COUNTERFEIT PHARMACEUTICAL INTER-AGENCY WORKING GROUP REPORT TO THE VICE PRESIDENT OF THE UNITED STATES AND TO CONGRESS

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Counterfeit Pharmaceutical Inter-agency Working Group Report to the Vice President of the United States and to Congress

This report was prepared by the Office of the Intellectual Property Enforcement Coordinator, the Food and Drug Administration, U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, the Departments of Justice, State, and Commerce, and the Agency for International Development. Recommendations contained herein are being presented to the Vice President of the United States and to Congress.

Introduction

This Administration is focused on rebuilding the American economy, creating jobs, and increasing exports. To do so, we must be vigilant in enforcing our intellectual property rights. It is also of paramount importance to protect the public health. The U.S. has stringent statutory, regulatory and enforcement regimes to protect consumers against dangerous counterfeit, unapproved or illegally prescribed pharmaceuticals. However, increasing access to the Internet coupled with new methods of manufacturing and distributing illegal pharmaceuticals have created new challenges to safeguarding the legitimate pharmaceutical supply chain. Thousands of websites openly sell unapproved and/or counterfeit drugs, as well as prescription drugs without requiring a valid prescription, all in violation of federal and state law. Many of those sites are hosted by U.S. registrars, accept payment by U.S. payment processors, and ship their products via U.S.-based express courier companies or the U.S. Postal Service. In addition, other countries, particularly those in Africa, face extremely high percentages of counterfeits in their domestic supply chain and the United States is committed to helping them to address this scourge.

Counterfeit medicines use a falsified mark in connection with a genuine medicine with the intent to deceive consumers. Subsequently, counterfeit medicines have not undergone regulatory review and thus must be considered substandard. Although it is difficult to quantify the harm caused globally by counterfeit drugs, it is clear they pose a significant and growing threat to health at both the individual and the community levels, potentially causing treatment failure or death and contribution to increased anti-microbial resistance. Last year, counterfeit anti-anxiety drugs sold to U.S. consumers over the Internet were found to contain pentobarbital—a drug typically used for sedation before administering lethal injections. This year, counterfeits of a U.S. company's vaccine for pneumococcal bacteria distributed in El Salvador, were found to be missing the essential ingredient—providing families with a false sense of disease protection. Similarly, counterfeits of two cancer drugs trademarked by a U.S. company and illegally manufactured in China and Indonesia were devoid of the critical active ingredient for the treatment of cancer.

The U.S. government will not wait for a full-blown crisis before taking appropriate action. This fall, Victoria Espinel, the White House Intellectual Property Enforcement Coordinator, led a comprehensive study of this issue. The outcomes of that study are contained in this report.

Espinel also challenged the private sector to voluntarily participate in the effort to address rogue online pharmacies responsible for distributing illegal pharmaceuticals. The private sector rose to this challenge and, on December 14, 2010, the White House announced that American Express, eNom, GoDaddy, Google, MasterCard, Microsoft, Network Solutions, Neustar, PayPal, Visa, and Yahoo! have agreed to support a non-profit group which will educate the public and start taking voluntary enforcement action against illegal Internet pharmacies.

The U.S. government will remain vigilant. We will increase our enforcement efforts and continue to collaborate with our foreign law enforcement partners to disrupt and dismantle illicit networks trading in these harmful counterfeits. We will explore new and creative solutions to stop the trade in counterfeit medications and relieve our express courier and U.S. mail facilities of the burden of the thousands of small packages being shipped from illegal pharmacies worldwide. And, we will increase training and public awareness efforts, both domestically and internationally.

Counterfeit pharmaceuticals are not just an issue within the United States—they are a global health problem. The United States will not only be leading by example domestically, but also support the fight against this global crime internationally.

The following report is the product of a collaborative effort among U.S. government agencies with equities in the issues related to counterfeit medicines. These agencies will continue to work together in the coming months to implement this plan, and to make certain that the U.S. government is doing everything possible to protect U.S. consumers against this growing threat.

