles-with-remote-drug-inspections-while-pharma-burns.

[20] *See* U.S. FOOD & DRUG ADMIN., Draft Guidance for Industry—Conducting Remote Regulatory Assessments, Questions and Answers ["Conducting Remote Regulatory Assessments"], at 2; s*ee also* U.S. FOOD & DRUG ADMIN., FDA issues guidance on using remote oversight tools to help approve drugs, https://www.fda.gov/drugs/drug-safety-and-availability/fda-issues-guidance-using-remote-oversight-tools-help-approve-drugs.

[21] *See* Conducting Remote Regulatory Assessments at 6; *see also* U.S.C. § 374(a)(4).

D. Third-Party Inspections

FDA has programs in place that allow certified, validated third parties to provide inspectional material for regulated companies in the medical device[22] and food space.[23] Similar initiatives might be appropriate in a lower risk drug facility, although one must acknowledge the added layer of complexity that doing this would add to international inspections.

V. What does success look like?

FDA may be able measure success by aligning some metrics. As it embarks on several internal re-organizations with the hopes of focusing certain offices on inspections and investigations, we might see an increase in trained staff, inspections, and subsequent enforcement actions. The Agency may also somehow seek to quantitatively measure the depth of its relationships with foreign authorities in a similar fashion.

VI. Conclusion

As FDA evolves its international inspection policies, it bears focusing on not only the impact that changes will have directly on the drug-consuming public. These policies also have the potential to impact domestic drug production, making it safer in the process and providing a level of national security to the regulated industry.

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[22] *See* U.S. FOOD & DRUG ADMIN., Third-Party Inspection (Devices), https://www.fda.gov/medical-devices/postmarket-requirements-devices/third-party-inspection-devices.

[23] *See* U.S. FOOD & DRUG ADMIN., Accredited Third-Party Certification Program, https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certificationprogram#:~:text=Accredited%20Third%2DParty%20Certification%20is,certifications%20of%20foreign%20food%20facilities.