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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

JOE BARTON, TEXAS
CHAIRMAN

September 22, 2004

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BUD ALBRIGHT, STAFF DIRECTOR

The Honorable David M. Walker
Comptroller General
Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

I am writing to thank you for your ongoing work on the entry of controlled substances into this country through mail and consignment delivery, and to provide you with additional information. Attached is a response from the U.S. Drug Enforcement Agency (DEA) dated July 26, 2004, to my letter of May 5, 2004, to DEA Administrator Karen Tandy (also attached). My original correspondence underscored a number of concerns repeatedly voiced to DEA regarding the growing flow of controlled substances entering the United States through the international U.S. mail facilities and the express consignment carriers (such as Federal Express and United Parcel Service). Unfortunately, the vagueness of the responses to my questions continues to convince me that neither the DEA nor the Bureau of Customs and Border Protection (Customs), has a workable strategy on how to effectively confront the growing problem of controlled substances entering the U.S. through these facilities. Moreover, nothing in this correspondence suggests that DEA is making progress at a rate even closely approximating the dimensions of this problem.

Significant quantities of scheduled drugs are continuing to enter this country. Customs inspectors continue to be overwhelmed by both the volume and the antiquated system used to seize and process inbound drugs. Inconsistencies on how to handle large shipments of dangerous drugs (e.g., known counterfeit or controlled substances) are apparently still occurring from facility to facility. There is no indication that a meaningful strategy exists on how to effectively work with the credit card companies and the express consignment carriers, both of which are being used by rogue drug peddlers to circumvent U.S. law. In short, DEA's response to this problem continues to appear outdated, unrealistic, and notably unsuccessful.

On November 13, 2004, I wrote you to request that GAO examine how DEA, Customs and FDA are addressing the growing problem of controlled substances entering the U.S. via these mail facilities. The attached correspondence from DEA should help in your ongoing work, and also raises the following questions:

1. DEA mentions that the President has put forward a comprehensive written plan in the National Drug Control Strategy. Does this plan adequately address the multitude of issues repeatedly observed at various airport mail facilities by our respective staff?
2. Is DEA making significant progress in shutting down those purveyors who are illegally shipping controlled substances into the U.S.? Does the Agency have any measures to demonstrate what progress is being made? If not, why not, and how is DEA assessing its progress in addressing this growing threat to public health?
3. Does DEA's plan to undertake a comprehensive approach to working with the express consignment carriers and credit card companies seem effective? Specifically, what is that plan and how much work has been done by DEA to create a methodology that will include these entities? Have these plans been shared with the Department of Justice (DOJ)? Moreover, has DEA asked DOJ to conduct the requisite legal analysis to understand what the agency can or cannot do in terms of conducting "controlled purchases" of scheduled drugs from foreign web sites working with the credit card companies?
4. Reference is made in the attached DEA correspondence that DOJ is in the process of reviewing legislative proposals to provide "enhanced authorities to address the problem of 'rogue' internet pharmacies." What are these proposals and specifically what agencies are working on them? I have heard vague references to such proposals for years, and nothing of significance has come from either the DOJ or the DEA on this matter. Are these new proposals and have they been turned over to GAO for any review?

GAO's evaluation of the efforts by both DEA and Customs to stem the growing tide of controlled substances entering the U.S. via the mail from foreign sources will be of great use to the Congress, and it would be very helpful if the GAO's ongoing work could address these additional issues. If you have any additional questions on this matter, please have your staff contact Christopher Knauer, Minority Investigator with the Committee on Energy and Commerce, at 202-226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER

The Honorable David M. Walker
Page 3

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Norm Coleman
United States Senate

The Honorable Carl Levin
United States Senate

The Honorable Karen Tandy, Administrator
Drug Enforcement Administration

The Honorable Robert C. Bonner, Commissioner
United States Customs Service

Lester M. Crawford, D.V.M., Ph.D, Acting Commissioner
Food and Drug Administration



U. S. Department of Justice
Drug Enforcement Administration

AUG 04 2004

www.dea.gov

Washington, D.C. 20537

JUL 26 2004

The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Dingell:

Thank you for your letter of May 5 to Administrator Tandy reiterating your concerns with respect to the problem of illegal entry of controlled pharmaceuticals into the United States by mail resulting from illegal sales over the internet. I apologize for the delay in this response.