1. Law Enforcement Actions Domestically—Striving for a More Strategic Approach, Obtaining Better Data, and Sharing Information

Background on the Relevant Responsibilities of Federal Law Enforcement in the Interdiction of Counterfeit/Illegal Pharmaceuticals Domestically

U.S. Customs and Border Protection (CBP) is the primary federal agency responsible for securing America's borders. The Agency has broad authority to act against imports that violate U.S. laws. Its Intellectual Property Rights (IPR) strategy is multi-layered and includes: partnerships with the private sector to secure supply chains and share intelligence; identifying, seizing, forfeiting, and destroying products that infringe trademarks and copyrights; denying entry to goods that violate exclusion orders issued by the U.S. International Trade Commission; conducting audits of importers; levying monetary penalties; and supporting criminal investigations. CBP works with other federal agencies, including ICE and FDA, to enforce their laws at the border.

The Food and Drug Administration (FDA) is the federal public health agency responsible for approving drugs and medical products for safety, efficacy, and quality. Given the global nature of the pharmaceutical and medical product industries, FDA also works with industry and other relevant law enforcement agencies, such as the Drug Enforcement Administration, Customs and Border Protection, and U.S.

Postal Service inspectors, to secure the increasingly complex global drug supply chain. FDA has been incorporating a risk-based strategy into its efforts to identify drugs most likely to be counterfeited, contaminated, or adulterated. This risk based approach is being applied in its enforcement efforts at the border to target shipments for additional sampling and testing. FDA's Office of Criminal Investigations (OCI) is responsible for investigating criminal violations involving FDA-regulated products.

U.S. Immigration and Customs Enforcement (ICE) is responsible for investigating violations of customs and other criminal laws. In addition, ICE manages the National IPR Coordination Center (IPR Center), which is a state-of-the-art facility with representatives from a number of federal agencies, including CBP and FDA. The IPR Center provides a venue for member agencies to share information, develop initiatives, coordinate enforcement actions, and conduct investigations related to IP theft, including counterfeit pharmaceuticals.

CBP/FDA Domestic Enforcement Strategy

To ensure a consistent USG enforcement response at our borders, CBP and FDA will jointly develop a strategic approach to illegal pharmaceuticals in ports of entry in early 2011. FDA, working with CBP, will develop an Import Operation Strategic Plan for imported FDA-regulated products by the end of Fiscal Year 2011. As part of this process, FDA and CBP will examine the flow of imported pharmaceutical products through different ports of entry, identify all available legal authorities, and develop best practices to enhance collaborative enforcement efforts. FDA and CBP will identify any additional legal authorities necessary to ensure that only compliant pharmaceuticals are imported into the U.S. and that appropriate enforcement action is taken against illegal pharmaceuticals. For example, FDA and CBP will explore ways to ensure that, under appropriate circumstances, products are destroyed rather than returned to sender. CBP and FDA will explore approaches to improve targeting of counterfeit pharmaceutical imports. And CBP, in coordination with FDA, will create a uniform, progressive enforcement posture in which CBP will assess civil penalties against repeat violators and importers of commercial quantities in order to deter future purchases. This strategy will build on specific roles and responsibilities for each agency to increase efficiency, facilitate trade, and strengthen enforcement.

ICE will leverage its 27 domestic IP Theft Enforcement Teams that bring together federal, state and local law enforcement, to strengthen IP enforcement efforts. ICE and its IPR Center partners will continue to develop and conduct joint operations such as Operation Guardian and Operation Apothecary that focus on: counterfeit products affecting health and safety; increasing efforts to target the growing threat of counterfeit pharmaceuticals sold over the internet; and helping to ensure that the federal government's supply chain is free from counterfeit pharmaceuticals.

