NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

May 28,2002

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, NW
Washington, DC 20503

Re: Draft Hcport To Congress On The Costs And Benefits Of Federal Regulations

Dear Mr. Morrall:

415 North Lee Street
PO Box 1417-D49
Alexandria, Virginia
22313-1480

The National Association of Chain Drug Stores **("NACDS")** hereby submits comments on the Draft Report to Congress on the *Costs* and Benefits of Federal Regulations, which was recently published by the Office of Management and Budget ("OMB"). ***See*** 67 Fed. Reg. 15014 (Mach 28,2002). As discussed below in the format requested by OMB, NACDS suggests that a guidance document issued by the Food and Drug Administration should be rescinded or revised through notice and comment rulemaking procedures.

NACDS members are nearly 200 chain community pharmacy companies. Chain community pharmacy is the largest component of pharmacy practice, with over 100,000 pharmacists working in more than 34,000 retail community pharmacies. Chain operated community retail pharmacies fill over 70% of the 3 billion prescriptions dispensed annually in the United States, with annual sales totaling over $450 billion. NACDS membership also includes over 1,200 suppliers of goods and services to chain community pharmacies, as well as 130 international members from 34 countries. NACDS was founded in 1333 and is based in Alexandria, Virginia.

1. Name Of Guidance Document:

Coverage of Personal Importations (referred to herein as the "Guidance").

2. Regulating Agency;

Department of Health and Human Services **("HHS")**
Food and Drug Administration ("FDA")

3. Citation:

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

FDA Regulatory Procedures Manual, Chapter 9 (available at: http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html).

4. Authority:

No statute or regulation authorizes the Guidance.

5. Description of Problem:

As discussed below, federal laws generally prohibit mail order imports of prescription drugs for the personal use of a consumer. However, the Guidance is a vague statement that the FDA will not enforce these prohibitions in some circumstances. The Guidance has resulted in tidal waves of imported mail order drugs that are illegal, dangerous to consumers, and unfair to pharmacies and drug manufacturers.

A. The FDA Refuses To Enforce Laws Banning Mail Order Imports of Prescription Drugs

It is illegal to import prescription drugs through the mail for a customer's personal use. A prescription drug *that* is manufactured in the United States and then exported may not be reimported into the U.S. by anyone other than the manufacturer of the drug.[1] In addition, prescription drugs may not be imported into the United States unless they are approved by the FDA, properly labeled, and accompanied by evidence that they were made in an FDA-inspected facility in accordance with good manufacturing practices. According to a senior FDA official, "In general, all drugs imported by individuals fall into one of these prohibited categories."[2]

The FDA issued the Guidance in 1988, without giving the public notice or an opportunity to comment. The Guidance does not directly state that it creates a right to import prescription drugs for an individual's personal use. In subsequent commentary regarding the Guidance -- but unfortunately not in the Guidance itself -- the FDA has stated that "the guidance document is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the US, and even if all the factors noted in the guidance are present, the drugs remain illegal and FDA may decide *that* such drugs should be refused entry or seized."[3]

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[1] 21 U.S.C. § 381(d)(1). This statute also allows the FDA to authorize reimportation "for emergency medical care," but to our knowledge the FDA has not done so.

[2] 21 U.S.C. §§ 331(d), 334(a), 335(a), 381(a).

[3] See enclosed memorandum from FDA to HHS (May 21, 2001), *reprinted in* FDA Week pp. 7-8 (Nov. 23, 2001). A recent statute gives the Attorney General discretion to allow consumers to carry a small quantity of certain controlled substances across the border, but that statute *does* not authorize mail order imports. *See* Controlled Substances Trafficking Prohibition Act, P.L. 105-357 (1998); testimony of Drug Enforcement Administration's Laura Nagel before the House Energy and Commerce Committee (June 7, 2001).

[4] FDA, Information on Importation of Drugs, available at http://www.fda.gov/ora/import/pipinfo.htm.

