The Importation of Bulk Counterfeit Pharmaceutical Products

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Mr. Chairman and Members of the Subcommittee:

Good morning. My name is Patricia L. Maher. I am a Deputy Assistant Attorney General in the Civil Division of the Department of Justice. In that capacity, one of my responsibilities is to oversee the Office of Consumer Litigation (OCL) -- the Civil Division's office that handles civil and criminal cases brought under a number of federal consumer protection statutes including the Federal Food, Drug, and Cosmetic Act (FDCA). This morning, at your invitation, I will speak to you about our experience prosecuting traffickers of counterfeit pharmaceutical products that are manufactured outside of the United States. At your request, I will also offer some ideas regarding additional tools that would be helpful to combat this problem.

Prosecutions of the type I will be discussing are both important and difficult. They are important because the targets in these cases introduce drugs of unknown safety and efficacy into the United States. Successful prosecutions signal to traffickers the world over that tainting the drug supply in the United States will not be tolerated. The cases are difficult because much of the evidence of unlawful activity is located overseas, and thus is more difficult to obtain than evidence located within our borders. While we have been successful in overcoming these hurdles and obtaining convictions, we need your help to eliminate obstacles that slow investigations and create questions regarding the applicability of the FDCA to the behavior that is at issue in these cases. In that connection, we will work and consult with FDA regarding needed changes in the Food, Drug and Cosmetic Act, such as those described in this testimony.

As evidence of U.S. law enforcement's commitment to combat the threat posed by counterfeit pharmaceuticals, the Department of Justice, FBI, and Customs Service hosted last month the first meeting of law enforcement experts of the G-8 countries to address intellectual property crimes. Under the auspices of the Senior Law Enforcement Experts on Transnational Organized Crime (Lyon Group), representatives from all G-8 countries discussed mechanisms for improved cooperation and information-sharing in responding

to a variety of intellectual property crimes, including trafficking in counterfeit pharmaceuticals.

I. The Danger Posed by the Importation of Counterfeit Pharmaceutical Products

The FDCA defines a counterfeit drug to include a drug which, without authorization, bears an identifying mark of another drug manufacturer that did not manufacture the drug. (21 U.S.C. § 321(g)(2).) Under the FDCA, the term "drug" includes both finished drug products and components of drug products that are referred to as "bulk" pharmaceuticals or active pharmaceutical ingredients. In the pharmaceutical industry, the term "counterfeit drug" is generally used to refer to a compound that is not made by the authorized manufacturer, but is presented to the consumer as if it were.

There are also drug products that are manufactured in whole or in part by unauthorized factories or facilities, and then shipped with the complicity of the authorized manufacturer under its name and trademark. These drugs may not technically fit the legal definition of "counterfeit drug" if the authorized manufacturer has approved the use of its own trademark and the like. Nonetheless, these drugs involve the marketing of a product where the identity of the true manufacturer is misrepresented to, or withheld from, consumers and the Food and Drug Administration (FDA) and the drug is misbranded under the FDCA. As a consequence, some or all of the process of manufacturing the drug could fall outside the supervision of the FDA and could render the drug adulterated or misbranded. Because such drugs also involve a false representation about their true place of manufacture, they can be referred to as misbranded or adulterated.

Counterfeit drugs pose a number of potential public health issues. The World Health Organization (WHO) has found that the majority of counterfeit drugs reported to the organization contain a less potent active ingredient than claimed, ingredients other than those listed, or no active ingredient at all, which makes them less effective and possibly toxic to unknowing consumers. WHO has estimated that as much as ten percent of the world's supply of branded medicines are counterfeit, with the level rising to fifty percent in some developing countries.

Even where the product in question contains the represented amount of the drug's active ingredient, it can pose hazards. The effectiveness of drugs depend on a long chain of factors that include measures in quality control, distribution, and inventory control. The FDCA requires that all drugs in this country be manufactured under pursuant to the good manufacturing practice regulations to ensure the consistent safety and efficacy of the drug product.

The scope of the problem in the United States should be substantially less than it is in the rest of the world. Several legal provisions help to assure that imported products comply with legal requirements. Drug companies in this country are required to sample and test bulk drugs, whether obtained domestically or internationally, that will be used in finished drug products, as well as to examine the labeling of any such shipments. (See 21

C.F.R. § 211.84.) These measures help to assure that bogus drugs will be detected if they are sold to a legitimate finished dosage manufacturer in the United States.