Obtaining Better Data to Assist Law Enforcement with Risk Assessment

Large quantities of illegal pharmaceuticals are entering the stream of commerce through our express carrier and U.S. mail facilities. Small packages of illegal prescription pharmaceuticals are being sent from international destinations, posing increasing challenges for U.S. law enforcement. Three principle agencies share law enforcement responsibility for combating imports of illegal pharmaceuticals. CBP, FDA, and ICE play critical roles in combating the trade in counterfeit and illegal pharmaceuticals. These federal agencies will be working in concert in the coming months to proactively address the problems

faced by express carrier and U.S. mail facilities in identifying, inspecting, investigating, and destroying counterfeit/illegal pharmaceuticals.

CBP and FDA are currently working together to develop a pilot compliance measurement program to be implemented in April 2011 in which they will randomly inspect packages entering the United States through mail facilities and collect data on the results of these random inspections. Compliance Measurement (CM) is a tool that CBP currently uses to collect objective statistical data to determine the degree to which commercial imports comply with U.S. trade laws, regulations, and agreements. CM forms the foundation of CBP's risk management approach to trade, which provides a baseline measurement for trade compliance and establishes a feedback loop to hone targeting efforts and identify new risks and trends. This new CBP/FDA pilot will provide data on importations of pharmaceuticals through international mail. The resulting data will provide CBP and FDA with a better understanding of the importation trends and methods for pharmaceuticals, and the rate at which imported pharmaceuticals comply with the laws enforced by CBP and FDA.

Later in the year, the CM process will be duplicated for express carriers, and in FY 2012, for commercial air cargo. The resulting data will be available on a quarterly basis and will help drive future targeting and enforcement efforts. In addition, the CM process will help identify any process gaps that need to be addressed to enhance enforcement.

CBP's risk-based strategy for IPR enforcement also depends, in part, upon information technology- based targeting. Thus, increasing the quantity and quality of information available for targeting will enhance CBP's ability to identify shipments likely to contain counterfeit pharmaceuticals. Early in 2011, CBP will create an internal working group to examine current information technology systems along with data processing and analysis techniques to generate strategies and analyses optimized for pharmaceutical imports. Ultimately, the working group will produce processes to enhance the quality and quantity of data available for targeting models and use intelligence to increase the success of special operations. To ensure information is used effectively to generate leads and to support criminal cases, CBP will confer with ICE, FDA, and the Department of Justice (DOJ) to determine the types of information necessary to support criminal investigations and enhance prosecutions. This will not only boost CBP's targeting efforts, but also increase case referrals for criminal investigation and prosecution.

Initially this will prove most effective in commercial cargo environments where more information is available on imports. However, it may also yield useful information in the mail and express carrier environments. CBP, FDA, DOJ, and ICE will also explore the expansion of information sharing capabilities within existing systems to enhance targeting and investigation of shipments with intellectual property, substandard/tainted, and unapproved drug violations.

Streamlining the Trusted Supply Chain

A Secure Supply Chain (SSC) pilot program is being developed by FDA's Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA). This program, which will be further developed in early 2011, is part of FDA's risk-based approach to ensure the safety of imported drugs. The program will help expedite shipments of drugs that meet the SCC pilot criteria because the FDA has greater confidence in the drugs that are imported by a company in control of its supply chain. The FDA will

review a limited number of applications, accept the most reliable of supply chains used, and audit the program to ensure compliance. This will enable FDA to focus its resources on unknown companies and drugs imported through higher risk supply chains.

Similarly, CBP is developing an IPR supply chain management program that builds on its existing supply chain partnership programs, the Customs-Trade Partnership Against Terrorism and the Importer Self Assessment Program. CBP and FDA will coordinate their programs to enable the pharmaceutical industry and the public to benefit from the concerted FDA and CBP efforts to secure imported drug supply chains.

Integrating Private Sector Business Practices and Information Sharing

CBP announced the opening of its Pharmaceutical Center of Excellence and Expertise (CEE) pilot on November 1, 2010. This Center works with industry stakeholders to enhance CBP's understanding of private sector business practices and to share information generated through private sector brand protection programs. The CEE's mission includes expanding the Agency's knowledge base about the pharmaceutical industry, creating a centralized source of expertise for pharmaceuticals, driving uniform implementation of policies and procedures, and working with FDA to improve targeting for counterfeit, substandard, and unapproved drugs.

Over the next six months, the CEE will compile data and information from industry and within CBP to be distributed to FDA and CBP targeting centers and ports of entry to enhance targeting. This enhanced targeting is valuable for raising awareness of counterfeit pharmaceutical trends in ports of entry, increasing collaboration between DOJ, ICE, FBI and FDA on criminal investigations, and increasing the likelihood of success of CBP's special operations in the express carrier and mail environments. The CEE will also increase uniformity across CBP by identifying the laws, processes, and best practices applicable to pharmaceutical imports and will provide guidance to the ports to ensure uniform application.

DOJ IP Task Force

In February 2010, the Attorney General announced the creation of an IP Task Force as part of a Department-wide initiative to confront the growing number of domestic and international IP crimes. The Task Force monitors and coordinates the Department's overall IP enforcement efforts, with increased focus on international IP enforcement, organized crime, and civil enforcement efforts. Through the Task Force, the Attorney General has prioritized investigating and prosecuting IP offenses that pose a risk to public health and safety, including the illegal manufacture and distribution of counterfeit pharmaceuticals.

DOJ's ongoing health and safety initiative brings together private, state, and federal enforcement resources to address the proliferation of counterfeit and illicit goods posing a danger to consumers, including counterfeit and illegally prescribed pharmaceuticals. Examples of significant health and safety prosecutions as well as grants awarded to support state and local IP Task Forces are described in DOJ's FY2010 PRO IP Act Report. See http://www.cybercrime.gov/proipreport2010.pdf.

2. Law Enforcement Actions Internationally—Improving Cooperative International Law Enforcement Efforts

Background on the Relevant International Responsibilities of Federal Law Enforcement in Combating Counterfeit/Illegal Pharmaceuticals

ICE's Homeland Security Investigations (HSI) represents the Department of Homeland Security's (DHS) largest investigative agency, and with 69 foreign offices in 47 countries, has the broadest international footprint within DHS. ICE HSI is a leading voice in the international customs enforcement community; its agents are recognized internationally for their expertise in enforcing customs and other criminal laws, and ICE HSI attachés establish strong working relationships with host country counterparts, strengthening ICE HSI's capacity to conduct successful domestic, international, and multilateral operations. Through the IPR Center, ICE HSI engages and supports other customs administrations and national police agencies in joint international enforcement activities to combat IP theft worldwide; as such, the IPR Center actively investigates the manufacture, importation, and sale of counterfeit pharmaceuticals. In fiscal year 2010, the IPR Center established itself domestically as the primary resource for the investigation of IP theft. Looking forward to fiscal year 2011, the IPR Center will focus on its two areas of expertise, investigations and operations/training, to increase its prominence internationally.

CBP partners with foreign customs authorities and FDA partners with foreign regulatory and law enforcement authorities to share practices and information, and for border enforcement operations.

FDA-Office of Criminal Investigations (OCI) is a founding member of the Permanent Forum on International Pharmaceutical Crime (PFIPC). PFIPC is an international enforcement forum of 15 member countries throughout the world aimed at protecting public health and safety through the exchange of information and ideas to foster mutual cooperation. OCI engages in frequent exchange of information with PFIPC member countries regarding counterfeit or otherwise dangerous pharmaceuticals, dietary supplements and medical products. OCI both provides investigative assistance to the PFIPC member countries and obtains investigative assistance from those same entities in cases involving pharmaceuticals and other medical products.

DOJ is the lead prosecution agency for federal intellectual property and pharmaceutical regulatory offenses. DOJ also takes an active role in prosecuting international cases of pharmaceutical counterfeiting, and training law enforcement authorities in other countries to more effectively combat the production, smuggling and sales of counterfeit drugs.