Nevertheless, the Guidance gives FDA personnel discretion to refuse to enforce the laws against drug importation. According to the Guidance, individual FDA personnel may ignore the statutory prohibitions against illegal drug importation:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a serious health risk; or

2. when a) the intended use is unapproved and for a serious condition for which effective treatment may Dot be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by *those* involved in the disuibution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

The vague language of the Guidance has allowed foreign companies to create the false impression *that* mail order imports of prescription drugs are legal. These companies incorrectly argue that the Guidance creates a "personal use exemption" from the prohibition on personal importation of prescription drugs. Many of these off-shore pharmacies advertise and operate through the Internet websites.

The result has been an explosion of mail order imports of prescription drugs. The FDA estimates that mail order imports grew by 450 percent in 1999 alone.[5] Consumers have been lead to believe that the FDA has legalized mail order imports of prescription drugs, despite the fact that the Guidance "was never intended to he a way for patients to bring lower priced drugs into this country; nor was it a means for patients to buy drugs that are already available in the United States."[6]

B. The Vague FDA Guidance Has Lead To Illegally Imported Drugs That Are Dangerous To Consumers' Health And Safety

Importing drugs for personal use is dangerous and potentially harmful to consumers. When the ban on personal reimportation of drugs was enacted in 1987, Congress determined that reimported drugs "are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping," and because they provide "cover for the importation of foreign counterfeit

[5] See enclosed memorandum from FDA to HHS (May 21, 2001), *reprinted in* FDA Week pp. 7-8 (Nov. 23, 2001).
[6] Library of Congress Congressional Research Service, Prescription Drugs: Importation For Personal Use, p. 4 (No, RS20996 Aug. *24, 2001*).

drugs."[7] Since 2000, when Congress asked HHS to authorize reimportation of prescription drugs, both the past and present Secretaries of HHS formally declared that HHS could not guarantee adequate prescription drug safety if reimportation is allowed.[8]

When drugs are prepared for distribution within the United States, the FDA oversees the manufacturing process to ensure that the manufacturer has satisfied stringent federal safety standards. Regulators are able to track the chain of ownership of drugs, and are able to ensure that the directions lor use, package inserts and other labeling satisfies federal standards and are appropriate for American consumers. State boards of pharmacy also ensure that community pharmacies employ licensed pharmacists and satisfy safety standards. When drugs are dispensed at local pharmacies, state laws ensure that a licensed pharmacist is available to advise the patient about proper drug use.

In contrast, when drugs are mailed into the United States from foreign countries there is no way to ensure that the drugs were prepared, packaged, transported or stored in compliance with federal and state standards. The potential for counterfeiting drugs is high, because the FDA has no opportunity to track the drugs. The drug labeling may satisfy the standards of foreign governments, but not FDA standards. Moreover, the companies that dispense the drugs are not licensed by the consumer's state and may not satisfy state safety standards. No pharmacists are available to consult with the patients about their drugs.

In 2001 the FDA conducted a survey of drug products mailed into the U.S. through a Carson City, California mail facility. The FDA idcntificd "serious public health risks" associated with "many" of the intercepted drugs. The risks included "drugs of unknown origin or quality" and drugs dispensed without a prescription or without "continued oversight of the physician." For example, some of the intercepted drugs had been previously withdrawn from the U.S. market due to deadly side effects. Controlled substances and narrow therapeutic index drugs were also intercepted. This Carson City survey convinced the FDA that it could not trust the safety of drugs imported by mail.[9]

In sum, thcrc is a complex safety net of federal and state laws designed to ensure that prescription drugs arc manufactured, stored, shipped, dispensed and used in a safe manner. That safety net is eliminated by drug importation schemes.

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[7] Prescription drug Marketing Act of 1987. Y.L. 100-293, § 2.
[8] HHS Press Release, "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible" (July 10, 2001), available at www.hhs.gov/news.
[9] Testimony of William Hubbard, FDA Senior Associate Commissioner for Policy, Planning and Legislation, before the House Energy and Commerce Committee (June 7, 2061).