The President's National Drug Control Strategy for 2004, issued on March 1 of this year, set forth a comprehensive and coordinated national plan to deal with the problem of illegal diversion and abuse of prescription drugs, including the proliferation of "rogue" internet pharmacies. For our part, the Drug Enforcement Administration ("DEA") has been working to implement the enforcement initiatives outlined in Administrator Tandy's January 14, 2004 letter to you, including improved capacity to identify illicit internet pharmacy operations, increased DEA staffing and resources dedicated to the problem of diversion over the internet, and closer cooperation with organizations inside and outside the government on related matters. The online investigations system you discussed in your letter is now operational and providing investigative information.

We appreciate your continued comments, suggestions and questions on these initiatives and will continue to take them into account in addressing the problem of "rogue" internet pharmacies. Specifically, you asked us to address the following questions:

1. Does DEA have a coordinated comprehensive written plan to address what is clearly a growing threat to the public health? If so, please provide that plan. If not, please explain why no such plan exists and/or whether such a plan is being prepared.

As I mentioned earlier, the President put forward a comprehensive written plan in the National Drug Control Strategy for his Administration to address the problem of illegal diversion and abuse of prescription drugs as a whole. A summary of the relevant portion of the Strategy is enclosed for your information.

2. Has DEA determined whether Customs has the ability to change its internal "processing" procedures with respect to personal (or small) shipments of controlled substances (Schedules II-V) entering the U.S. via the U.S. mail, and the major consignment carriers? Is it planning to do so? Also, please describe (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process controlled substances; and (2) the average time it takes Customs inspector to process a single package containing a controlled substance.

I am unable to respond to questions regarding internal procedures of another federal agency, but the DEA is not aware of any specific changes that have taken place with respect to handling small packages containing controlled substances at international mail facilities. We are continuing to work closely with the Bureau of Customs and Border Protection ("CBP") and the Food and Drug Administration ("FDA") to review and streamline relevant procedures. The DEA does not maintain specific statistics regarding time expended by Customs personnel on inspections or processing of incoming shipments of controlled substances, but we are certainly aware that the volume of such parcels is significant and must be addressed as a priority.

3. How rapidly is the quantity of unregulated dangerous drugs entering the U.S. via mail, and mail-related channels, growing? Does DEA have estimates of the quantity of prescription drugs that are now entering the U.S. each month via (1) the U.S. mail facilities and (2) the major consignment carriers? Are they collecting meaningful data on this problem, and if so, in what form? If not, why are such statistics not gathered?

The DEA does not specifically estimate the quantity of illegal imports of pharmaceutical controlled substances entering the United States through the mail and by private carriers. This is because CBP has primary responsibility for illegal entries at U.S. ports of entry. Again, however, we are aware that the volume is significant and must be addressed as a priority.

4. Does DEA have a plan to address the problem of the many Internet sites that purportedly appear to be both advertising and shipping controlled substances into the U.S. via Federal Express, United Parcel Service, and all other relevant consignment carriers? If so, please describe that plan in detail and how it changed since the late 1990's. Does DEA believe that the consignment companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that consignment carriers are making as a result of these illegal drug transactions?

The National Drug Control Strategy directs federal agencies to enlist the support of responsible businesses affiliated with online commercial transactions, including credit card companies, shippers, and Internet service providers. These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require internet pharmacies to display on their websites the physical street address of their primary business locations.

Officials from the DEA have already held several meetings with both Federal Express (FedEx) and United Parcel Service (UPS) on this issue and have also visited the FedEx Mail Hub in Memphis, Tennessee to evaluate the processing of international parcels. Both FedEx and UPS continue to support

DEA investigative informational requests and are aware that their businesses are being exploited for illegal purposes. DEA has no overall estimate of the profit these companies are generating from individuals exploiting their businesses to facilitate illegal imports.

Our investigations related to the internet have significantly increased since the late 1990s, when it became clear that internet drug sales were undergoing a transition from "lifestyle" drugs (such as Propecia and Xenical) to controlled pharmaceutical substances.

5. What role does DEA believe that the major credit card companies (such as Visa and MasterCard) and underwriting banks are playing in selling controlled substances via the Internet? Does DEA believe that these credit card companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that credit card companies are making as a result of these illegal sales?

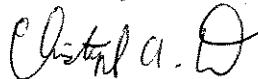
One of the key elements of Administrator Tandy's vision for the DEA is to renew a significant emphasis on taking away the proceeds of all illicit drug trade. Accordingly, DEA officials have met with both Visa and Master Card. Both companies are aware that their businesses are being exploited for illicit purposes and are willing to assist in investigations. It is important to note, however, that legal and operational issues may bear on a case-by-case basis on the ability to cut off accounts used by illicit internet pharmacy sites. The DEA does not have a reliable estimate of the amount of money that is flowing as a result of these illegal sales.