Leveraging and Expanding International Law Enforcement Partnerships

ICE HSI special agents and Justice Department prosecutors will continue efforts to combat the production and distribution of counterfeit pharmaceuticals by expanding on our international partnerships. This will include leveraging ICE HSI's attaché network and DOJ's LEGAT network overseas. DOJ will also continue to provide prosecutorial development and training to foreign law enforcement counterparts to build capacity in other countries to more effectively combat a wide array of IP crime, including the manufacture and distribution of counterfeit drugs.

During the course of the next year, CBP and FDA will seek to conduct joint operations with foreign authorities on counterfeit pharmaceuticals in coordination with ICE and the IPR Center. This year, FDA will provide internet investigative training to PFIPC member countries at FDA headquarters in Washington.

In 2011, DOJ will build upon the Attorney General's recent visit to China to emphasize the importance of working cooperatively, with the goal of identifying specific cases designed to disrupt the operation of producers and smugglers of counterfeit medicine through the IP Criminal Enforcement Working Group of the U.S. China Joint Liaison Group. DOJ will also continue to use its IP Law Enforcement Coordinators in Asia and Eastern Europe to increase regional enforcement of laws prohibiting counterfeit pharmaceuticals.

Developing and Conducting Multilateral International Investigations

ICE, working with FDA and CBP, will propose the development of multilateral international operations to target the unauthorized shipment of active pharmaceutical ingredients (API) through engagement with international customs organizations and law enforcement authorities. Similar operations have proven successful; as such, the proposed operations will be modeled after recent ICE-led operations designed to combat the threat posed by mislabeled, counterfeit, and substandard pharmaceuticals, such as Operations Mercury I and II and Operations Pangea I, II and III.

The World Customs Organization

ICE and CBP maintain productive relationships with several international organizations through engagement on operational and training initiatives, and seek to develop additional alliances and expand cooperative efforts with existing partners. Ongoing and active engagement with the WCO and its member countries, as described above, makes this organization critical to ICE operational success internationally. In addition, ICE HSI holds the positions of Vice Chair for the WCO's Enforcement Committee (EC) and Chair of the Commercial Fraud Working Group (CFWG), which includes IP enforcement. In 2009, at the request of ICE, the CFWG obtained oversight of the WCO's pharmaceutical smuggling program. During the December 2010 meeting of the CFWG, ICE HSI brought together customs administrations, INTERPOL, and regulatory agencies to discuss cooperative efforts to combat pharmaceutical smuggling. Through involvement with the WCO, ICE has introduced and implemented several multilateral international operations, such as Mercury and Pangea. Working with the FDA and CBP, ICE will propose the development of multilateral international operations to target the unauthorized shipment of API. CBP holds the position of Chair of the WCO Scientific Subcommittee, which organizes the international Harmonized Tariff Schedule and Explanatory Notes so that pharmaceutical pre-cursors and counterfeit pharmaceuticals can be more easily traced in the flow of international trade. In 2011, the WCO Scientific Sub-Committee will engage in a dialogue with the pharmaceutical industry to leverage the industry's "track and trace" technology to enhance supply chain security.

The Strategic Alliance Group (SAG)

The Strategic Alliance Group (SAG) is a partnership of law enforcement agencies from the United States, Canada, the United Kingdom, Australia, and New Zealand. The mission of the SAG is to reduce the threat of global organized crime and its international impact through improved collaboration and information

sharing. Enforcement of IPR is a recent topic of discussion among SAG principals, which ICE will leverage to propose joint IP investigations.

