



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

APR 13 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the February 27, 2014, hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains," before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. This is a partial response for the record to questions posed by you, in a letter we received on March 14, 2014.

If you have further questions, please let us know.

Sincerely,



Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

We have restated each of your questions below in bold, followed by FDA's responses.

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?**

In many counterfeit drug investigations, the counterfeit drug is manufactured in a foreign location. Because of the difficulties in locating the actual counterfeiters, FDA's ability to prosecute those who facilitate the distribution of counterfeit drugs by turning a blind eye to the source of their drugs is critical to the Agency's success in combating the counterfeit drug problem. However, as a practical matter, it is often difficult to prove that criminals who acted as purveyors, rather than manufacturers, of counterfeit drugs knew that the drugs were counterfeit. Counterfeit drugs are, by definition, represented to be the genuine product and are often visually indistinguishable from genuine product. In fact, the profit from drug counterfeiting depends on selling the product as if it were the legitimate drug. Therefore, unless the defendant was involved with the manufacture of the counterfeit product, it can be difficult to prove beyond a reasonable doubt that the defendant had actual knowledge that a particular drug was 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?**

We believe that it would be easier to prove a defendant's knowledge that drugs were not FDA-approved (i.e., unapproved) than it would be to prove a defendant's knowledge that a drug is counterfeit. Counterfeit drugs are intended to masquerade as the genuine drug product; their counterfeit nature is concealed and difficult to detect without testing or close examination. Certain unapproved drugs, on the other hand, are more easily identified. For example, those products manufactured for a foreign market often bear labels that are in a foreign language or easily distinguishable from the FDA-approved label. Unlike counterfeit drugs, the unapproved nature of a drug is often readily apparent by visual inspection.

- 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?**

Generally, the existing maximum penalty for counterfeit and foreign unapproved drug violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) is one year in prison. The maximum penalty increases to three years in prison if the Government can prove beyond a reasonable doubt that the offense was committed with intent to defraud or mislead. These maximum penalties are significantly lower

than the maximum penalty for most other serious Federal offenses. For example, the maximum penalty for health care fraud is 10 years generally; 20 years if the offense results in serious bodily injury; and life if the offense results in death. The maximum penalty for mail fraud, wire fraud, and smuggling is 20 years in prison. The maximum penalty for securities and commodities fraud is 25 years and for bank fraud, 30 years.

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

We believe that stronger penalties would have a deterrent effect. The relatively low maximum penalties currently provide little punishment or deterrence, especially viewed in relation to the huge profits offenders can reap from selling drugs in violation of the FD&C Act. The harm caused by these violative products is not merely financial; consumers who use counterfeit or unapproved drugs may suffer harm, or even die, because they did not receive recognized, effective therapies or because the products contain dangerous substances. The distribution of counterfeit and unapproved drugs is almost always an economically motivated crime, and the offenders may perceive that the potential profits outweigh possible punishment. Increasing the potential penalties, both in terms of prison time and monetary penalties, would help to deter those who believe that the risks of engaging in this conduct are minimal, especially in comparison to the perceived gains. What's more, while it is critical to use all available tools, including general criminal statutes such as mail fraud, wire fraud, or smuggling, to prosecute the distribution of counterfeit and unapproved drugs, it is also important to note that these general statutes do not encompass the full range of specific conduct that violates the FD&C Act, nor are they meant to do so. It is also important to consider which elements of criminal violations can be proven. Having appropriate penalties for violations of the FD&C Act can reflect the specific harm that may come from those violations the priority that the Government should place on prosecuting such conduct.

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?

While we believe that stronger penalties may increase the likelihood that more counterfeit and foreign unapproved drug cases could be prosecuted by the Department of Justice (DOJ), DOJ itself is in the best position to answer this question.

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.

We do not believe that the existing penalties under the FD&C Act provide sufficient deterrence, given the high-profit incentives. We also note that to prove a felony under the Act, we must prove that the offense was committed with the specific intent to defraud or mislead. This means that the Government must prove more than just knowledge that the drugs were unapproved or counterfeit. The Government must prove that the defendant acted with a specific intent to defraud or mislead. This high burden of proof, in combination with relatively low penalties, poses challenges to successful prosecution of offenders. What's more, while it is critical to use all available tools, including general criminal statutes such as mail fraud, wire fraud, or smuggling, to prosecute the distribution of counterfeit and unapproved drugs, it is also important to note that these general statutes do not encompass the full range of specific conduct that violates the FD&C Act, nor are they meant to do so. It is also important to consider which elements of criminal violations can be proven. Having appropriate penalties for violations of the FD&C Act can reflect the specific harm that may come from those violations the priority that the Government should place on prosecuting such conduct.

