United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

October 22, 2018

[redacted]
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[redacted]:

Today's consumers can buy medicine quick and conveniently from online pharmacies. In most cases, these sites operate legally and offer adequate safeguards to purchase medicines. However, when a patient buys their medicine from a rogue online pharmacy[1], there is no guarantee that the product is genuine or even contains the active ingredients needed to treat their condition. Since 2008, the National Association of Boards of Pharmacy has reviewed more than 11,000 online pharmacies—of which there are over 30,000—and determined that 95 percent were out of compliance with U.S. laws. Of the websites identified as being noncompliant, the majority were found to be dispensing medicines without a valid prescription. The ease in which consumers can purchase medicines online highlights the need to improve collaboration and information sharing among the industry and Federal, state, and local law enforcement as a way of protecting the public and raising awareness on the issue of counterfeits.

After the passage of the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), I requested that the Government Accountability Office (GAO) evaluate the law's effectiveness in aiding U.S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE) as the primary agencies working to curtail the importation and distribution of counterfeit products sold on e-commerce platforms. On February 27, 2018, GAO published its report, "Agencies Can Improve Efforts to Address Risks Posed by Changing Counterfeits Market" and on March 6, 2018, the Committee held a hearing titled "Protecting E-commerce Consumers from Counterfeits." The hearing assessed CBP and other federal agencies' efforts to improve collaboration and information sharing to protect U.S. consumers from counterfeit products.

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[1] The Food and Drug Administration (FDA) lists the signs of a rouge online pharmacy on its website. These include: (1) allowing consumers to buy without a valid prescription; (2) not offering state-licensed pharmacists to patients; (3) offering prices that seem too good to be true; and, (4) are located outside the U.S. or ship worldwide. See *How to Buy Medicines Safely from an Online Pharmacy*, FDA, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm (last updated Jan. 25, 2018).

The theme of public-private partnership and collaboration is consistent across many sections of TFTEA. The legislation codified existing CBP activities and support efforts to protect U.S. economic security through trade enforcement and promotes direct engagement with the private sector. Specifically, TFTEA directs the Intellectual Property Rights Center to share information and best practices with private sector entities in order to coordinate public and private efforts to combat the infringement of intellectual property rights. In many ways, information sharing is critical to prevent the distribution and sale of counterfeit goods. Public and private entities empowered with this information can raise public awareness, train law enforcement partners, and pursue voluntary enforcement actions when appropriate.

The pharmaceutical industry plays a fundamental role in protecting U.S. consumers from counterfeit medicines sold online. Many companies conduct test buys to ensure that the products sold online are legitimate and share information regarding counterfeit products with industry members and law enforcement. By sharing information and pooling resources, pharmaceutical companies have the ability to root out the bad actors and prevent the sale of counterfeit medicines before any injury occurs. Therefore, I write to request information on the types of activities your organization participates in, facilitates, or otherwise has knowledge of to help us better understand how the pharmaceutical industry collaborates with CBP, ICE, and U.S. Federal, state, and local law enforcement on efforts to curtail the sale of counterfeit medicines. My Committee staff will use this information to help inform a public report.

I ask that you provide answers to the following questions as they apply to you and/or your affiliated member organizations:

1. How does your organization warn consumers about the risks of purchasing counterfeit medicines on e-commerce platforms?
    a. Do you believe that consumers understand the health and safety risks associated with purchasing medicines online? If not, how can we better communicate these risks to consumers?
    b. What challenges exist in informing consumers of the risks associated with purchasing medicines online?
2. What tools do you provide your members when a medicine has been identified as a counterfeit and is being sold, distributed, and/or advertised on an e-commerce platform as genuine?
3. Please describe how you coordinate with e-commerce platforms to curtail the sale of counterfeit medicines.
4. Once you and/or your members suspect that a counterfeit medicine is being sold, distributed, or advertised via an e-commerce platform within the U.S. or abroad, what types of actions, including the initiation of litigation, do you pursue? Please provide examples.
5. Do you and/or your members participate in medicine verification programs provided by e-commerce platforms or any other intermediary? What features of such programs have been useful in identifying and eliminating counterfeit medicines?
6. What other services, tools, protection, and assistance do you provide your members?
7. In your view, what are the challenges in assisting consumers from inadvertently purchasing counterfeit medicines? What steps can be taken to address these challenges?

8. When counterfeit medicines have been identified, do you coordinate with your members to prevent the sale on e-commerce platforms? If so, please explain.
9. Do you engage with U.S. Federal, state, or local law enforcement to remove counterfeit medicines from the stream of commerce and to curtail their distribution in the U.S.? If so, what authorities and types of activities and coordination efforts have proven successful?
10. Do you engage with foreign governments to curtail the sale of counterfeit medicines? If so, what types of activities and coordination efforts have proven successful? What has not?
11. If you and/or your member becomes aware of a counterfeit medicines sold via an e-commerce platform, what, if any, action can you take to prevent the sale of the good?
12. If there are any other pieces of information, details, or data you feel would be helpful to the Committee, we respectfully request that you submit them as part of your answers as well.

Counterfeit medicines pose a significant health and safety risk to U.S. consumers. That is why it is important that we remain diligent and engaged to ensure that consumers are protected from inadvertently purchasing these products. Therefore, I ask that you respond electronically to this request no later than November 19, 2018. Please provide your answers on a question-by-question basis, indicating which question you are answering. Thank you in advance for your cooperation with this request. If you have any questions, please contact [redacted] with my Committee staff [redacted].

Sincerely,

Orrin G. Hatch
Chairman