Focus on Special 301 Priority Watch List Countries

Through its network of international attachés, ICE maintains offices in nine of the 11 countries listed as Priority Watch List countries in the U.S. Trade Representative's Special 301 Report. In these countries, ICE will leverage its relationships with host country law enforcement to propose and conduct bilateral and multilateral investigations, and to provide training on IP enforcement matters. Three existing concepts may serve as examples for future collaboration. In Korea, ICE HSI Attaché Seoul has partnered with the Korean Ministry of Justice to embed an ICE HSI agent within the Korean Prosecutor's Office. In China, the ICE HSI Assistant Attaché Guangzhou has been designated as the point of contact on all IPR matters in China for ICE. Through the Assistant Attaché, ICE HSI has agreed to provide the Chinese Ministry of Public Security (MPS) with data about CBP seizures with a nexus to China and with actionable information from ICE investigations and operations in order to further investigations in both countries. Also in China, ICE and MPS signed a Letter of Intent (LOI) to collaborate on intellectual property rights investigations. Using these examples as a template, ICE HSI will designate IPR points of contact in selected attaché offices and seek to embed personnel with host country law enforcement in priority countries. Additionally, draft LOIs with Russia and Thailand are under negotiation, and ICE will seek to reach similar agreements with other priority countries as well.

Examples of Ongoing Operational Initiatives

Conducted in 2009, **Operation Mercury** was a multi-day surge operation involving HSI, CBP, FDA OCI, the U.S. Postal Inspection Service (USPIS), and 45 WCO member states combating the threat posed by mislabeled, counterfeit, and substandard pharmaceuticals at international mail facilities and express carrier hubs. **Operation Mercury II**, conducted in June 2010, involved 35 WCO member states and targeted the importation and distribution of substandard and counterfeit pharmaceuticals. Seized drugs included antibiotics, steroids, human growth hormones, heart medications, psychiatric medications, endocrine system medications, and lifestyle medications. In total, 17,123 mail/express carrier parcels were determined to contain pharmaceuticals, 3,277 parcels were not properly declared, 3,347 parcels were detained, and 1,309 parcels were seized.

Operation Apothecary addresses, measures and attacks potential vulnerabilities in the entry process that might allow for the smuggling of commercial quantities of counterfeit, unapproved, and/or adulterated drugs through the Internet, international mail facilities, express carrier hubs, and land borders. In fiscal year 2010, HSI conducted 12 Apothecary enforcement surges in conjunction with CBP, FDA OCI, and USPIS at international mail facilities and express carrier facilities. Apothecary surges have resulted in the examination of approximately 8,125 parcels, 842 of which were either detained or seized by CBP, FDA, U.S. Department of Agriculture, U.S. Fish and Wildlife Service, or the National Oceanic and Atmospheric Administration.

Conducted in October 2010, **Operation Pangea III** was the largest Internet-based action of its kind coordinated by the WCO, INTERPOL, the Permanent Forum of International Pharmaceutical Crime, Heads of Medicines Agencies Working Group of Enforcement Officers, the pharmaceutical industry and

online payment systems providers in support of the International Medical Products Anti-Counterfeiting Taskforce. The third annual world-wide week of action targeted the online sale of counterfeit and illegal medicines to raise awareness of the associated health risks in 45 countries. The operation resulted in arrests across the globe and the seizure of thousands of potentially harmful medicines. The U.S. operation, managed by the IPR Center, included HSI, CBP, FDA-OCI, USPIS, and the Drug Enforcement Administration (DEA). Operations were conducted at mail facilities in several U.S. cities. With just over 35 countries reporting their results to date, Internet monitoring revealed more than 820 websites engaged in illegal activity – including those offering controlled or prescription-only drugs. Of those, nearly 300 websites have now been taken down. Worldwide, participants inspected more than 278,000 packages and seized nearly more than 11,000 of them. Those packages and those identified during follow-up investigations contained 2.3 million illicit and counterfeit pills worth more than $6.8 million. During the operation, 130 search warrants were executed and 87 individuals were arrested or are under investigation for a range of offenses.

On September 18, 2010, ICE HSI and CBP concluded **Operation Safe Summer**, a two-month initiative involving several separate surge operations. The operation targeted the importation of IPR infringing health and safety related items at seven international mail facilities and express carrier hubs in the United States and Mexico. HSI, CBP, and the Mexican Tax Administration Service initiated this operation to target, interdict, and investigate the importation of items through the mail that violate IPR, focusing on those that threaten public health and safety. To date, approximately 800 seizures have been made, including counterfeit automobile airbags, rifle sites, cellular phones and chargers, and health and beauty products. Mexican authorities seized 306 tons of counterfeit merchandise at mail facilities and land, air, and sea ports of entry.