Misbranded versions of a number of drug products have appeared in the United States, nevertheless. The potential for an increase in such traffic exists because of the increasingly global nature of the pharmaceutical business. Moreover, the ease with which counterfeit products can be distributed by "pharmacies" that appear on the Internet makes this an issue that affects consumers directly.

II. Obtaining Assistance from Foreign Governments and Prosecuting Conduct Occurring Outside the United States

A. The Need for Credible Criminal Deterrence

Underlying the FDCA's statutory scheme to protect the public health is the requirement that regulated businesses deal truthfully with the FDA. Most businesses do so. Because the FDA and our national scheme for drug safety rely on information supplied by regulated businesses, it is necessary to take strong action against those that provide false information to the FDA. The means for punishing fraudulent conduct are contained in the criminal provisions of the FDCA. The general provisions of the criminal code that prohibit false statements to government agencies also apply to false statements made regarding pharmaceuticals. The importation of counterfeit drugs very often involves fraud on the FDA and purchasing customers about the true source or nature of the drug. This is classic felony conduct under the FDCA.

Counterfeiting products can yield huge profits and is a longstanding practice in some areas around the globe. Furthermore, the incentive to mislead FDA about the source of a product's manufacture may exist even where the product contains the same active ingredients. The market for pharmaceutical drugs in the United States is substantial, and it is only open to drug products that are properly approved. Because proper approval is rigorous and demanding, there is a strong economic incentive to mislead FDA to obtain market access without the full expense of proper testing and evaluation. Similarly, there is a strong economic incentive to get FDA approval before other companies, and to maximize the output of a drug before other companies obtain approval for a competing version of the drug. One way for a drug manufacturer to maximize output within such a window is to obtain drug components or drug products from other, non-approved, facilities without notifying customers or the FDA.

Prosecutions are necessary to reach counterfeit operations that fall outside the regulatory system, where the drugs are going to be introduced into the United States. The operations of some drug counterfeiters are much the same as those of the narcotics trade, crossing many borders and involving the use of clandestine facilities. In such circumstances, FDA's regulatory measures and controls are less likely to uncover the activity and impose a punishment sufficient to act as a deterrent.

B. Previous Experience in Obtaining Evidence Abroad in Prosecutions Involving the Importation of Counterfeit Pharmaceutical Products

Prosecutions for importation of counterfeit products have relied primarily on evidence gathered domestically, whether the defendants are citizens of this country or foreign nationals. For example, the 1987 prosecution of a ring importing millions of counterfeit birth control pills from Spain and Guatemala was based entirely on evidence gathered in the United States. Similarly, the Flavine International case, which involved a group importing counterfeit antibiotics from China, also was based primarily on evidence gathered within the United States. I will elaborate on these examples of our experience prosecuting importation of counterfeit pharmaceuticals.

1. Example: the prosecution of importers of counterfeit birth control pills

In the mid 1980s, approximately two million counterfeit birth control pills were imported as part of a drug diversion scheme. A large number of the pills contained subpotent estrogen or no estrogen. The case began when a group of traffickers acting both inside and outside the United States began importing, repacking, and distributing counterfeit birth control pills that had been manufactured in Barcelona, Spain. The tablets were similar in appearance and composition to genuine Ovulen-21 tablets made by Searle. These pills were shipped from Spain to intermediary countries, and then smuggled into the United States and sold. The proceeds of the sales, including over $200,000 profits, were deposited in a Panamanian bank account.

Having made a substantial profit on the counterfeit Ovulen, the defendants next solicited a small company in Guatemala to make counterfeit pills that again would appear to be genuine, but in this case would have no active ingredient at all. The Guatemalan company shipped 12,000 cycles of the pill to the United States in August 1984. FDA learned of the counterfeit birth control pills in October 1984. The government gathered evidence from witnesses in the United States, including some of the traffickers who decided to cooperate.

An Indictment filed in the Southern District of Florida in February 1987 charged six defendants who resided in the United States. All defendants were convicted either after pleading guilty or going to trial. The defendants were sentenced to terms of imprisonment of up to twenty-four years.