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.

Providing clear asset forfeiture authority under the FD&C Act would help eliminate the financial motivation behind criminal violations of the Act by depriving offenders of the proceeds of their crimes. The proposed remedy would serve as an important and effective deterrent.

Civil asset forfeiture authority is particularly critical to FDA's effort to protect the global supply chain and combat the increasing number of offenders who operate from foreign locations and import counterfeit and unapproved drugs into the United States. Because these offenders are not in the United States, prosecuting them is time-consuming and sometimes impossible due to foreign legal requirements and the refusal of some countries to extradite. The proposed civil forfeiture authority would enable FDA to seize and forfeit proceeds of these offenses under some circumstances, even when the criminal offender cannot be prosecuted. This ability would serve as a significant disincentive to offenders, who otherwise could continue to operate from their foreign locations with impunity and profit, from selling harmful products to American consumers.

For example, FDA could conduct an investigation that identifies an individual in a foreign location operating a website that offers counterfeit or other substandard drugs for sale to customers in the United States in violation of the FD&C Act. FDA might not be able to prosecute the offender because of the lack of an extradition treaty between the foreign country and the United States. However, through an investigation of the offender's financial transactions, FDA might identify funds in bank accounts and other assets, in the United States and elsewhere, which are the proceeds of or are traceable to the proceeds of the FD&C Act violations. With clear asset forfeiture authority, FDA could seek judicial forfeiture of those proceeds, even though FDA might not be able to prosecute the individual offender.

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?

Currently, FDA does not have the authority to issue administrative subpoenas in connection with criminal investigations. To obtain records needed to pursue a criminal investigation, FDA typically must request, through DOJ, that a grand jury subpoena be issued for records. The need to use grand jury subpoenas to compel the production of records can be detrimental to FDA's public health mission and is an inefficient use of Government resources.

First, information obtained via a grand jury subpoena is subject to broad secrecy requirements. Rule 6(e) of the Federal Rules of Criminal Procedure imposes strict rules against disclosure of grand jury matters. In some cases, these secrecy requirements have prevented FDA's Office of Criminal Investigations from disclosing pertinent information to other divisions of FDA and to other public health and law enforcement agencies, even when the information pertains to ongoing conduct that poses a risk to the public health.

Grand jury subpoenas are issued by Assistant United States Attorneys (AUSAs), who typically carry a significant case load and must balance many competing law-enforcement priorities. Many other agencies have administrative subpoena authority for criminal investigations, and as a result may have more complete information by the time they bring a case to an AUSA.¹ The need to consult AUSAs for grand jury

¹ Examples of law enforcement agencies that are authorized to use administrative subpoenas in criminal investigations include: all Inspectors General (5 U.S.C. App. (III) 6), United States Postal Inspection Service (18 U.S.C. § 3061), Internal Revenue Service (26 U.S.C. § 7602), Immigration and Customs Enforcement (19 U.S.C. § 1509, 21 U.S.C. § 967, 50 U.S.C. § 1701 and 8 U.S.C. § 1225(d)(4)), Drug Enforcement Administration (21 U.S.C. § 876), Department of Labor (29 U.S.C. § 1134(c)), Small Business Administration (15 U.S.C. § 634(b)), United States Secret Service (18 U.S.C. § 3486(a)(1)(A)(ii)), Nuclear Regulatory Commission (42 U.S.C. § 2201(c)), Bureau of Alcohol, Tobacco, Firearms and Explosives (15 U.S.C. § 49 and 27 U.S.C. § 202(g)), and Federal Bureau of Investigation (21 U.S.C. § 876; 18 U.S.C. § 3486). In addition, the Department of Justice, through the United States Attorneys, is authorized to issue administrative subpoenas for investigations of Federal health care offenses, RICO, and Foreign Corrupt Practices Act.

subpoenas can, in some cases, cause delays, giving offenders time to alter or destroy critical evidence, move locations, or change their criminal behavior in an effort to escape prosecution. Because trafficking in counterfeit or unapproved drugs often involves distribution from abroad into many different judicial districts, there may be multiple districts in which grand jury subpoenas might be issued. Currently, FDA is not always able to fully develop a criminal case or identify districts in which criminal prosecution is most likely appropriate before presenting the case to a United States Attorney's Office. Therefore, an AUSA may be reluctant to open a criminal case and issue a grand jury subpoena, if the evidence FDA has been able to gather contains little to indicate that the target is either located in or distributing significant quantities into the AUSA's district.

