ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM

To: Members and Staff, Subcommittee on Oversight and Investigations

From: Majority Committee Staff

Re: Hearing on "Protecting American Health Security: Oversight of Shortcomings in the FDA's Foreign Drug Inspection Program."

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, February 6, 2024, at 10:30 a.m. (ET). The hearing will take place in 2322 Rayburn House Office Building. The title of the hearing is "Protecting American Health Security: Oversight of Shortcomings in the FDA's Foreign Drug Inspection Program."

I. WITNESSES

- Dinesh S. Thakur, Public Heath Activist, Thakur Family Foundation, Inc.
- John W.M. Claud, Counsel, Hyman, Phelps & McNamara
- Mary Denigan-Macauley, Director of Public Health, Government Accountability Office

II. OVERVIEW

The U.S. Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (HHS), is responsible for ensuring the quality of drugs available in the United States under the Federal Food, Drug, and Cosmetic Act (FFDCA). This is an immense task since the globalization of the U.S. supply chain for is active pharmaceutical ingredients (API), the components of a medication that generates its health effects, and finished drug products.

Manufacturers based in India and China account for at least 45 percent of the facilities registered to make APIs for drugs made in the United States.[1] Moreover, India is a large manufacturer of finished drug products, supplying nearly one-quarter of all finished drug products to the U.S. market, while in turn, India imports approximately 80 percent of its API from China.[2] Reliance on foreign manufacturers is particularly acute with respect to generic drugs.

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[1] U.S. Food & Drug Admin. (FDA), *Drug Shortages: Root Causes and Potential Solutions*, (2019), *available at* https://www.fda.gov/media/131130/download.
[2] *Id.*

The FDA's foreign drug inspection program has faced challenges dating back decades. For example, a March 1998 report by the non-partisan Government Accountability Office (GAO) found the FDA struggles to hold foreign manufacturers accountable for repeatedly violating regulations.[3] The COVID-19 pandemic has only exacerbated problems with the FDA postponing all but the most critical in-person foreign inspections.[4] The FDA announced in April 2022 that it would restart its unannounced foreign inspections pilot in India but that it had not been able to relaunch a similar pilot in China.[5] As of October 2023, the unannounced inspection pilot program was active in both countries, however the scale of unannounced inspections remains unclear.[6] This hearing will provide an opportunity to understand the FDA's foreign inspection program and to explore opportunities to address challenges to protect and promote the public health.

III. BACKGROUND

The FDA oversees more than 4,000 establishments that manufacture drugs for the U.S. market, more than half of which are foreign drug manufacturers.[7] More than one-third of foreign drug manufacturing establishments are located in China and India.[8] Approximately 32 percent of generic drugs and 45 percent of APIs used to manufacture drugs are from China and India.[9] Historically, Chinese and Indian manufacturers receive the most FDA Warning Letters about quality control issues, such as destroyed or falsified data and sterility problems in manufacturing.[10]

Experts have increasingly voiced concerns on the United States' overreliance on sourcing from foreign manufacturers who have a demonstrated pattern of repeatedly violating FDA safety regulations. Time and again, the FDA has posted recall, market withdrawal, and safety alerts related to contaminated imported drugs coming from China and India. In many instances, these alerts are issued in response to Americans having experienced severe adverse health effects from contaminated drugs.

One expert report found that there was a 79 percent decrease in the number of FDA foreign inspections from 2019 to 2022.[11] The Department of Defense recently announced plans to

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[3] U.S. Gov't Accountability Office, GAO/HEHS-98-21, Food and Drug Administration: Improements Needed in the Foreign Drug Inspection Program (1998), https://www.gao.gov/assets/hehs-98-21.pdf.
[4] U.S. Gov't Accountability Office, GAO-22-103611, Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program (2022), https://www.gao.gov/products/gao-22-103611.
[5] Joanne S. Eglovitch, *Unannounced FDA Inspections Have Started in India, Not China*, Regulatory Focus (Apr. 2022), https://www.raps.org/News-and-Articles/News-Articles/2022/4/Unannounced-FDA-inspections-have-started-in-India.
[6] Jill Wechsler, *FDA Inspections Face Continued Overhaul and Changes*, Applied Clinical Trials (Oct. 2023), https://www.appliedclinicaltrialsonline.com/view/fda-inspections-face-continued-overhaul-and-changes.
[7] *Supra*, note 3.
[8] *Id.*
[9] Drug Shortages Task Force, U.S. Food & Drug Admin., Drug Shortages: Root Causes and Potential Solutions (2019), https://www.fda.gov/media/131130/download.
[10] *Preparing for and Responding to Future Public Health Security Threats: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce,* 118th Cong. (May 11, 2023).
[11] Emily Cuddy et al., *FDA Global Drug Inspections: Surveillance of Manufacturing Establishments Remains Well Below Pre-COVID-19 Levels*, J. Health Affairs (Dec. 2023), https://doi.org/10.1377/hlthaff.2023.00686.

independently test the quality and safety of the imported generic drugs it purchases.[12] A 2022 GAO report also found the FDA faces "unique challenges" and is failing to hold foreign manufacturers accountable for repeatedly violating regulations.[13] In particular, the GAO was concerned that the FDA's practice of conducting preannounced foreign inspections is ineffective and raises "questions about the equivalence of foreign to domestic inspections."[14]

Between 2014 and 2015, the FDA conducted a pilot program in India that eliminated extended advance notice for inspections. Despite the pilot's success at exposing widespread misconduct and blatant regulatory violations, FDA chose to discontinue it.[15] Under pressure from Congress, the FDA has recently resumed unannounced inspections in India.

