E&C Republicans Press FDA Again for Information Regarding Foreign Inspection Program

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Health Letter Letter - Health

Letter - Oversight and Investigations

Washington, D.C. — In a new **letter** to Food and Drug Administration (FDA) Commissioner Robert Califf, House Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-WA), Subcommittee on Health Chair Brett Guthrie (R-KY), and Subcommittee on Oversight and Investigations Chair Morgan Griffith (R-VA) are pressing for more information regarding the agency's foreign drug inspection program.

The letter continues the Committee's investigation into FDA inspection practices, which include a **July 18, 2023, letter**, a **December 13, 2023, letter**, and a **February 6, 2024, oversight hearing** at which the FDA declined to make an official available to testify.

BACKGROUND:

In the letter, the Members discuss the Committee's analysis of FDA inspection outcomes in India and China from January 2014 to April 2024, limiting its review to inspectors with ten or more inspections in either China or India.

EXCERPT OF THE ANALYSIS:

"The results of this analysis were surprising, revealing tremendous variation in inspection outcomes. Some FDA inspectors found compliance issues during all or almost all of their inspections. Other inspectors rarely reported finding a single compliance issue. Two inspectors never found a single compliance issue over the course of a combined 24 inspections in India. Another inspector found zero compliance issues in 20 out of 23 inspections (85 percent) in China while finding compliance issues with almost half of domestic inspections during the same period. These are unusual inspection outcomes, the opposite of what would be expected given the widely reported failures in quality control and lack of adherence to current good manufacturing techniques by drug manufacturing facilities in China and India.

"By contrast, 16 FDA inspectors, with over 325 inspections collectively in India, found compliance issues during every inspection they conducted. As a measure of what a pattern of rigorous inspections should look like, the Committee reviewed the inspection outcomes for 3 FDA inspectors with professional reputations for thoroughness who also had at least 10 inspections in China or

India during the studied time period. These expert inspectors reported finding no compliance issues during inspections in China at a rate of only 6.7 to 11.4 percent and at a rate of zero to 9.5 percent in India."

KEY LETTER EXCERPT:

"Such large variations in inspection outcomes are troubling, and they merit further investigation. At a minimum, the Committee is concerned that these findings suggest vast differences in the skill, thoroughness, and competence of FDA inspectors. The difference in inspection outcomes appears to be just another **example** of institutional weaknesses and dysfunction in the FDA's foreign drug inspection program. Prior to the pandemic, media reporting found that some FDA inspectors took an inappropriately lenient approach with foreign drug manufacturers with serious compliance violations. There were also reports of, and concerns about, foreign manufacturers attempting to bribe or improperly influence inspectors. The Committee is seriously evaluating the disturbing possibility that some of the variation in inspection outcomes could be the result of bribery or fraud."

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