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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

March 14, 2014

Mr. Howard Sklamberg
Deputy Commissioner for Global Regulatory Operations and Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Sklamberg:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, February 27, 2014, to testify at the hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Friday, March 28, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Tim Murphy

1. Please describe the difficulties in prosecuting counterfeit drug crimes under current Federal law. For example, what are the difficulties in proving that a defendant knew the drugs were counterfeit?

2. Please explain if it would be easier for Federal prosecutors to prove that a defendant knew the drugs were unapproved rather than proving the defendant knew that the drugs were counterfeit?

3. Are existing penalties for counterfeit and foreign unapproved drugs substantially lower than the penalties for violations relating to intellectual property or economic loss? If so, what are some examples?

4. Would increasing penalties for counterfeit drug and foreign unapproved drug violations to the same level for other comparable criminal violations deter criminal actors?

    a. GAO has stated that agencies and U.S. Attorneys' Offices may not pursue cases because they believe the penalties will not meet minimum thresholds established to prioritize cases. Would increasing penalties for counterfeit and foreign unapproved drug violations lead to more of these cases being investigated and prosecuted?

    b. To what extent has FDA observed that comparatively low penalties fail to deter criminals from trafficking in counterfeit or foreign unapproved drugs? Please explain whether FDA believes that existing offenses and penalties deter counterfeit or unapproved drug traffickers from repeating the same behavior.

5. Would criminal actors be deterred from manufacturing and selling counterfeit and foreign unapproved drugs if they were subject to forfeiting the proceeds of their illegal activities? Please explain to what extent providing forfeiture authority under the Federal Food Drug and Cosmetic Act would help with cases where Federal authorities were not able to get at the individual due to difficulties with foreign investigations.

6. Please describe the difficulties FDA has encountered when trying to gather information for counterfeit/foreign unapproved or rogue Internet pharmacy cases. To what extent would administrative subpoenas strengthen investigations and prosecutions of counterfeit and foreign unapproved drug cases?

7. Does FDA have the authority to bring cases against Internet pharmacies that merely require users to fill out a survey rather than requiring an actual prescription?

    a. GAO cited a DOJ official as saying that prosecuting Internet pharmacies for dispensing drugs without a prescription is difficult due to having to determine which state laws best match the circumstances of each case. Would extending the Ryan

Haight Act's definition of "valid prescription" (and telemedicine exemption) to the FFDCA to apply to drugs not containing controlled substances help solve this problem?

b. GAO has said that there are over 36,000 active rogue Internet pharmacies. For online pharmacies offering controlled substances, the Ryan Haight Act requires them to disclose on their website which states they are licensed in, their pharmacists' credentials, and contact information such as a name, address, telephone number and email address. Would extending the Ryan Haight Act's requirement so that all online pharmacies provide this information, not just ones selling controlled substances, help address the problem of rogue Internet pharmacies selling counterfeit or unapproved prescription drugs that are not controlled substances?

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Tim Murphy

1. Please provide the Committee with detailed recommendations for what additional tools you need to help prevent, discover and punish these criminal actions.

The Honorable Marsha Blackburn

1. During your testimony you said that twelve companies have already applied to FDA's security supply chain pilot project.

    a. What countries are these companies located in?

    b. Please explain the successes that you have had in analyzing the project, how you are equating the variables, and what you see as your deliverables from the project as we move forward.

The Honorable Michael C. Burgess

1. From FDA's perspective, is the heparin contamination still an open and ongoing investigation? Please explain.

The Honorable Morgan Griffith

1. Was the gentleman in Utah who was recently convicted of shipping over $5 million in unapproved drugs but only received a 1-year prison sentence charged with any other crimes as part of his scheme?

The Honorable Billy Long

1. During the hearing you discussed the difficulties of detecting, investigating, apprehending, and punishing those involved in international organized crime. Please explain what Congress can do to help you better navigate the international organized crime problem.

The Honorable John D. Dingell

1. Are the bottles that you referenced in the lighter fluid slide, displayed during your testimony, glass or plastic medicine bottles?

2. Please submit any changes that you recommend we make with regards to improving the efforts of the Office of Drug Supply, Integrity and Recalls.

3. Please submit to the Committee any suggestions that you have regarding what it is you need in the way of authority to address the questions regarding information sharing with Internet service providers needed in rogue Internet pharmacy investigations that you described during the hearing.

4. Please submit to the Committee whether you have authority to go after the people who manufacture and ship imported pharmaceuticals into the United States and what additional authorities you would need to do so.

5. The FDA Safety and Innovation Act gave your agency new authorities such as registration of foreign drug facilities and mandatory detention to help the agency deal with the globalized drug supply chain. Is your authority sufficient? If not, what more is required?

6. Please elaborate on what additional authorities FDA needs to keep Americans safe from counterfeit and substandard drugs that are coming from abroad.

7. Please provide a written response explaining what resources FDA needs to carry out the new authorities granted to the agency in the FDA Safety and Innovation Act.

8. Please submit your comments on if and how it would be helpful to take the penalties that we collect and turn them over to the FDA for additional enforcement, like we already do for narcotics.

9. The maximum penalty you mentioned in your testimony for these activities is only $10,000 or 3 years in prison. What does FDA believe is the appropriate maximum penalty? Please define that by relating it to other questions involving narcotics and other events that are similar.

10. Does FDA support strong civil monetary penalties against those charged with misbranding or counterfeiting drugs? Please explain.

11. Last year, the FDA worked with international regulatory and law enforcement agencies to shut down more than 1,600 illegal pharmacy Web sites. During the hearing you agreed that most of those websites claimed to be Canadian pharmacies and the medicines that they were selling were FDA approved or brand-name drugs, which they were not. Please further explain how many of the 1,600 sites claimed to be Canadian.

12. During the hearing, you mentioned that you have difficulty with the funding of your agency. If you could get the funding of your agency to do as it has been done by the drug enforcement people, where the proceeds of these crimes could be seized and utilized for sale so that you could get revenue or so that you could get other help, would that be of assistance to you in terms of increasing your levels of funding to deal with these problems?