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# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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August 6, 2019

## VIA ELECTRONIC TRANSMISSION

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services

Dr. Norman Sharpless  
Acting Commissioner  
Food and Drug Administration

Dear Secretary Azar and Acting Commissioner Sharpless:

This committee has an obligation to ensure that the Food and Drug Administration (FDA) upholds its responsibility to protect the public's health by properly overseeing the nation's drug supply and ensuring that the drugs Americans use are safe and effective. I read with interest your "Safe Importation Action Plan" and am pleased that the administration continues to take steps to address high prescription drug prices while protecting innovation. As you are aware, I believe that drug importation will help to reduce drug costs for American consumers and patients. However, I have also noted that my position is predicated on the FDA ensuring the safety and efficacy of those drugs.

Accordingly, I want to raise concerns with you that I originally raised with the FDA in an oversight letter on June 27, 2019, regarding the FDA's foreign drug inspection program.<sup>1</sup> Unbeknownst to many consumers, according to recent news reports and a GAO report highlighting safety and quality concerns at foreign drug manufacturing facilities, 80 percent of Active Pharmaceutical Ingredients (API) are produced abroad, the majority in China and India; however, the FDA only inspected one in five registered human drug manufacturing facilities abroad last year.<sup>2</sup>

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<sup>1</sup> Didi Martinez, Brenda Breslauer & Stephanie Gosk, *Tainted drugs: Ex-FDA inspector warns of dangers in U.S. meds made in China, India*, NBC NEWS (May 10, 2019, 1:01 PM EDT), available at <https://www.nbcnews.com/health/health-news/tainted-drugs-ex-fda-inspector-warns-dangers-u-s-meds-n1002971>.

<sup>2</sup> Katherine Eban, *Americans Need Generic Drugs. But Can They Trust them?*, THE NEW YORK TIMES (May 11, 2019), available at <https://www.nytimes.com/2019/05/11/opinion/sunday/generic-drugs-safety.html>. See also, U.S. Gov't Accountability Off., GAO-17-143, DRUG SAFETY: FDA HAS IMPROVED ITS FOREIGN DRUG INSPECTION PROGRAM, BUT NEEDS TO ASSESS THE EFFECTIVENESS AND STAFFING OF ITS FOREIGN OFFICES I (Dec. 2016). Didi Martinez, Brenda Breslauer & Stephanie Gosk, *Tainted drugs: Ex-FDA inspector warns of dangers in U.S. meds made in China, India*, NBC NEWS (May 10, 2019, 1:01 PM EDT), available at <https://www.nbcnews.com/health/health-news/tainted-drugs-ex-fda-inspector-warns-dangers-u-s-meds-n1002971>.

Under the Administration's Action Plan, it would draft a Notice of Proposed Rulemaking ("NPRM") that would address, in part, the implementation of section 804(b)-(h) in the Federal Food, Drug, and Cosmetic Act (Act). The Act allows for drug importation as long as certain conditions are met including drug quality, record-keeping, testing, and protections against counterfeiting. The Action Plan notes the "NPRM would list those requirements and invite proposals as to how those conditions would be met by a demonstration project." The NPRM would also allow manufacturers of FDA-approved drugs to import versions of those drugs sold in foreign countries into the United States. However, it is not clear how track-and-trace would apply to such products, potentially exacerbating manufacturing quality concerns.

Since my June 2019 letter to the FDA, I have learned that the FDA does not track in its databases whether a foreign inspection was subject to an announced or unannounced visit. Further, I have learned that the FDA generally does not perform unannounced visits of drug manufacturing facilities in foreign countries but does perform unannounced visits at facilities based in the United States. Should the Action Plan be put into effect, the administration must require more foreign inspections generally and unannounced inspections specifically, particularly compared to previous administrations.

For example, in 2013 the FDA created a pilot program in India that eliminated advanced notice and instead used short notice or unannounced visits.<sup>3</sup> The pilot program also arranged for FDA inspectors' travel to be arranged through the U.S. embassies instead of through FDA offices or manufacturer-arranged travel plans to provide more secrecy in the lead-up to inspections. According to reports, the new inspection regime "exposed widespread malfeasance" that had otherwise been hidden because of the advanced warning system.<sup>4</sup> Among the findings, the inspections found bird infestations, missing samples, and fake laboratories, all of which negatively impact drug quality and safety.<sup>5</sup> Under the pilot program, the FDA issued a 60 percent increase in "Official Action Indicated" findings.<sup>6</sup> In 2015, the pilot program was shut down without explanation.

It is unclear why the Obama administration shut the pilot program down in light of its apparent success. However, because of its reported successes, I strongly encourage the administration's demonstration projects to include unannounced inspections in foreign manufacturing facilities to determine whether they meet the required API and drug quality and safety standards to include sufficient record-keeping, testing, and protections against counterfeiting.

Sincerely,



Charles E. Grassley  
Chairman  
Committee on Finance

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<sup>3</sup> Katherine Eban, *Bottle X: Exposing Impurities in the Generic Drug Business*, Newsweek Magazine (July 2, 2019).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*