C. Illegal Imports Harm Legitimate American Pharmacies And Drug Manufacturers

Illegal drug imports harm American pharmacies and drug manufacturers. There are well over 50,000 pharmacies in the United States that employ over 100,000 pharmacists and millions of other employees. These pharmacies and their employees pay federal and state taxes, and They work hard to satisfy federal and state licensing and safety standards.

The federal laws discussed above do not allow American pharmacies to purchase drugs at the lower prices available in Canada, Mexico and other countries. By allowing foreign companies to purchase drugs at lower foreign prices, and then mail those drugs to customers in the U.S., the FDA has created a playing field tilted against U.S. pharmacies. Legitimate pharmacies in the U.S. lose business each time a consumer buys from a drug importer rather than visiting their local pharmacy. Pharmacies are in favor of competition, but the Guidance has created a marketplace that is unfair to American pharmacies.

American drug manufacturers are also harmed by the Guidance. Foreign companies are able to purchase drug manufacturers' products at artificially low prices due to drug price controls in foreign countries. Companies that facilitate mail order drug imports are essentially importing price controls into our country.

6. Proposed Solution:

The Guidance should be permanently rescinded. The FDA itself has asked HHS for permission to revoke the Guidance to the extent it applies to mail order drugs. Although the FDA made this recommendation over one year ago, to our knowledge HHS has never responded to the FDA."[10]

In the alternative, the Guidance should he revised through notice and comment rulemaking. The FDA's failure to explain the Guidance and solicit public comments caused the misunderstandings discussed above. Moreover, a federal court has ruled that the FDA should not have issued the Guidance without following the notice and comment rulemaking requirements of the Administrative Procedure Act. See *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992). The court first indicated that the Guidance is "substantive rulemaking" in light of "the breadth of its language. . ." *id.* at 289 n.7. Even if the Guidance is merely an interpretive rule or agency practice or procedure. the court held that the FDA's own regulations required the agency to conduct APA rulemaking at the time the Guidance was issued. *Id.* at 289-90.

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[10] *See* enclosed memorandum from FDA to HHS (May 21, 2001), *reprinted in* FDA Week pp. 7-8 (Nov. 23, 2001).

7. Estimate Of Economic Impact:

We are unaware of any studies of the economic impact of mail order drug importation. The phenomenon is so recent, and is growing so exponentially, that any study would be quickly outdated. However, we can state with great confidence that the Guidance has a negative economic impact on consumers, pharmacies, drug manufacturers and even the government.

Consumers import drugs to take advantage of foreign price controls, so the Guidance has a superficially positive economic impact on consumers. As discussed above, however, the FDA has identified "serious public health risks" associated with mail order imports. Widespread use of imported drugs inevitably leads to increased health complications and hospitalizations, as consumers use unapproved drugs without the supervision of licensed pharmacists or physicians. The resulting increase in health care costs more than offsets any initial savings on the cost of imported drugs.

American pharmacies are also harmed by the Guidance. Legitimate pharmacies are losing millions of dollars as a result of improper drug import schemes. Every time a consumer purchases a drug from a foreign importer, a legitimate American pharmacy loses revenues.

American drug manufacturers are also harmed by the Guidance. Rather than make sales in the U.S. at market prices, every drug mailed into the U.S. was purchased at artificially low prices fixed by foreign governments.

Ultimately, state and local governments are harmed by decreased tax revenues. Consumers who buy drugs through the mail from foreign countries do not pay U.S. taxes on those purchases. Foreign companies that sell the imported drugs do not *pay* U.S. taxes. To the extent that their sales are decreased, American pharmacies and manufacturers will pay decreased U.S. taxes. The companies that suffer reduced sales will employ fewer workers, who will in turn pay fewer taxes.

The bottom line is that the Guidance enriches foreign companies at the expense of American consumers, businesses and the public at large. At the very least, the FDA should have given proper notice and received public comments before implementing such a policy.