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?

Under section 503(b) of the FD&C Act, FDA has legal authority to take action against the sale or dispensing of a prescription drug without a prescription (21 U.S.C. § 353(b)(1)). Nevertheless, Internet pharmacies have prescribed drugs to U.S. citizens based solely on their answers to online surveys without any other information. Due to the absence of a definition of "valid prescription," FDA's authority to take action in such circumstances is subject to challenge.

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 FDCA to apply to drugs not containing controlled substances help solve this problem?

Extending the Ryan Haight Act's definition of "valid prescription" to non-controlled prescription drugs would help standardize what constitutes a valid prescription. This legislative change was included as one of the recommendations of the March 2011 Report to the Vice President of the United States and to Congress of the Counterfeit Pharmaceutical Inter-Agency Working Group.² Currently, states have different definitions of what constitutes a valid prescription. Internet pharmacies typically operate across state lines. The pharmacy may be in one state (or overseas), the doctor who issues the prescription may be in another state, and the customer may be located in a third state. In such cases, it is not clear which state law applies. A Federal definition of what constitutes a "valid prescription" for non-controlled prescription drugs would provide clarity in Internet pharmacy investigations, where there is a question as to whether the drugs are being dispensed pursuant to a valid prescription, and it is not clear which state law applies.

² See pages 15-16 of the Report, available at https://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf.

- 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?**

The online pharmacy disclosure requirements embodied in the Ryan Haight Act have strengthened the Government's ability to take enforcement actions against rogue online pharmacies engaged in the marketing and distribution of controlled substances. We would be happy to work with the Committee going forward on exploring potential avenues to address the issues posed by rogue online pharmacies, including, but not limited to, extending the Ryan Haight Act's disclosure requirements to all online pharmacies, defining what constitutes a "valid prescription" under the FD&C Act; a requirement that Internet pharmacies disclose their locations, pharmacist in charge, contact information, and other salient contact information, for transparency and accountability and so that consumers can contact the pharmacy if there is a problem; a requirement that Internet pharmacies have to notify FDA that they are selling prescription drugs to U.S. consumers and what state(s) they are licensed in, providing FDA with information about which entities are selling prescription drugs online; a requirement that the online pharmacy be located within the United States, facilitating jurisdiction, oversight, and prosecution; and a requirement that Internet pharmacies comply with state licensing and registration laws.



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Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the February 27, 2014, hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains," before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. We provided a partial response on April 13, 2015. This letter is our final response.

If you have further questions, please let us know.

Sincerely,



Thomas A. Kraus
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

Attachment 2 – Member Requests for the Record

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 following tools would significantly aid FDA’s ability to combat rogue Internet pharmacies.

- (1) Providing FDA with civil and criminal forfeiture authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- (2) Administrative Subpoena authority for criminal investigations.
- (3) Increasing the statutory maximum penalties for drug offenses under the FD&C Act.
- (4) Extending the Ryan Haight Act definition of “valid prescription” to non-controlled prescription drugs regulated under the FD&C Act.

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?**

Sixteen firms applied to the Secure Supply Chain Pilot Program, and FDA accepted 13 to participate. The participants all have headquarters in the United States; however, each supply chain has a manufacturer located in a foreign country. These countries are: India, Japan, China, Belgium, Italy, UK, France, Czech Republic, Switzerland, Israel, and Sweden.

- (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 pilot program has been operational since February 5, 2014. It is too soon to determine the successes. FDA is in the process of addressing issues specific to each supply chain. FDA is establishing a performance baseline in order to evaluate the pilot program and identifying process improvements and lessons learned. FDA hopes to understand better how firms transmit imports data upon the submission of an imports entry and what improvements can be made both by FDA and firms to gain greater compliance with FDA requirements for imported drugs.

The Honorable Michael C. Burgess

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

The primary criminal investigation was closed by FDA on January 20, 2010. There is, however, an open and ongoing related investigation into the contaminated heparin.

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?**

In the case referenced, *United States v. Michael Lawrence O'Donnell* (2:11-cr-00556-DN, District of Utah), the original indictment charged 12 counts of mail fraud and 13 counts of engaging in wholesale distribution of prescription drugs without a license. Mr. O'Donnell pleaded guilty to one count related to the unlicensed wholesale distribution of prescription drugs.

