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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

April 16, 2007

The Honorable Henry Waxman
Chairman, Committee on Oversight and Government Reform
United States House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Waxman:

Per the requirements of sections 1107 and 1108 the ONDCP Reauthorization Act of 2006, I am pleased to provide to the Congress a Strategy to Stop Internet Advertising of Prescription Medicines without a Prescription and a plan to conduct a Study on Diversion and Inappropriate Uses of Prescription Drugs.

In June 2006, the Administration set forth its coordinated effort to reduce prescription drug abuse in the *Synthetic Drug Control Strategy*. This document set a goal of reducing illicit prescription drug use by 15% over three years (2005 – 2008). In addition, the Synthetic Drug Control Strategy highlights the Administration's concern with the problem of Internet diversion and the need for better data regarding prescription drug diversion and inappropriate use.

The enclosed document, developed in consultation with the Drug Enforcement Agency and the Food and Drug Administration, provides specific information regarding the Administration's plans to move forward on these issues. We look forward to continuing to work with Congress, Administration partners, medical providers, and industry to reduce prescription drug abuse and misuse.

Should there be any questions, please contact me directly at (202) 395-6700 or Erin Raden of my Office of Legislative Affairs at (202) 395-4748.

Respectfully,

John P. Walters
Director

Report on Strategy to Stop Internet Advertising of Prescription Medicines without a Prescription and Plan to Conduct a Study on the Diversion and Inappropriate Uses of Prescription Drugs

This report is submitted to the United States Congress pursuant to Sections 1107 and 1108 of the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109-649). Because both reports relate to the illicit use of prescription drugs, the Administration respectfully submits a combined report intended to satisfy both requirements.

Background

The report required in Section 1107 directs the Office of National Drug Control Policy (ONDCP) to submit a "strategy to stop advertisements that provide information about obtaining over the Internet drugs...for which a prescription is required without the use of such lawful prescription." The report in Section 1108 requires, in relevant part, a report "including a plan to conduct a study on the illegal diversion and inappropriate uses of prescription drugs," and further specifies detail as to the nature of that plan.

Both of these requirements complement ongoing Administration efforts to reduce the diversion and misuse of prescription drugs, particularly those listed as Controlled Substances. In the Administration's *Synthetic Drug Control Strategy,* released in June 2006, a goal of reducing illicit prescription drug use by 15% over three years (2005 – 2008) was set. Among other topics, the problem of Internet diversion and the need for better data were both identified as priorities within the Administration's approach to reducing prescription drug abuse.

> **SEC. 1107. REQUIREMENT FOR STRATEGY TO STOP INTERNET ADVERTISING OF PRESCRIPTION MEDICINES WITHOUT A PRESCRIPTION.**
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> Not later than 120 days after the date of the enactment of this Act, the Director of the Office of National Drug Control Policy shall submit to Congress a strategy to stop advertisements that provide information about obtaining over the Internet drugs (as defined in section 702(3) of the Office of National Drug Control Policy Reauthorization Act of 1998) for which a prescription is required without the use of such a lawful prescription.

Discussion

At the outset, the Administration notes that a strategy to stop Internet advertising of prescription medicines without a prescription must be careful not to impede the lawful advertising, and the lawful prescribing and dispensing, of prescription drugs. As a general matter, valid prescriptions are required for prescription drugs to be dispensed legally by online pharmacies that are located domestically and domestic online pharmacies must comply with state licensing and appropriate federal requirements. However, numerous online pharmacies purport to offer prescription drugs such as those containing hydrocodone or oxycodone without a prescription, or offer prescription drugs from outside of the United States, and are functioning outside the law. This includes importing prescription drugs into the United States from Canada or other countries, because imported prescription drugs generally violate the Federal Food, Drug, and Cosmetic Act (FDCA)

since they are typically unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353; see also 21 U.S.C. §§ 331 (a) and/or (d)), or dispensed without a valid prescription (21 U.S.C. §353(b)(1)).

Advertisements for the illicit online pharmacies tend to take two forms: webpage advertisements and mass, unsolicited email advertisements (or "spam" email). The Administration's strategy seeks to respond to both forms.