8. Conclusion

NACDS **sympathizes** with consumers seeking lower prescription drug costs. But the Guidance raises serious issues of legality, safety, and fairness. We hope that OMB will correct this situation.

Please let me know if there is anything NACDS can do to help your investigation. You can contact me at (703) 549-3001.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel

Enclosures

SUBCHAPTER

COVERAGE OF PERSONAL IMPORTATIONS

PURPOSE

To provide guidance for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail and to gain the greatest degree of public protection with allocated resources.

BACKGROUND

Because the amount of merchandise imported into the United States in personal shipments is normally small, both in six and value, comprehensive coverage of these imports is normally not justified. This guidance clarifies how FDA may best protect consumers with a reasonable expenditure of resources.

There has always been a market in the United States for some foreign made products that are not available domestically. For example, individuals of differing ethnic backgrounds sometimes prefer products from their homeland or products labeled in their native language to products available in the United States. Other individuals seek medical treatments that are not available in this country. Drugs are sometimes mailed to this country in response to a prescription-like order to allow continuation of a therapy initiated abroad. With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in the United States.

In addition, FDA must be alert to foreign and domestic businesses that promote or ship unapproved, fraudulent or otherwise illegal medical treatments into the United States or who encourage persons to order these products. Such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the exportation of products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such operations, FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.

PERSONAL BAGGAGE

FDA personnel are not to examine personal baggage. This responsibility rests with the U.S. Customs Service. It is expected that a Customs officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL GUIDANCE below) an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown risk to health.

When items in personal baggage are brought to FDA's attention, the district office should use its discretion, on a case-by-case basis, in accordance with the guidance provided under GENERAL GUIDANCE below, in deciding whether to request a sample, detain the article, or take other appropriate action.

MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. It is expected that a Customs officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held or an FDA-regulated article that appears to represent a health fraud or unknown risk to health.

FDA should audit those parcels set aside by Customs in accordance with the guidance provided under GENERAL GUIDANCE below, using the following procedures.

Prepare a Collection Report for each parcel sampled. Generally, a physical sample is not required on mail importations because a documentary sample (for example, labeling, labels and inserts) will be sufficient for most regulatory purposes. If a physical sample is needed, collect only the minimum necessary for analysis by the laboratory. The remaining portion should not be removed from the custody of the Customs Mail Division.

Importations detained in accordance with this guidance should be held by Customs until they are either released or refused entry. Attached as guidance are two specimen letters that may be sent with the Notice of Detention and Hearing when a parcel is detained. (See Exhibit 9-3 for use in general mail importations and Exhibit 9-4 for use in unapproved drug or device mail importations).

On occasion, products detained by FDA will be mixed with non-FDA-regulated products. When we refuse admission of the FDA-regulated portion, any request for the release of the non-FDA-regulated portion should be referred to the Customs Mail Division with a Notice of Refusal of Admission covering the detained article. Final disposition of all merchandise, including the destruction of detained merchandise, is the responsibility of Customs.

GENERAL GUIDANCE

The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments

Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Products Other than Drugs and Devices

Many products other than drugs, biologics, and devices that individuals seek to import in personal quantities do not pose a significant health risk although they appear to be violative and may be the subject of an import alert or automatic detention based on standards violations, filth, and/or labeling problems. When such items are brought to FDA's attention by Customs, it may be appropriate for FDA personnel to use their discretion to "Release with Comment" and advise the importer of the agency's concerns. FDA personnel should be alert to and should detain those products that do pose a significant health risk.

Drugs, Biologics, and Devices

When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs and devices subject to Import Alerts are not amenable to this guidance. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter. Drugs subject to Drug Enforcement Agency (DEA) jurisdiction should be returned to Customs for handling.

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or

2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing *that* it is for the patient's own use (generally not more than 3 month supply)and provides the name and address of the donor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

If there are any questions about the application of these factors to any product, the product should be detained and FDA personnel should consult with the appropriate headquarters office.