2. Example: the prosecution of counterfeit antibiotics from China

The prosecution of a New Jersey corporation, Flavine International, Inc. (Flavine), its owner who was a German national, and other company managers was based on the substitution of an unapproved foreign product for an FDA-approved foreign product. The investigation, which was conducted by the United States Customs Service and the FDA, revealed that on numerous occasions from August 1985 through November 1991, the defendants solicited and received orders from drug manufacturers in the United States for bulk antibiotics that are FDA-approved for use in the United States. The drugs

included oxytetracycline, gentamicin sulfate, and sulfamethazine. The drugs were sold for use in animal and human drugs. To fill these orders, defendants bought drugs from an unapproved overseas manufacturer, falsely declaring their origin.

Once the unapproved products arrived in the United States, the defendants, when necessary, had the product repacked in new containers that more closely resembled those of the approved manufacturer. Defendants removed labels from containers and affixed fraudulent labels to containers in order to falsify the origin and manufacturer of the drug product. They also replaced the manufacturers' certificates of analysis with fraudulent certificates of analysis that falsely claimed that the drugs were made by an approved manufacturer. These acts were performed without the authorization of the approved manufacturer whose name was used.

In April 1997, Flavine was fined a total of $925,000, and its owner was sentenced to two years in prison and fined a total of $75,000 for illegally importing counterfeit pharmaceuticals from China and laundering money in a kickback scheme.

C. Obtaining and Developing Evidence of Conduct Abroad

There are unique challenges when groups acting outside the United States import counterfeit pharmaceutical products. Even in those circumstances in which extraterritorial jurisdiction exists over crimes committed abroad, principles of sovereignty limit what measures we can take unilaterally to investigate and prosecute such crimes. In some cases, law enforcement agencies in the United States, such as the Customs Service and the Food and Drug Administration (FDA), may make requests of law enforcement agencies abroad informally or through Interpol. State ethics rules, however, may effectively prevent contact with employees of corporations under investigation through such informal contacts. This occurs because federal law now requires Department of Justice attorneys to comply with state ethics rules. Such rules (see Model Rule 4.2) often can effectively bar contacts with employees of corporations unless corporate counsel authorizes the communication. FDA also currently has the authority to conduct inspections abroad. (See 21 U.S.C. § 374.) Letters rogatory are the customary method of obtaining assistance from abroad in the absence of a treaty or executive agreement. (See 28 U.S.C. § 1781.)

In order to improve our ability to investigate and pursue evidence and defendants abroad, the Department has supported extradition treaties to obtain the return of defendants, and mutual legal assistance requests to obtain documents, witness testimony, or other evidence. Of course even when extradition treaties and mutual legal assistance procedures are in place with a foreign jurisdiction, they may not always ensure that we will be able to obtain all of the international law enforcement cooperation we would like in every case. For example, even our most modern extradition treaties require that an offense for which extradition is sought be a crime in both the requesting and the requested state (the "dual criminality" principle). Thus, to the extent that some foreign countries have to date not criminalized the counterfeiting of pharmaceuticals, the extradition of persons from such countries wanted for prosecution in the United States

may not be possible. In addition, some older extradition treaties do not clearly cover offenses that are perpetrated in a foreign country yet take effect in the United States; and despite our continuing efforts, some countries still refuse to extradite their own nationals.

Moreover, while we may seek to obtain the statements or deposition testimony of foreign witnesses unwilling to come to the United States (through the traditional "letters rogatory" method, or through our increasing number of mutual legal assistance treaties (MLATs)), in the best of circumstances this can be a time consuming process. In the worst of circumstances, legal privileges or other foreign law requirements may completely frustrate our efforts.

Despite their limitations, however, modern international extradition treaties and MLATs remain among the more effective mechanisms available for obtaining the international cooperation we need. We ask that Congress continue to support our efforts to expand the network of such agreements.

D. Jurisdictional Questions

Among the considerations in obtaining evidence and pursuing prosecutions in these cases is the extraterritorial application of the FDCA. Congress has the power to address the problem of counterfeit pharmaceutical imports even when it involves conduct occurring overseas that has an impact in the United States. Amending the FDCA to make the extraterritorial application of the FDCA to persons affecting the United States by their actions abroad explicit instead of implicit would aid the investigation of criminal cases in these situations. Such an approach would be consistent with the international law principles that United States courts apply. Indeed, international law principles have expanded to permit jurisdiction upon a mere showing of intent to produce effects in this country, without requiring proof of an overt act or actual effect within the United States. Although cases involving intended but unrealized effects are rare, international law does not preclude jurisdiction in such instances, subject to the principle of reasonableness. Thus, we believe that foreign manufacturers of pharmaceutical bulk materials who know that the product will be used in the United States are subject to the jurisdiction of the United States and the FDCA.