Webpage Advertisements

Many popular search engines such as Google and Yahoo offer advertising services. Specifically, a business can place advertisements on webpages. Additionally, after searching for a specific product or category of products, search engines like Google respond with both the search results as well as advertising weblinks related to the search topic. In either case, the user "clicks" on the link and is taken to the advertiser's website.

The Drug Enforcement Administration (DEA) and Food and Drug Administration have met with Google and Yahoo to request that advertisements for online pharmacies not be allowed if the advertisement, or the online pharmacy, offers prescription drugs without a valid prescription (including offering to import prescription drugs from outside of the United States), or otherwise violates Federal or State laws (including, but not limited to, the Controlled Substances Act [CSA] or the FDCA). The Food and Drug Administration (FDA) has engaged in an ongoing dialogue with Internet service providers regarding such websites and associated advertising risks. Both Google and Yahoo use a third-party system called PharmacyChecker (located at www.pharmacychecker.com) to verify whether websites seeking to advertise an online pharmacy are legitimate. However, PharmacyChecker has approved several websites from Canada that may be operating lawfully in Canada, but offer prescription drugs to United States consumers in violation of Federal law. Of the 33 Internet pharmacies certified by PharmacyChecker, the majority appear to be Canadian pharmacies offering to provide prescription drugs to Americans; as previously referenced, drugs imported into the U.S. from Canada generally violate the FCDA. Moreover, a recent search on two search engines that utilize PharmacyChecker yielded a website with the same name as a website that was the subject of a public warning issued by FDA in August 2006, thus, raising safety concerns and questions about the certification process.

In addition to the PharmacyChecker website used by those two search engines, there is a more rigorous standard: the National Association of Boards of Pharmacy's (NABP's) Verified Internet Pharmacy Practice Sites (VIPPS), which has certified thirteen online pharmacies as acting lawfully under Federal and relevant State laws. It is important to note that the State Boards of Pharmacy (which are collectively represented by NABP) are the government entities with regulatory authority over all United States pharmacies. VIPPS is currently the only certification system requiring that an online pharmacy be held to the same standards as brick-and-mortar pharmacies regarding compliance with Federal and State laws. However, not all VIPPS pharmacies appear to be recognized in the PharmacyChecker system. For all of these reasons, PharmacyChecker is not an adequate, reliable verification system, and consumers who utilize the service may violate Federal and State laws and regulations.

The DEA, Food and Drug Administration (FDA) and/or ONDCP will meet with the major Internet advertising services (Google, Yahoo and others) to encourage voluntary action such that only online pharmacies in compliance with Federal and State laws are advertised through the major Internet advertising services. Search engines will be requested to voluntarily adopt standards that comply and encourage consumer compliance with Federal and State laws and regulations, and Boards of Pharmacy standards. This will be done in consultation with the State Boards of Pharmacy through the NABP. Criteria for online pharmacies that are in compliance with Federal and State laws will also be disseminated to search engine sites, secondary sites and to consumers who browse search engines.

Concurrently, the DEA continues to target illicit online pharmacies violating Federal law, in part by investigating unsolicited "spam" emails offering prescription drugs without a prescription. The offering of prescription drugs without a prescription is a clear indicator that an online pharmacy is highly likely to be acting in violation of Federal law. The DEA will continue to actively investigate and submit for prosecution cases against online pharmacies (including affiliated web facilitators, physicians or other prescribers, and pharmacists) that violate Federal law. There have been numerous investigations leading to prosecutions of rogue Internet pharmacies over the last several years. Additionally, various components of FDA meet regularly to discuss strategies and take enforcement action against websites that sell drugs online in violation of the FDCA.

Additionally, another important component of the Internet advertising are the payment transfer companies. These are companies that handle the transfer of funds between consumer and business, including some situations where payment is rendered to an Internet advertising company from the website. The DEA and/or ONDCP will also meet with the major payment transfer and credit card companies (e.g., VeriSign) to encourage voluntary action such that customers purporting to be a legitimate online pharmacy are verified, and payment transfer agreements are only initiated and completed with those companies that are in compliance with Federal law.

SEC. 1108. REQUIREMENT FOR STUDY ON DIVERSION AND INAPPROPRIATE USES OF PRESCRIPTION DRUGS.