When a shipment is not refused entry, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that 1) the drug (or device) that has been obtained for personal use appears to be unapproved in the United States; 2) the drug (or device) should be used under medical supervision; 3) FDA may detain future shipments of this product; and 4) the patient's physician should consider for example, enrolling the patient in an investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

IMPORT ALERTS

FDA personnel should recommend to the Division of Import Operations and Policy (HFC-170) the issuance of an import alert if they encounter:

1. personal importation of products that represent either a direct or indirect health risk; or

2. the promotion of unapproved foreign products for mail order shipment; or repeated importation of products that represent fraud*.

*(See Compliance Policy Guides Manual, Section 120.500,"Health Fraud - Factors in Considering Regulatory Action" (CPG 7150.10))

Customs Service lack sufficient resources to adequately monitor port-of-entry, and it is difficult to identify a medicine by its appearance and it may be falsely labeled.

Schwetz says in the May 24 letter that FDA adopted its personal importation policy in 1954 "when the small number of personal imports did not warrant devoting significant time and effort to detain such products" and the policy has been modified several times over the years.

In 1988, the agency began allowing the importation of prescription drugs for humanitarian purposes in response to concerns about the unavailability of potentially effective treatment for *AIDS*.

But now, "due to faster review times and various regulatory mechanisms through which patients can obtain unapproved treatments for humanitarian purposes, the need to import therapies not available in the United States has diminished," writes Schwetz.

FDA Asks HHS Secretary to Revoke Personal Importation Mail Policy

May 24, 2001

TO: The Secretary
Through:

FROM: Acting Principal Deputy Commissioner

SUBJECT: Mail Importation of Prescription Drugs for Personal Use — DECISION

PURPOSE

FDA recently met with HHS staff to discuss the importation of prescription drugs through the mail for personal use. At the meeting, FDA presented a proposed approach for dealing with the growing number of drugs imported for personal use and the dangers they may pose to the public health. At the request of the staff, we have written this memorandum to describe that proposal described herein and to discuss any other options that you may wish to consider.

BACKGROUND

The number of prescription drugs for personal use imported through the mail has probably increased in recent years. According to Customs, seizures of parcels containing scheduled/controlled substances at international mail facilities increased by 450% in FY 1999, primarily due to drug sales over the Internet. However, this increase may not have a bearing on the number of imported parcels containing non-controlled substance prescription drugs. In addition, part of the reported rise in the number of seizures may be due to increased surveillance by Customs.

Much of this increase in drug imports appears to be driven by economic factors, particularly by consumers seeking to purchase lower-priced medications from abroad (foreign versions of U.S.-approved drugs), and by individuals who want to purchase medicines without first obtaining a prescription. Most of the latter products are lifestyle drugs, such as Viagra.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, unapproved misbranded, and adulterated drugs are prohibited from importation into the United States, including foreign versions of U.S.-approved medications, as is reimportation of approved drugs made in the United States. In general, all drugs imported by individuals fall into one of these prohibited categories.

From a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice. FDA and the public do not have any assurance that unapproved products are effective or safe, or have been produced under U.S. good manufacturing practices. U.S.-made drugs that are reimported may not have been stored under proper conditions or may not be the real product, because the United States does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit. In addition, some foreign web sites offer to prescribe medicines without a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications because of misdiagnoses, or fail to receive appropriate medications or other medical care.

FDA'S PERSONAL IMPORTATION POLICY

Under FDA's personal importation policy, as described in guidance to the Agency's field personnel, FDA inspectors may exercise enforcement discretion to permit the importation of certain unapproved prescription medication for personal use.

First adopted in 1954 when the small number of personal imports did not warrant devoting significant time and effort to detain such products, the policy has been modified several times over the succeeding years. It was last modified in 1988 in response to concerns about the unavailability of potentially effective treatments for *AIDS* patients. The agency expanded the guidance for humanitarian purposes to allow individuals suffering from serious medical conditions to acquire medical treatments legally available in foreign countries but not approved in the United States.

The current policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug if:

(1) the product is for personal use (a 90-day supply or less and not for resale);

(2) its intended use is for a serious condition for which effective treatment may not be available domestically (and, therefore, the policy does not permit inspectors to allow foreign versions of U.S.-approved drugs in to the United States);

(3) there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product;

(4) the product is considered not to represent an unreasonable risk; and

(5) the individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the U.S. licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

FDA believes that the need for the policy is far less than

when the current version of the policy was developed in 1988. Now due to faster review times and various regulatory mechanisms through which patients can obtain unapproved treatments for humanitarian purposes, the need to import therapies not available in the United States has diminished. (Indeed, approved new drug therapies typically appear in the United States before they are marketed abroad.)

IMPLEMENTATION OF THE PERSONAL IMPORTATION POLICY

At mail facilities, Customs officials identify parcels that may be violative of the FD&C Act. FDA inspectors then determine if these products should or should not be permitted to enter the country. If detained, FDA must issue a notice to the addressee describing the potential federal violation and provide the individual with an opportunity to respond. If the addressee does not respond or provides an inadequate response, FDA will give the parcel to Customs to have it returned to the importer. Due to the notice and opportunity to respond requirements, detaining and refusing entry of mail parcels is resource incentive.

If FDA would adequately enforce the FD&C Act and implement its personal importation policy as written, few personal imports would be allowed into the United States.

The policy is generally not implemented as written because (1) FDA (and Customs) lacks sufficient resources to adequately monitor ports-of-entry; and (2) the personal importation policy as written is difficult to implement, in part, because it is difficult to identify a medicine by its appearance, and labeling may falsely identify a product.

CARSON MAIL FACILITY PILOT

Earlier this year, FDA and Customs conducted a 5-week survey of imported drug products entering the United States through the Carson City, California, mail facility, one of 14 international mail facilities in the United States. The purpose of the pilot was to closely examine incoming mail shipments of pharmaceutical products over a specified time frame in order to identify both the volume and the types of drug products entering the States. FDA also hoped to better assess the resources required to cover mail importations at a mail facility, and to gain a better understanding of what the public health implications of these importations may be for U.S. consumers.

The Carson pilot was accomplished by temporarily reassigning four inspectors from their normal duties to staff the facility on a full-time basis. Typically, FDA staffs the Carson facility with one inspector who provides approximately one half-day service every 1 to 2 weeks, which is the maximum level of resources FDA can allocate to this facility.

Based on this pilot, Customs estimated that it would detain approximately 3,300 packages each *week* at the Carson facility for FDA to examine. To meet this volume and comply with existing notice requirements, FDA would need to deploy at least 12 full-time inspectors at the Carson facility.

PROPOSAL

The number of unapproved prescription drugs imported for personal use is increasing. If FDA does not take a more aggressive approach, consumers could be injured by dangerous imported products and the number of such imports will likely grow, because of the lack of an adequate enforcement presence. Therefore, FDA suggests that:

- The Agency would revoke the application *of the* personal importation policy to mail imports, thereby prohibiting the use of the mail for personal importation of prescription medicines. Patients could still obtain unapproved medications for the treatment of serious conditions for which therapy is not available in the United States through the existing single patient investigational new drug process.
- FDA remove the requirement that it issue a notice before it could refuse and return personal use quantities of FDA-regulated products that appear violative of the FD&C Act. Unless the notice requirement is eliminated, FDA could not effectively prohibit mail importations for personal use. This change will probably require legislation.

As a consequence. FDA could effectively use its current resources to protect the American public from potentially dangerous foreign medications.

Bernard A. Schwetz, D.V.M., Ph.D.

DECISION

Revoke FDA's personal importation policy as it applies to mail and remove the requirement that the Agency first issue a notice before refusing a violative product.

Approved_____ Disapproved_____ Dare_____

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