6. What additional legal authority is needed? I note that informal requests from Congressional staff for comments on draft language have gone unanswered. Have you considered whether new laws are needed? What was your conclusion, and why?

The Department of Justice is in the process of reviewing legislative proposals to provide enhanced authorities to address the problem of "rogue" internet pharmacies. We appreciate your interest and support on this issue and will provide additional information as soon as it is available.

We look forward to continuing to work with you on this important matter. Please let my office know whenever we may be of assistance.

Sincerely,



Christopher A. Donesa

Chief

Congressional and Public Affairs

Enclosure

REDUCING PRESCRIPTION DRUG ABUSE

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. Emergency room visits associated with narcotic pain relievers have increased 163 percent since 1995.

The President's National Drug Control Strategy engages Federal, state, and local officials; the medical community; and businesses working in the area of Internet commerce to prevent and stop the illegal sale, diversion, and abuse of prescription psychotherapeutic drugs.

The Strategy focuses on three core tactics for reducing prescription drug abuse:

- Business outreach and consumer protection
- Investigation and enforcement against the illegal sale and diversion of prescription drugs
- Education and training of physicians and consumers

Business Outreach and Consumer Protection: The Food and Drug Administration (FDA) will work to ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances so that commercial advertising fully discloses safety issues associated with the drug's use. Specific examples include labeling that properly identifies patients for whom these products are appropriate and that recommends a "stepped care" approach to the treatment of chronic pain, in accordance with treatment guidelines.

- FDA will consider Risk Management Programs (RiskMAPs) during the approval process for Schedule II opiate drug products. RiskMAPs help ensure the safe prescription and use of these drugs through identification of appropriate patients and monitoring for adverse outcomes.
- FDA, the Drug Enforcement Administration (DEA), and the White House Office of National Drug Control Policy will work with physician organizations to encourage comprehensive patient assessment prior to prescription of opiate therapy. Identification of persons at risk for opiate abuse and addiction will help their medical caretakers to more effectively monitor for signs of abuse.
- Federal agencies are enlisting the support of responsible businesses affiliated with online commercial transactions. Such businesses include credit card companies, shippers, and Internet Service Providers (ISP). These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require Internet pharmacies to display on their websites the physical street address of their primary business locations.

Investigation and Enforcement: The Internet is one of the most popular sources of diverted prescription drugs. An increasing number of rogue pharmacies – or "pill mills" – offer controlled substances and other prescriptions direct to consumers online. These unscrupulous entities are often foreign-based and undermine state licensing systems, exposing consumers to potentially counterfeit, adulterated, and contaminated products.

- The FDA's Office of Criminal Investigations (OCI) and DEA work together on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances.

Investigation and Enforcement (continued):

- DEA will deploy sophisticated web crawler/data mining technology to generate investigative leads that could lead to enforcement actions against illegal pill mills.
- ONDCP and DEA will work with state officials to expand the number of Prescription Monitoring Programs (PMPs) and to facilitate information sharing among jurisdictions. Currently, 20 states have PMPs to identify individuals who attempt to fill multiple prescriptions from numerous doctors ("doctor shopping"). This information can help reputable physicians and pharmacies prevent illegal diversion of controlled substances.
- FDA and U.S. Customs and Border Protection (CBP), with assistance from DEA, continue to do spot examinations of mail and courier shipments for foreign drugs to U.S. consumers to help FDA and CBP target, identify, and stop illegal and potentially unsafe drugs from entering the U.S. from foreign countries via mail and common carriers.

Education and Training: One potential means of preventing diversion and abuse of prescription drugs is wider dissemination of continuing medical education programs for physicians and other health professionals regarding pain management. These programs will seek to balance the legitimate needs of patients against the risk of diversion and abuse.

- The DEA, with support from the FDA, is working to consult with medical associations to identify existing best practices in physician training in the field of pain management. The agencies plan to develop a mechanism to support the wider dissemination and completion of approved Continuing Medical Education (CME) courses for physicians who prescribe controlled substances. The curriculum will educate doctors on the appropriate medical use of opioids as well as the risks of abuse and addiction.
- ONDCP, DEA, and FDA will develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making direct purchases of controlled substances online. Currently, FDA, along with its sister agency, the Substance Abuse and Mental Health Services Administration (SAMHSA), have jointly developed a public service announcement campaign to better educate consumers on the abuse of prescription pain killers.

Protecting Safe and Effective Use of Medications: Some estimate that more than 10 million Americans suffer from chronic pain. The efforts outlined in the National Drug Control Strategy to prevent and reduce the diversion and abuse of prescription drugs will help to ensure that patients have full and appropriate access to the medications that best meet their needs and that their healthcare providers are informed and trained to effectively manage pain while limiting potential for misuse, abuse, and addiction.

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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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CHAIRMAN

May 5, 2004

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RUD ALBRIGHT, STAFF DIRECTOR

The Honorable Karen Tandy
Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, Virginia 22301

Dear Administrator Tandy:

I am writing to you because of the failure of the Drug Enforcement Administration (DEA) to address adequately the continuing and increasing problem posed by the thousands of illegal controlled substances now entering the United States each day through the consignment carriers and the many international mail branch facilities. Both the scale and the diversity of controlled substances now entering the U.S. through various mail systems have grown exponentially over the last five years.

The issue of controlled substances entering the U.S. via the consignment carriers and international mail facilities has been a concern of mine for years. Moreover, it has also been the subject of numerous hearings held before the Committee on Energy and Commerce (at which DEA, Customs, and FDA have all provided testimony). To this latter point, I am attaching a copy of the relevant pages of a hearing held July 30, 1999, before the Subcommittee on Oversight and Investigations of this Committee. These passages are important because they represent the testimony of FDA and the Department of Justice regarding their plan to address this problem almost five years ago.

The central themes of this previous plan, however, appear largely identical to the proposals now being discussed by your agency, as evident in a recent briefing given to Committee staff by senior DEA and Department of Justice officials. The individuals at that briefing told staff of a "strategic plan" to have a functioning "webcrawler" and the formation of a new interagency "task force" to coordinate how to best approach this issue. Yet this "new" task force (made up of the very agencies that have been involved in previous task forces on this matter -- namely FDA, Customs, and DEA) appears strikingly similar to the task force of the late 1990s.

Moreover, according to your senior staff, this new task force is to develop strategies for the use of information gleaned from the new webcrawler to then shut down foreign rogue sites and offending shippers. But the formation of a special webcrawler was the centerpiece of the strategic plan of 1999, and that earlier task force and the earlier webcrawler failed to make a dent in this problem. And DEA officials at this latest briefing were not even aware that an earlier webcrawler had been developed and deployed by FDA.

DEA lawyers and operational managers at the briefing offered the same tactics and procedures that have so far proved completely ineffective in dealing with this matter. Those tactics are based largely on the traditional narcotics enforcement model which, unfortunately, appears to have little realistic application to the problem of individual imports of schedules II-V drugs ordered over the Internet, which are often comprised of relatively small shipments going to individuals. DEA officials informed staff that upon the identification of these foreign traffickers, DEA field offices (in the counties from where drugs were sent) would be supplied this information and then asked to procure the assistance of foreign governments to halt such shipments (and then presumably apply whatever criminal sanctions were available under the foreign law). When asked how often this model has, over the past five years, resulted in shutting down illegal websites and shippers sending drugs to the U.S., no estimates could be obtained from DEA. To my recollection, in the past five years, this approach has only resulted in shutting down a single website (after substantial work with the government of Thailand). Of course, hundreds of websites are currently offering dangerous drugs for sale to U.S. residents. Given the time involved in shutting down this single site, it is unrealistic to expect this model to have any measurable impact on the broader problem.

Some apparently believe this ineffectual model must be followed in order to avoid contaminating potential criminal prosecutions or compromising the rights of the traffickers. There might be some justification for this position regarding domestic internet sites operated by U.S. citizens. It is clear, however, that regardless of the effectiveness of the new webcrawler, this model will result in few (if any) criminal prosecutions of foreigners involved in foreign websites. Nonetheless, the DEA apparently refuses to consider alternative means of stopping these shipments.

On February 24, 2004, I sent you a letter which described a potential solution to this burgeoning problem. DEA was informed that at least one, and probably all, major credit card companies and at least one, and probably all, major consignment carriers were prepared to work with the DEA to cut off the credit and the shipping rights of anyone using their cards or shipping services to traffic controlled substances into the United States. Because such imports are illegal, several of these firms were told by your agency that they were not permitted to make the "buys" necessary to identify which of their customers are violating U.S. law. Our discussions, however, have produced assurances that these private sector firms would act unilaterally and quickly deny the banking services necessary to facilitate these shipments. This would require that DEA conduct the necessary foreign "buys" so that the scofflaw sites could be identified, something I see no evidence DEA is doing.

