December 13, 2023

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Califf,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the Food and Drug Administration’s (FDA) foreign drug inspection program. On July 18, 2023, the Committee sent you an oversight request letter seeking information and documents relevant to this ongoing investigation. To date, the FDA has not provided any response to the Committee. We now reiterate our earlier requests for information and documents in this letter to expedite our investigation.

Since our first letter to the FDA, it has come to light that the FDA ended its unannounced foreign inspection program out because the agency believed it was an obstacle to deeper collaboration with India.\(^1\) The same reporting also alleges that the FDA undermined a Department of Defense initiative to independently test the quality of imported drugs used by the military out of fear that it would undermine the FDA’s credibility.\(^2\) In addition, a newly published study has confirmed that FDA foreign inspections in 2022 were down 79% compared to 2019 while at the same time the number of “citations rose dramatically, despite all establishments being given advance notice of inspections.”\(^3\)

Since July there have also been additional drug recalls from Indian manufacturers and plant closures in the United States. In August, Indian drug manufacturers, Alembic and Aurobindo

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2 *Id.*
Pharma, issued voluntary drug recalls citing quality and manufacturing deficiencies, respectively.⁴ Alembic recalled over 80,000 bottles of tobramycin, used to treat bacterial eye infections, due to “failed impurities/degradation specifications.”⁵ Aurobindo recalled rufinamide tablets used to treat seizure disorders.⁶ As you are aware, both companies have a history of drug recalls and quality control failures. Last year, the FDA issued Alembic a Form 483, which cited its manufacturing plant in Panelav, Gujarat with four observations following a 10-day inspection.⁷

Meanwhile, domestic production of vital medicines continues to be under stress. In early August, Pfizer announced it would limit the distribution of injectable drugs manufactured at its North Carolina plant after the facility suffered damage in the aftermath of a tornado.⁸ In September, autoinjector maker Aktiv Pharma Group (“AktiVax, Inc.”) announced the closure of three manufacturing facilities.⁹ AktiVax produces autoinjectors to treat life threatening conditions.¹⁰ Just last year, the company was awarded over $45 million to supply a nerve agent antidote to the Strategic National Stockpile.¹¹ Shortages of cancer drugs appear to have eased slightly in recent months, but demand continues to outstrip supply.¹²

In short, drug shortages plague our nation. The U.S. cannot afford additional disruptions to the drug supply chain that reduce the availability of essential medications and force doctors and patients to make difficult treatment decisions. Members of this Committee have repeatedly expressed concern regarding the effectiveness of the FDA’s foreign drug inspection program, including at two separate hearings this Congress before the Subcommittee on Oversight and Investigations and the Subcommittee on Health.¹³

Addressing drug shortages remains a top priority for the Committee. The Committee has a right to the requested information and documents, which are necessary to carry out its constitutional oversight responsibilities and to inform pending legislation. Accordingly, to assist

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⁵ Id.
⁶ Id.
the Committee in our oversight, please respond, by January 5, 2023, to the questions put forward in our July 2023 letter, reiterated here for your convenience:

**Foreign Inspections Generally**

1. Section 3112(e) of the CARES Act gave the FDA additional authority to require manufacturers to report certain supply chain information to it. The FDA’s May 9, 2023, letter to the Committee stated that only 44 percent of facilities are reporting the required data to the FDA.\(^4\) Based on the FDA’s letter, a disproportionate percentage of noncompliant API and finished dose formula facilities are located outside of the United States. How many regulatory actions has the FDA enforced against noncompliant foreign facilities regarding the CARES Act reporting requirements? Provide a list of all foreign facilities that have been penalized for noncompliance. Include in your response a detailed description of the action taken by the FDA.

2. The FDA ensures the quality of drugs and other pharmaceutical products through manufacturers’ compliance with facility registration and Current Good Manufacturing Practice (CGMP) regulations. The Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144) contained several provisions providing the FDA greater insight into the original sources of excipients, API, and finished dosage products. Specifically, Section 703 requires that drug manufacturers identify the name and place of business of all establishments involved in the production of drug excipients, while Section 711 revises CGMP regulations to require oversight over the production of any raw materials for the manufacture of a drug. The FDA has indicated in its recent requests for additional authorities over supply chain information that it does not currently have access to original sources for API and other drug excipients, notwithstanding these and other provisions providing such authorities.

   a. Given its authorities under FDASIA, why does the FDA take the position that it does not have visibility into where API and drug excipients are sourced?

   b. Explain in detail, how the FDA processes information received under Sections 703 and 711. As part of your response, explain how has the data received under Sections 703 and 711 informs FDA’s foreign inspections programs and drug shortage response efforts?

3. Was the FDA consulted by the Department of Defense regarding its decision to test independently the quality and safety of generic drugs it purchases? If yes, provide communications and documents related to the consultation.

4. Has the FDA considered a plan to end preannounced inspections of foreign manufacturing facilities? If no, explain in detail why not? If yes, provide copies of any such plans.