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 following recommendations would significantly aid FDA's ability to combat rogue internet pharmacies.

- (1) Providing FDA with civil and criminal forfeiture authority under the FD&C Act.
- (2) Administrative Subpoena authority for criminal investigations.
- (3) Increasing the statutory maximum penalties for drug offenses under the FD&C Act.
- (4) Extending the Ryan Haight Act definition of "valid prescription" to non-controlled prescription drugs regulated under the FD&C Act.

The Honorable John Dingell

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

The bottles were 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.**

The Office of Drug Security, Integrity and Response (ODSIR) is currently handling drug supply chain security issues through the Division of Supply Chain Integrity and imports, exports,

recalls, and shortages issues through the Division of Imports Exports and Recalls. Within these program areas, ODSIR handles many important Agency functions, including, but not limited to, implementing important Food and Drug Administration Safety and Innovation Act (FDASIA) and Drug Supply Chain Security Act provisions that will improve the security of our nation's drug supply; combating counterfeit, substandard, and otherwise unapproved drugs sold to U.S. consumers at retail and over the Internet; facilitating the removal of adulterated and/or misbranded products from the market; notifying the public about counterfeit, substandard, and otherwise unapproved drugs; and working to prevent the importation of adulterated, misbranded, and unapproved drugs. Additionally, ODSIR is responsible for identifying and coordinating compliance activities related to significant public health threats related both to supply chain security and others. ODSIR's new role in responding to public health incidents is the reason the office was renamed ODSIR (formerly Recalls). The divisions within ODSIR are linked by subject matter and deal with an array of responsibilities and issues. We handle these responsibilities effectively and with limited staff and resources.

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.

In an effort to receive timely information from Internet service providers, FDA is in need of administrative subpoena authority for criminal investigations involving the Internet. Currently, FDA must obtain a grand jury subpoena, through the Department of Justice, to obtain such information. The need to consult with the Department of Justice for grand jury subpoenas can in some cases cause delay.

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.

The illegal importation of adulterated products that are counterfeit or have hidden and potentially dangerous, undeclared active pharmaceutical ingredients can pose dangerous risks to American consumers. In an effort to keep Americans safe, FDA proposes a change be made in section 306 of the FD&C Act to extend the authority to debar importers of food under limited circumstances to drug importers as well. Currently, FDA can debar food importers for a limited time for certain criminal conduct related to the importation of food or where the importer demonstrates a pattern of importing food that poses a substantial hazard. We propose that this authority be extended to drug importers and those offering drugs for import. This authority would provide an administrative remedy and useful tool to address dangerous illegal importation where it is currently impractical to pursue injunctions in Federal court.

Under the FD&C Act, FDA has the authority to pursue persons who import adulterated, misbranded, or unapproved new drugs into the United States from foreign sources. In many cases, FDA's ability to exercise this authority is limited by the challenges of criminally investigating conduct that occurred largely in foreign locations and of extraditing offenders to

stand trial in the United States. We further refer to additional authorities mentioned in other responses.

Despite our extraterritorial jurisdiction, FDA does not often have the authority to “go after” people who manufacture and ship pharmaceuticals to the United States. For various reasons, including claims of lack of knowledge about shipment of the product to the United States, foreign firms are often insulated from liability. Typically, our approach is to take action against the foreign product. This approach could be enhanced by enforcement tools that would allow FDA to cause a loss to the person who violates the law. The Agency currently uses the authorities under 21 U.S.C. 381 to administratively refuse entries of drugs that appear to be, among other violations, adulterated, misbranded, or unapproved.

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?

FDA is currently engaged in the process of implementing FDASIA Title VII. FDA does not yet have sufficient data to assess the impact of the newly granted authorities on improvement in the integrity of the drug supply chain, especially in light of evolving risks. If additional needed authorities are identified, FDA will work with Congress as appropriate.

The FDASIA authorities are valuable, but additional authorities would be very helpful in protecting the public health. In particular, FDA could benefit from the following: Subpoena authority; seizure authority; asset forfeiture authority; remove Interstate commerce elements from the FD&C Act and PHS Act; and increased civil and criminal penalties.

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

FDASIA provided FDA with many new authorities that will help FDA keep Americans safe from counterfeit and substandard drugs coming from abroad. Specifically related to the importation process, section 708 provides FDA the authority to destroy FDA-refused drug products under a certain value threshold; section 713 provides FDA the authority to mandate certain reporting requirements at the time of entry; and section 714 requires commercial importers of pharmaceuticals to register with FDA. These authorities provide FDA better access to pharmaceutical supply chain information, which allows us better opportunity to block the importation of illegitimate pharmaceutical importations and to facilitate compliant trade. The destruction authority enables FDA to better ensure these illegitimate shipments will not return to the United States through other channels.