Because these offers of private sector assistance were made to Congressional staff, it would appear that DEA would have little trouble working out an acceptable program that would at least assure a substantial dent in this form of drug dealing. Not only could some Internet sites be shut down quickly, but the increase in uncertainty of receiving the ordered contraband from any Internet site would presumably deter adolescents and other U.S. customers of these drugs from placing orders at all. While your agency provided some vague concerns about various court rulings on this matter, neither DEA nor the DOJ staff provided any formal analysis or opinion as to whether this was feasible.

DEA, of course, is only part of the problem. Customs has failed to modernize its regulations dealing with an important administrative roadblock caused by the sheer volume of these illegal imports. Specifically, Customs requires a strict accounting of the receipt and disposition of all imports that violate the Controlled Substances Act. This would appear appropriate as a means of assuring that these dangerous but valuable street drugs do not get lost or stolen in the interdiction and destruction process. This is arguably necessary when dealing with tons of marijuana, and kilos of cocaine, but dangerously inefficient in the processing of thousands of relatively smaller shipments of schedules II-V substances. For example, Customs field officials have repeatedly told staff that they spend between 30 minutes to more than an hour to seize (e.g., process paperwork) a single shipment of a controlled substance that arrives in a mail facility. When hundreds if not thousands of shipments may arrive weekly, this is clearly untenable. Customs has undoubtedly been informed of these inefficiencies from its inspectors at the international mail facilities. Additionally, Customs officials have been informed in private briefings, and public hearings, of our concerns for at least the past four years. Clearly, some provision must be made to deal with bulk-drug custody (and accounting) and subsequent destruction. But, to my knowledge, this critical bottleneck has not been alleviated, nor has DEA exerted any leadership or initiative to rectify this failure.

In conclusion, I remain highly skeptical that a new webcrawler, a new task force, working closely with foreign countries to seek criminal prosecutions of offending shippers, and sending cease and desist letters -- tactics which have all been tried in the past -- will help significantly. New approaches are clearly needed. Moreover, until FDA deploys more inspectors at the mail facilities (which it has not asked for) and DEA, Customs, and FDA obtain the tools they need to rapidly seize and destroy the illegal and dangerous substances entering these facilities (which will require new legislation, yet to be proposed), the flood of illegal controlled substances will only worsen.

Please reexamine the adequacy and effectiveness of your agency's policies and procedures. As part of that review, please respond to the following questions:

1. Does DEA have a coordinated comprehensive written plan to address what is clearly a growing threat to the public health? If so, please provide that plan. If not, please explain why no such plan exists and/or whether such a plan is being prepared.

2. Has DEA determined whether Customs has the ability to change its internal "processing" procedures with respect to personal (or small) shipments of controlled substances (Schedules II-V) entering the U.S. via the U.S. mail, and the major consignment carriers? Is it planning to do so? Also, please describe (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process controlled substances; and (2) the average time it takes a Customs inspector to process a single package containing a controlled substance.
3. How rapidly is the quantity of unregulated dangerous drugs entering the U.S. via mail, and mail-related channels, growing? Does DEA have estimates of the quantity of prescription drugs that are now entering the U.S. each month via (1) the U.S. mail facilities and (2) the major consignment carriers? Are they collecting meaningful data on this problem, and if so, in what form? If not, why are such statistics not gathered?
4. Does DEA have a plan to address the problem of the many Internet sites that purportedly appear to be both advertising and shipping illegal controlled substances into the U.S. via Federal Express, United Parcel Service, and all other relevant consignment carriers? If so, please describe that plan in detail and how it has changed since the late 1990s. Does DEA believe that the consignment companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that consignment carriers are making as a result of these illegal drug transactions?
5. What role does DEA believe that the major credit card companies (such as Visa and Master Charge) and underwriting banks are playing in selling controlled substances via the Internet? Does DEA believe that these credit card companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that credit card companies are making as a result of these illegal sales?
6. What additional legal authority is needed? I note that informal requests from Congressional staff for comments on draft language have gone unanswered. Have you considered whether new laws are needed? What was your conclusion, and why?

Thank you for your assistance in addressing this extremely important public health matter. If you have any questions about this request, please contact me or have your staff contact Christopher Knauer or David Nelson of the Committee on Energy and Commerce Democratic staff at (202) 226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER

The Honorable Karen Tandy
Page 5

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services

The Honorable Robert C. Bonner, Commissioner
United States Customs Service

Lester M. Crawford, D.V.M., Ph.D, Acting Commissioner
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Mr. John P. Walters, Director
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