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5. How many FDA inspectors are currently conducting domestic inspections?

6. How many FDA inspectors are currently conducting foreign inspections? Include in your response how many of these inspectors are operating in each country.

7. How many positions are currently open for foreign inspections? In your response, please identify the country where the open position is located and how long the position has been unfilled.

8. The FDA has noted there is a backlog in conducting foreign inspections. How large is the backlog and what progress has the FDA made in closing it? Include in your response a complete list of the foreign facilities in the backlog.

9. In the last 10 years, for each year, what percentage of FDA inspections of foreign facilities have been preannounced, and what was the lead time given for each preannounced inspection?

10. In the last 10 years, for each year, what percentage of the FDA’s inspections of U.S. domestic facilities have been preannounced, and what was the given lead time was given for each preannounced inspection?

Inspections in India

11. Explain in detail why the FDA ended the unannounced inspection pilot program conducted in India between 2014 to 2015.

12. Does the FDA plan to reinstate the unannounced inspection program in India? If not, explain in detail why not.

13. For foreign facilities in India that have received a Warning Letter in the last 10 years, provide a list of which of these facilities have been inspected in-person, inspected remotely, or not inspected at all since the Warning Letter was issued.

14. In the last 10 years, how many times has a foreign manufacturer in India been inspected and had their Warning Letter lifted before the FDA investigator filed a report, allowing the company to get approval for a drug shortage product or its abbreviated new drug application (ANDA)? Provide a list of these companies, dates of approval, dates of inspection, and the product that was approved.

15. As early as November 2022, the FDA was aware of significant, repeated quality control failures at Intas Pharmaceuticals’ Ahmedabad, India manufacturing facility. At the time, this facility was one of only five finished product manufacturers supplying the U.S. market
with chemotherapy drugs carboplatin and cisplatin.\textsuperscript{15} Intas voluntarily stopped operations at its Ahmedabad plant in response to quality control failures on June 5, 2023.

During a June 9, 2023, briefing with Congressional staff on cancer drug shortages the FDA stated that it was not aware of the company’s plans to halt operations at its Ahmedabad, India, manufacturing facility until after the plant had shut down operations. This lapse in communication is concerning, as the FDA was ostensibly aware of the ongoing quality issues at the plant, as well as Intas’ significant U.S. market share for cisplatin and carboplatin and the disruption a plant closure would cause in the supply of these drugs.

It is important for the Committee to understand exactly how and when the FDA was made aware of Intas’ plans to halt voluntarily operations at its Ahmedabad facility. Explain in detail and provide copies of any communications between the FDA and Intas Pharmaceuticals from January 2023 through June 2023 related to the company’s decision to halt voluntarily production at the Ahmedabad plant closure.

*Inspections in China*

16. What is the FDA’s plan to ensure that inspections in China can continue despite the expanded scope of China’s National Security Law? Provide copies of any analysis or relevant documentation related to China’s National Security Law and its implications for FDA’s foreign drug inspection program and drug safety.

17. What actions will the FDA take in response to an inspector being detained, arrested, or otherwise prevented from completing an inspection of a drug manufacturing facility in China?

18. Has an FDA inspector ever been detained, arrested, or otherwise prevented from completing an inspection of a drug manufacturing facility in China? Other countries?

19. Provide copies of all communications between the FDA and the Government of China regarding in-person inspections of drug manufacturing facilities in China from January 2020 to the present.

20. Does the FDA plan to start an unannounced inspection program in China? If not, explain in detail why not. If yes, provide copies of any such plans.

21. For facilities in China that have received a Warning Letter in the last 10 years, provide a list of which of these facilities have been inspected in-person, inspected remotely, or not inspected at all since the Warning Letter was issued.

22. In the last 10 years, how many times has a foreign manufacturer in China been inspected and had their Warning Letters lifted before the FDA investigator filed a report, allowing

the company to get approval for a drug shortage product or its ANDA? Provide a list of these companies, dates of approval, and the product that was approved.

In closing, the Committee is concerned that the Department of Health and Human Services (HHS), including the FDA, has made a deliberate decision to understaff and under-resource its ability to respond to oversight requests. Therefore, to carry out our constitutional oversight responsibilities, the Committee is prepared to issue a subpoena if the FDA does not produce the requested documents by January 5, 2024. The Committee has a right to obtain these materials to aid in its legislative activities and to ensure that the Executive Branch is complying with the law.

If you have questions about this correspondence, please contact the Majority Committee Staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,

Cathy McMorris Rodgers  
Chair  
Committee on Energy and Commerce

H. Morgan Griffith  
Chair  
Subcommittee on Oversight and Investigations

Brett Guthrie  
Chair  
Subcommittee on Health

CC: Frank Pallone Jr., Ranking Member, Energy and Commerce Committee  
Anna Eshoo, Ranking Member, Subcommittee on Health  
Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations