

Written Statement of James A. Dahl

SUBMITTED TO THE COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

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Mr. Chairman and members of the committee, thank you for the opportunity to testify today on this important issue. I appear before you as the recently retired Assistant Director of the FDA's Office of Criminal Investigations (OCI). I do not purport to represent the official position of the government on any topic, but I do hope to share the interests and opinions of the hard working special agents of FDA/OCI who have had considerable experience with many of the issues you are addressing today.

As you know the problem of foreign and domestic internet sales of controlled substances and other dangerous pharmaceutical products is a large and complex issue that appears to be growing exponentially. The problem is complicated by a myriad of political, commercial, public health, education, legal, and enforcement issues. I would like to direct my comments today to matters most closely related to the criminal enforcement component of the issue.

These dangerous drug products are sold using a number of schemes with an endless number of variations. The most common is the direct internet sale of finished dosage form drugs which too many Americans have come to view as a quasi- legal source for obtaining

what they choose to believe, but are unable to verify, are legitimate drugs. The websites of most concern are those that offer controlled substances along with many non-controlled “lifestyle” drugs. These websites often tout on-line physician consultations that almost always result in the sought after prescription. Although DEA regulations do not recognize this as a valid doctor patient relationship the various state laws regulating non-controlled prescription drugs vary widely on what constitutes that relationship. The propensity of these websites to accept any type of consumer supplied prescription ensures their continued growth in sales. Many other websites offer these dangerous products without any prescription whatsoever. The only real concern of the owners of these internet operations is not the health and well being of the consumer, but their ability to collect payment through the credit card used for the purchase.

Any kind of meaningful interdiction of the small, and not so small parcels, containing these drug products is almost impossible given the enormous volume of packages, the lack of sufficient government resources, and the cumbersome bureaucracy surrounding the seizure and ultimate destruction of the products. The purveyors of these products operate in a largely anonymous fashion through the use of complex networks sometimes involving hundreds of foreign and domestic website domain registrations, dozens of internet service providers and host computers at sites all over the globe, multiple packaging and shipping centers, and numerous domestic and international credit card processing and banking relationships.

Another problem is the use of the internet to distribute dangerous pharmaceutical chemicals usually intended for use by young people as hallucinogenic, weight loss, rave or

party drugs. Some of these chemicals may themselves be controlled by the DEA, but others are new designer drugs that may or may not be legally defined as controlled substance analogs. Even some over the counter (OTC) drugs are being sold in bulk quantities, put into capsules or other forms, and sold to teenagers as “legal” products. A common method of distribution of these chemicals is the use of internet “chat rooms” or message boards in which the products are “discussed” anonymously by interested parties. Methods of use including dosage and preparation are “discussed,” and websites selling the dangerous products are identified in the “chat rooms.” The websites themselves are usually full of disclaimers saying “not intended for human use” or “for research purposes only.” But our experience is their customers intend to use and/or further distribute the drugs, and the sellers clearly understand and cater to the (human) uses to which their products will be put.

The above described products are extremely dangerous not only because of the chemicals themselves, but especially because of the experimental method of self-dosage and the word of mouth tendency to call them “legal” or “natural” and by inference “safe” products. A few examples:

- Earlier this year five young people died over a three month period after overdosing on DXM (dextromethorphan), a common ingredient in OTC cough medications. The bulk material was purchased from an Asian chemical supplier, shipped to the United States, placed into capsules in Indiana, and sold nationwide over a domestic internet site. Although the FDA public health notice and follow up on this particular case was extremely weak, OCI was very

successful in quickly identifying and arresting the seller of this deadly product thereby putting him out of business.

- In another OCI case worked jointly with the DEA, search warrants executed at a location selling DXM, ecstasy analogs, and other controlled substance analog products disclosed a drug production and distribution operation that was filled with trash, lacked any attempt at GMPs, and had hazardous materials and other chemicals stored without any regard to safety. At least one death has been directly linked to this operation.
- A 2003 OCI investigation led to a mail fraud conviction for an individual selling DNP (2,4 Dinitrophenol) over the internet using the name “Dr. Evil.” He was promoting DNP for weight loss and body building uses, and his sales were linked to the death of one individual and several other very serious overdoses. DNP use for weight loss resulted in numerous deaths in the 1920s and 1930s and has been cited as one of the reasons for the passage of the Food and Drug Act in 1938.

Other illegal drug schemes involve products intended for athletic enhancement. The well publicized BALCO case being investigated by the IRS and FDA/OCI involves the illegal distribution of THG (tetrahydrogestrinone), to professional and world class athletes. Because THG was not yet listed as a controlled substance analog the primary criminal drug violation charged in the indictments is a Federal Food Drug and Cosmetic Act offense. You can be sure that other steroid analogs are constantly being developed for use in international athletic competition circles.

Along the same line huge quantities of human growth hormone (HGH) are being distributed illegally in the U.S. for athletic enhancement, fat loss, and age-slowng purposes. Because of its propensity for abuse and the dangers associated with unapproved use, HGH is addressed by a specific FD&C Act section making all off-label distribution and possession with the intent to distribute illegal. 21 USC 333(f). The growing abuse of human growth hormone can be linked to FDA's inaction with respect to enormous quantities of Asian HGH being allowed to cross our borders. Many American firms now openly import bulk amounts of HGH, and the problem is worsening daily. Too often these growth hormone products end up being distributed to aspiring young athletes along with illegal steroid products.

OCI has been involved in many joint criminal investigations with the Drug Enforcement Administration, the Bureau of Immigration and Customs Enforcement, the Federal Bureau of Investigation, the Postal Inspection Service, and various state and local law enforcement agencies. OCI actively seeks these joint investigations in order to leverage its very meager FTE resources of only 185 special agents. Joint cases also assist OCI investigations through the application of modern law enforcement powers, which otherwise are not always available to the FDA. These include criminal laws that adequately address the offensive conduct, maximum sentences and sentencing guidelines that effectively deter and punish that conduct, direct forfeiture authority that allows for effective dismantling of criminal organizations and the seizure of illegal proceeds, and administrative subpoena authority to promote timely, efficient and effective investigations.

In August 2005 I and an OCI colleague received a briefing at the DEA Special Operations Division (SOD) on their relatively new program for including internet controlled substance intelligence as part of the multi-agency SOD effort to analyze and track this type of criminal activity. This is clearly a step in the right direction and seeks to integrate and analyze all available U.S. Government information in one location. DEA extended an invitation for OCI to participate in this effort and it was clearly understood that there were mutual benefits to be obtained through the sharing of information on a real time basis and leveraging our combined skills and interests. To date, resource limitations have precluded OCI from assigning anyone to DEA/SOD.

The most current information I have is that FDA/OCI has two headquarters FTEs whose primary duties are to address internet crime (although drugs are their primary focus other illegal products sold over the internet are also their responsibility). There are no field agents fully devoted to this or any other specific issue within OCI's jurisdiction. In addition OCI has no presence in overseas locations where much of this problem originates.

Although most of the drugs discussed here today fall within the primary jurisdiction of the DEA and the Controlled Substances Act, FDA/OCI must be part of the overall enforcement strategy if the problem is to be fully addressed. There are just too many emerging, and as yet non-controlled, designer drugs, lifestyle drugs, and other related prescription drug investigations to leave OCI and FDA out of the enforcement part of the solution. But in my opinion FDA will not act on its own to emphasize and enhance OCI's potential contributions to a more robust enforcement effort. Congress will have to prod the

agency through direct appropriations for these efforts or through more aggressive Congressional oversight.

Recent Congressional efforts to pass new legislation to regulate internet drug sales have become bogged down in the complex political, legal, and commercial issues we read so much about. These problems must be overcome. In my personal (FDA/OCI influenced) opinion, any new legislation should also enhance the FDA portion of the enforcement solution to this problem. I suggest that the legislation include provisions for:

- More FTEs and operational funding so OCI can enhance its field and headquarters investigative and analytical efforts, begin to establish a formal strategy to effectively pursue criminal targets in foreign countries, and fully participate in multi-agency efforts such as the DEA/SOD initiative;
- Better laws to address pharmaceutical crime including: more severe maximum penalties linked to the actual or potential harm to individuals; improved sentencing guidelines; administrative subpoena authority; direct forfeiture authority; and a simplified and efficient method for interdicting and disposing of illegal imports.
- Extra-territorial jurisdiction allowing all U.S. law-enforcement agencies to prosecute foreign based individuals and organizations selling illegal dangerous drugs in the U.S. marketplace.

I would be pleased to continue to assist Committee staff in addressing any of the issues discussed here today. Thank you for the opportunity to contribute to this important discussion.

Statement Summary of James A. Dahl
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on Internet Drug Distribution, December 13, 2005

- Description of the problems associated with internet drug distribution
 - Direct finished dosage form drugs through complex international systems
 - Pharmaceutical chemical and CS analog sales advertised through internet “chat rooms” and message boards
 - Dangerous drugs for athletic enhancement, weight loss and other uses
 - Not all of our most dangerous products are covered by the CSA

- Effective enforcement methods
 - Joint investigations (FDA/OCI – DEA – FBI – ICE, etc.)
 - Sharing/Analysis of intelligence (DEA/SOD offer to FDA/OCI)

- Needs / Solutions
 - Realization by FDA that criminal enforcement cannot remain status quo
 - Increased in FTE resources and operational funding for FDA/OCI
 - New legislation to provide FDA with necessary enforcement tools including stricter penalties, better sentencing guidelines, administrative subpoena authority, direct forfeiture authority, and authorization the efficiently interdict violative products at ports of entry