The regulations and guidance documents for these FDASIA sections are progressing; it would be advisable to implement these authorities and gauge their impact before requesting new and additional authorities, such as:

- (a) The authority to use rapid-detection technologies to authorize FDA to seize and destroy counterfeit and substandard drugs from repeat offenders, without a hearing and without burden to U.S. Customs and Border Protection.
- (b) Public cease-and-desist orders that require a response from the foreign government regulating the exportation of the counterfeit or substandard drug.
- (c) Clear authority to take civil and criminal action against people and entities that facilitate the sale of counterfeit, substandard, and otherwise unlawful drug products over the Internet, including against third-party platforms and credit card companies that process the transactions.

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.

FDA is currently engaged in implementing FDASIA Title VII. FDA does not yet have sufficient data to assess the resources needed to fully implement these new authorities.

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.

For policy reasons, FDA does not believe that it would be appropriate for the Agency to benefit directly from the forfeiture of proceeds or other facilitating property. In some cases, other Federal agencies are able to obtain reimbursement of their investigative costs and expenses from the penalties, such as fines and restitution that are collected from criminal offenders.¹ A similar provision to enable FDA to receive reimbursement for its investigative costs from criminal offenders would be helpful to increase available resources to address the problem of counterfeit and unapproved drugs.

FDA, through its Office of Criminal Investigations (OCI), is currently a member of the Department of Justice's Asset Forfeiture Fund (the Fund). Proceeds of forfeitures in cases brought to the Department of Justice by FDA are deposited into the Fund. In accordance with the policies of the Fund, OCI may seek withdrawal from the Fund to assist ongoing investigations with the identification and removal of criminally derived assets.

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.

The maximum prison sentence for most FD&C Act offenses is three years in prison. We believe that a more appropriate penalty scheme would provide for a maximum of 10 years in prison for each offense, with an increase to a maximum of 20 years, if the offense results in serious bodily injury, and life in prison, if the offense results in death. These suggested statutory maximum sentences are modeled after, and commensurate with, the sentencing schemes for other Federal

¹ For example, the Inspector General of the Department of Health and Human Services is authorized to receive reimbursement for the costs of conducting investigations in certain circumstances (see 42 U.S.C. 1320a-7c(b)).

offenses with public-health significance. For example, the maximum penalty for tampering or attempting to tamper with a consumer product is 10 years, 20 years if the offense causes serious bodily injury, and life in prison if death results (see 18 U.S.C. § 1365(a)). Similarly, the maximum penalty for health care fraud is 10 years, 20 years if the violation results in serious bodily injury, and life in prison if the offense results in death (see 18 U.S.C. § 1347).

Although the maximum fine provided for in the FD&C Act for a felony offense is \$10,000, the actual maximum fine is governed by 18 U.S.C. § 3571, which provides for significantly higher maximum fines commensurate with other Federal offenses. We believe that the maximum fines provided for in 18 U.S.C. § 3571 are sufficient.

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

As noted previously, FDA's ability to combat misbranding or counterfeiting would be enhanced by clear authority to take civil and criminal action against persons and entities that facilitate the sale of counterfeit, substandard, and otherwise unlawful drug products over the Internet, including against third-party platforms and credit card companies that process the transactions. This would include strong civil monetary penalties.

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.

All of the 1,600 websites used templates claiming to be Canadian Pharmacies or would otherwise attempt to lead the consumer to believe they were Canadian. They branded themselves as follows:

- (a) Canadian Health & Care Mall
- (b) Canadian Family Pharmacy
- (c) Canadian Neighbor Pharmacy
- (d) Canadian Pharmacy
- (e) My Canadian Pharmacy LTD
- (f) Pharmacy Express
- (g) Toronto Drug Store

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?

As stated above, FDA, through its OCI, is currently a member of the Department of Justice's Asset Forfeiture Fund (the Fund) and is able to use money from the Fund to further its criminal investigations in accordance with Department of Justice policy. A similar provision to that used by HHS, as described above, whereby FDA could obtain reimbursement of investigative costs and expenses from penalties, such as fines and restitution, would help in increasing available resources to address the problem of counterfeit, unapproved, and substandard drugs.