Opening Statement of E&C Republican Leader Greg Walden
Subcommittee on Oversight and Investigations

"Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program"

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As Prepared for Delivery

Chair DeGette, thank you for this hearing. Our drugs and drug ingredients more and more come from overseas, especially from China and India. Manufacturers have ultimate responsibility for the safety and effectiveness of these products. But FDA has an indispensable role to protect public health by ensuring that drug firms are complying with good manufacturing practices. Through this hearing, I hope FDA can further strengthen its ability to fulfill its public health mission, and to protect the safety, effectiveness, and integrity of the U.S. drug supply.

Today, we have the benefit of the Government Accountability Office's (GAO) analysis to assist us. Over the years, GAO has provided invaluable work to this Committee on FDA's foreign drug inspection program. Not that long ago, GAO reported that FDA was not conducting enough drug inspections overseas and lacked resources and authorities to adequately meet this inspection need. This Committee responded by enacting the Food and Drug Administration Safety and Innovation Act or FDASIA and the Generic Drug User Fee Act or GDUFA. FDA now has additional resources and authorities and, to the FDA's credit, has addressed the previous disparity between the number of domestic and foreign inspections conducted.

Earlier this year, the Committee again asked GAO on a bipartisan basis to evaluate the current state of the foreign drug inspection program. While progress has been made in some areas, the GAO's preliminary observations indicate that FDA continues to face persistent challenges in its ability to conduct foreign drug inspections, particularly in India and China. This is concerning because FDA is identifying serious deficiencies during many foreign inspections.

For years, FDA leadership has spoken of transforming the agency into a global health organization, particularly in addressing imported drugs. But even with that stated priority and the influx of user fees, FDA has told the GAO and this Committee that it can't hire enough inspectors to fill vacancies among staff conducting foreign inspections. Having sufficient numbers of inspectors is not a new problem – the need to hire additional inspectors was part of the reason that Congress gave FDA the authority to collect user fees for generic drugs. Today, FDA not only has vacancies in its foreign offices but also does not have enough inspectors in its dedicated foreign drug cadre. FDA recently received direct-hire authority to address this problem, and I have questions today about how this authority will be used to fill these vacancies, as well as about FDA's hiring and retention efforts the past six years.

Other challenges to FDA's foreign drug inspection program remain. Unlike domestic drug inspections, most foreign drug firms receive advance notice of an FDA inspection. When FDA inspectors are traveling from the United States, which

is the case in most foreign drug inspections, the FDA pre-announces inspections. Foreign drug firms generally get 12 weeks advance notice on when FDA inspectors are coming to their plants. The concerns raised by recent investigative reports is that this system gives plants ample time to clean up evidence of unsanitary conditions, wrongdoing, or data manipulation.

In 2014, to address these issues, the FDA instituted an initiative in India giving plants only short or no advance notice of inspections. As a result, the serious violations uncovered by inspectors rose by almost 60 percent. The initiative was discontinued in July 2015. FDA told the Committee they discontinued the initiative because it lacked protocols and evaluation criteria. However, FDA still must believe there is value to short notice inspections, because they conduct such inspections in for-cause situations and conduct short notice inspections domestically.

Finally, in about 80 percent of inspections, FDA sends only one inspector, who is often reliant on the drug firm's employees or agents for translation. This solitary inspector, relying on the firm for translation and perhaps even travel arrangements, is allocated only a few days for the difficult task of inspecting a drug plant that can be the size of a small city. Meanwhile, the drug firm has about three months advance notice of the inspection. If the firm is unscrupulous, that is more than enough time to subvert regulations by fabricating records and concealing actual conditions.

Despite having the deck stacked against them, the Committee has seen and heard plenty of accounts about intrepid FDA inspectors who have discovered serious misconduct at firms in India and China, protecting our nation's drug supply in the process. We thank them for their service.

FDA needs to respond to the overall challenges of foreign drug inspections with more vigor. As they said in *Jaws*, "You're going to need a bigger boat." We must maintain public confidence and trust in our drug supply, and FDA needs to rise further to meet the challenge. I welcome our witnesses and look forward to the testimony.