Not later than 90 days after the date of enactment of this Act, the Director of the Office of National Drug Control Policy, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that includes a plan to conduct a study on the illegal diversion and inappropriate uses of prescription drugs, including the following:

(1) Methods to utilize both public use surveys that are in existence as of the date of enactment of this Act and other surveys to provide appropriate baseline data on the natural history of diversion and abuse of prescription drugs that are included in schedules under the Controlled Substances Act to evaluate the extent and nature of potential problems with such use to guide corrective actions which may reduce such problems without unintentionally hindering access to these drugs for legitimate medical purposes. Specifically, other surveys to be considered are those that address the abuse of these substances on a regional or national basis, and those that address the diversion of these substances on a regional or national basis.

(2) A scientifically based analysis of the relative contribution of both innate and acquired genetic factors, environmental factors, psychological factors, and drug characteristics that contribute to addiction to prescription drugs.

Discussion

Acquiring better data regarding the nature of prescription drug abuse and prescription drug diversion continues to be a priority of the Office of National Drug Control Policy. ONDCP is working with the Office of Applied Studies at the Department of Health and Human Services (HHS), National Institute on Drug Abuse (NIDA), Department of Justice (DOJ), and appropriate external organizations to identify what surveys exist that can be tailored to gain more extensive information, and also what new research will be required to understand the nature of prescription drug abuse and diversion.

The National Survey on Drug Use and Health (NSDUH) is an annual study designed to measure the extent and nature of drug use in the United States. In 2005, for the first time, questions were added to the Survey regarding the source of prescription drug diversion. The results indicated that 60% of prescription drug diversion begins with friends and family. Also identified as source of prescription drug diversion were the Internet, "doctor-shopping," and the exchange of prescription drugs for money (so-called "traditional drug dealing"). Because 60% of diversion is sourced from friends or family for free, the Administration developed "Prescription Drug Disposal Guidelines" which encourage the proper disposal of prescription after the medications are no longer needed (attached).

Additionally, for the 60% of individuals who received prescription drugs from family or friends for free, better information is needed as to where and how the family member or friend originally acquired the prescription drug. For example, it would seem reasonable to presume that some percentage of those family members or friends acquired the prescription drug pursuant to a lawful and a medically necessary prescription, while others did not. However, there is no reliable data indicating what percentage of the family members and friends acquired the prescription drug lawfully. Therefore, in 2006, SAMHSA added questions to the survey designed to elicit this information. Understanding these data will help the Administration improve on a strategy to reach out to medical professionals who prescribe and distribute these medications. These data are expected to become available in September of 2007.

Additionally, the Department of Justice works with most states that have a Prescription Drug Monitoring Program (PDMP). Most of those programs – particularly the ones that receive some grant funding for the program through DOJ's Office of Justice Programs – report on performance. The Department of Justice is examining whether enhanced data can be collected from State PDMPs regarding the sources of prescription drug diversion in each state.

Pursuant to Section 1108 of the Office of National Drug Control Policy Reauthorization Act, the National Institute on Drug Abuse is conducting a review of existing research and data regarding the following topics. The Administration plans to submit the results to Congress in the annual report to Congress on the implementation of the Synthetic Drug Control Strategy in Summer of 2007. NIDA is compiling information regarding existing surveys or studies that include:

1. Data or research on the natural history of diversion and abuse of prescription drugs.

2. Regional surveys or research on the diversion and abuse of prescription drugs.
3. Data or research regarding innate and acquired genetic factors that contribute to an addiction to prescription drugs.
4. Data or research regarding environmental factors that contribute to an addiction to prescription drugs.
5. Data or research regarding psychological factors that contribute to an addiction to prescription drugs.
6. Data or research regarding drug characteristics that contribute to an addiction to prescription drugs.

Additionally, ONDCP will seek to identify data on whether substance abusers (for both illicit drugs and for alcohol) are at a higher risk for prescription drug abuse; whether people who abuse prescription drugs are at higher risk for abusing other illicit drugs; and what medical indications tend to result in prescriptions for controlled substances outside conventionally recommended levels for specific conditions.

The DEA has threat assessments documenting the history of diversion of prescription drugs, and these will be incorporated into the study. Based on the presence or absence of these studies and surveys, ONDCP and NIDA will identify further research needs. These will be included in the Summer 2007 report to Congress on the implementation of the Synthetic Drug Control Strategy.