Although the number of foreign drug manufacturing inspections increased between 2016 and 2019, the COVID-19 pandemic brought this progress to a standstill. According to one report, in 2022, the FDA only inspected 6 percent of approximately 2,800 foreign manufacturers, and only 3 percent of Indian manufacturers.[16] In comparison, in 2019, the FDA inspected 37 percent of approximately 2,500 foreign manufacturers, and 45 percent of Indian manufacturers.[17] During the pandemic, the FDA resorted to alternative inspection methods, such as remote interactive inspections of facilities on a voluntary basis. These tools were not comparable to pre-COVID physical inspections. The effectiveness of these methods remains an area of debate, as does their continued use by the FDA post-pandemic.

Chinese drug manufacturers appear to pose a greater risk than Indian drug manufacturers. Between fiscal years (FY) 2020 and 2022, the FDA conducted only 40 inspections in China compared to 131 inspections in FY 2019 alone.[18] Despite the Chinese government ending quarantine requirements for international travelers in January 2023, the FDA was slow to resume physical facility inspections, waiting until April 2023.[19] In addition, recent changes to the interpretation of China's National Security Law would not only restrict the access of FDA

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[12] Anna Edney & Riley Griffin, *US Military Is So Worried About Drug Safety It Wants to Test Widely Used Medicines*, Bloomberg (June 7, 2023), https://www.bloomberg.com/news/articles/2023-06-07/drug-safety-fears-spur-pentagon-plan-to-test-widely-used-meds#xj4y7vzkg.
[13] U.S. Gov't Accountability Office, GAO-22-103611, Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program (2022), https://www.gao.gov/products/gao-22-103611.
[14] *Id.*
[15] Sidley, *Proposed Bill Seeks to Eliminate Preannounced Foreign Drug Inspections*, Sidley (Jan. 31, 2022), https://www.sidley.com/en/insights/newsupdates/2022/01/proposed-bill-seeks-to-eliminate-preannounced-foreign-drug-inspections; *Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program: Hearing Before the Subcomm. on Oversight & Investigation of the H. Comm. on Energy & Commerce*, 116th Cong. (Dec. 10, 2019), https://www.govinfo.gov/content/pkg/CHRG-116hhrg44495/html/CHRG-116hhrg44495.htm.
[16] Irena Hwang, *After Pandemic Delays, FDA Still Struggling to Inspect Foreign Drug Manufacturers*, ProPublica (Apr. 19, 2023), https://www.propublica.org/article/fda-drugs-medication-inspections-china-india-manufacturers.
[17] *Id.*
[18] Baker McKenzie, *United States: With China's Re-Opening: Staying Ahead of FDA Drug cGMP Enforcement*, Lexology (Feb. 3, 2023), https://www.lexology.com/library/detail.aspx?g=f20c187f-db67-4a97-8d96-b9b0a665f33c.
[19] U.S. Mission China, *COVID-19 Information*, U.S. Embassy & Consulates in China (Jan. 27, 2023), https://china.usembassy-china.org.cn/covid-19-information/.

inspectors to drug manufacturing facilities and pertinent records, but would further threaten their security by allowing Chinese officials to arrest FDA inspectors under espionage charges.[20]

Last year, the FDA announced a massive reorganization of the agency, including "a transformative vision" for the Office of Regulatory Affairs (ORA), which oversees all agency field activities, including foreign drug inspections.[21] The FDA overhaul has been branded one of the largest in the agency's history. The new proposal, which is in its final stages, will remodel the ORA into the Office of Inspections and Investigations. The FDA's reorganization also coincides with the departures of key FDA officials, including Principal Deputy Commissioner Janet Woodcock.[22]

IV. KEY QUESTIONS

The hearing may include discussion around the following key questions:

- What is the current status of FDA's foreign drug inspection program?
- What are the challenges that FDA inspectors face when conducting foreign drug inspections?
- What are the implications of using alternative tools instead of in-person inspections to oversee the safety and effectiveness of drugs made overseas?
- How do the frequency and quality of the FDA's foreign drug inspections compare with those of domestic inspections?
- How can the FDA strengthen its foreign drug inspection program?

V. STAFF CONTACTS

If you have any questions regarding the hearing, please contact John Strom or Joanne Thomas with the Subcommittee on Oversight and Investigations Majority staff at (202) 225-3641.

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[20] Nathaniel Taplin, *Beijing's Bain Raid, Espionage Law Are Self-Sabotage*, Wall St. J. (Apr. 28, 2023), https://www.wsj.com/articles/beijings-bain-raid-espionage-law-are-self-sabotage-40f87276?mod=article_inline; Yoko Kubota & Miho Inada, *In China, a Detention and a New Espionage Law Have Businesses Worried*, Wall St. J. (Apr. 28, 2023), https://www.wsj.com/articles/in-china-a-detention-and-a-new-espionage-law-have-businesses-worried-78fc88b1?mod=article_inline.

[21] Press Release, U.S. Food & Drug Admin., FDA Proposes Redesign of Human Foods Program to Enhance Coordinated Prevention and Response Activities (Jan. 31, 2023), https://www.fda.gov/news-events/press-announcements/fda-proposes-redesign-human-foods-program-enhance-coordinated-prevention-and-response-activities.

[22] Lauren Gardner & David Lim, *FDA Focuses on Reorg Plan*, Politico (Jan. 17, 2024), https://www.politico.com/newsletters/prescription-pulse/2024/01/17/fda-focuses-on-reorg-plan-00135884.