The FDCA prohibits the introduction into interstate commerce of adulterated or misbranded drugs
(21 U.S.C. § 331(a)), and defines "interstate commerce" to include commerce between "any State or Territory and any place outside thereof," (21 U.S.C. § 321(b)). In construing Title VII of the Civil Rights Act of 1964, which had a similarly broad statement of application, a divided Supreme Court found that such language falls short of demonstrating the affirmative legislative intent required to extend the protections of American law beyond our territorial borders. That
decision, EEOC v. Arabian American Oil Co., ultimately was superseded by statute. In this opinion, however, the Supreme Court specifically named the FDCA as a statute with "boilerplate" language that could be insufficient to convey a legislative intent to apply extraterritorially. (See Arabian American Oil Co., 499 U.S. at 251.) The Controlled

Substances Act, by contrast, contains explicit language creating jurisdiction in the United States for manufacturing or distributing drugs abroad, where the intent is to introduce unlawful drugs into the United States. (See 21 U.S.C. § 959.)

III. Proposals for Improving the Prospects for Criminal Prosecutions Involving Counterfeit Pharmaceutical Products

We believe that prosecutions of counterfeit drug producers and traffickers would be greatly aided by amending the FDCA to make explicit what is now implicit--that foreign companies and individuals who manufacture or distribute drugs and drug components for use in the United States are subject to the FDCA. The application of such a law, however, will necessarily be limited by due process considerations.

Second, we would ask that Congress review carefully treaties that might deny FDA full authority to inspect foreign establishments. The Department supports FDA retaining its current legal authority to inspect foreign establishments even where FDA has entered into agreements with foreign regulatory agencies to have those agencies conduct the inspections. In addition, the approval to manufacture and/or distribute drugs and drug components in the United States could be conditioned on the manufacturer's or distributor's agreement to make documents and witnesses available in criminal investigations in the United States. FDA currently has the right to inspect drug manufacturers (see 21 U.S.C. § 374), but this section does not explicitly provide the FDA authority to secure interviews with witnesses or any method by which the production of documents can be compelled independent of an inspection. As previously mentioned, it is difficult to obtain testimony of witnesses regarding conduct occurring outside the United States.

Clarifying FDA authority as outlined above would make foreign establishments subject to the same obligations, privileges, rights, and protections that apply to domestic firms. Currently, during FDA's regulatory investigations of foreign firms, only certain production records and personnel are made available to inspectors. (See 21 U.S.C. § 374.) An explicit requirement that a company must provide such cooperation could authorize FDA to withhold or deny approval of drug applications, and to withdraw a firm's existing approved applications, if FDA finds that the foreign firm is not cooperating in an investigation. This would be analogous to FDA's existing authority to refuse the new drug application of an applicant that has submitted false data to the agency. (See Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46191 (1991).) Foreign businesses choosing to market pharmaceutical products in this country should not be able to gain better treatment than domestic firms because of their location outside of the country.

Third, the Department requests that the Congress consider legislation requiring foreign exporters of drug products to provide original certificates of analysis establishing the integrity and authenticity of the drugs or drug components filled out by each manufacturer involved in the production of the shipment of a drug product. Such a

change would depart only slightly from current practice. The FDCA provides that a drug is misbranded if its labeling is false or misleading. (See 21 U.S.C. § 352(a).) In addition, the regulations establish that the appearance of a name on a drug product label, without qualification, is a representation that the company is the sole manufacturer. (See 21 C.F.R. § 201.1(h)(2).) If a manufacturer performs more than half of the operations, it meets its obligations if it states that certain manufacturing operations have been performed by other firms. (See id. at § 201.1(c)(1).) A simple means of ensuring authenticity of drug components could be accomplished by a minimal expansion of these requirements to apply to foreign
firms.

Finally, we believe that foreign countries should be encouraged to cooperate with the United States and, where appropriate, to prosecute manufacturers and distributors of counterfeit drugs in their own courts. Where foreign nations can prosecute such conduct, it is in the United States' interest to help such prosecutions go forward. Increased cooperation with foreign authorities could also facilitate the detection of such criminal activity.

The Department recommends these actions and policies to provide additional tools for the detection and prosecution of those who traffic in counterfeit pharmaceutical products. Where such activity is uncovered, we are committed to prosecuting such cases.

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to testify before the Subcommittee.

I look forward to answering your questions.