3. Tackling the Proliferation of Illegal Internet Pharmacies Through Voluntary Cooperative Efforts

Domestic Voluntary Efforts

On December 14, 2010, White House Intellectual Property Enforcement Coordinator (IPEC), Victoria Espinel announced that GoDaddy, Google, Microsoft, Yahoo!, Network Solutions, Neustar, eNom, PayPal, MasterCard, Visa, and American Express have agreed to support an initiative which will start taking voluntary action against illegal Internet pharmacies.

This fall, Espinel challenged the private sector to voluntarily address the health and safety issues presented by rogue online pharmacies. IPEC reached out to a broad array of private sector companies that are involved in issues relating to illegal online pharmacies: internet registries and registrars who provide domains that can be subsequently used for illegal purposes by rogue Internet pharmacies, search engines that provide ad space to those companies, payment processors that process the payments for those products, overnight shippers that transport the products, and a cross-section of governmental and non-profit entities also invested in this issue.

These discussions culminated in a well-attended, cross-industry meeting at the White House on November 9, 2010. At that meeting, GoDaddy and Google took the lead on proposing the formation

of a private sector 501(c)(3) non-profit organization dedicated to promoting information sharing, education, and more efficient law enforcement of rogue internet pharmacies. The non-profit will be stood up in early 2011.

The non-profit will be based around four operating principles:

- **Information Sharing:** Organization members will share information about rogue websites selling pharmaceuticals in violation of federal law. The primary purpose of the information sharing principle is to allow members to take advantage of information that others have amassed about rogue pharmacies and to reduce the likelihood that bad actors will simply forum shop if they are not successful in attempting to sell pharmaceuticals through particular mediums.
- **Education:** The group intends to fund educational campaigns that underscore the dangers of purchasing drugs online from unauthorized pharmacies.
- **Expanded White Lists:** The organization's information sharing mechanism will support an expansion of the National Association of Boards of Pharmacies' Verified Internet Pharmacy Practice Sites ("VIPPS") list. This expanded "White List" of legitimate on-line pharmacies will allow search engines and others to know which pharmacies are operating in compliance with federal law and can therefore lawfully advertise on their space.
- ***Enforcement:*** The organization's members agree to share information with law enforcement about unlawful Internet pharmacies where appropriate, accept information about Internet pharmacies operating illegally, and take voluntary enforcement action (stop payment, shut down the site, etc.) where appropriate.

International Voluntary Cooperative Efforts

During the first half of 2011, the IPEC will continue to engage the private sector in establishing voluntary cooperative efforts. The IPEC will also engage other countries who have an interest in combating intellectual property theft, to explore whether our domestic voluntary cooperative efforts will serve as a good model for other countries to pursue. These efforts will include the sharing of best practices and relevant data with our international partners.

4. Improving Public Awareness About Counterfeit Medicines within the United States

Leveraging Existing Public Awareness Resources

The Departments of Commerce and Justice, FDA, USPTO, and others have engaged cooperatively on a number of activities focused on raising public awareness, education and outreach on counterfeit medicine and related issues. Currently these agencies are developing and working on new solutions to decrease demand for unsafe drug products through researching consumer behavior patterns and impact metrics so that we may deliver more successful public health campaigns. The U.S. Government will share the methodologies of these projects and the results of the research and survey conclusions, as appropriate, and will partner with industry and other stakeholders, to leverage existing public awareness resources and develop further targeted anti-counterfeiting campaigns in 2011.

Pursuant to congressionally mandated appropriations for Intellectual Property initiatives, USPTO will work with Widener University to conduct a study on the connection between counterfeits and public health and safety threats and concerns, which will form the basis for the development of both a course curriculum for trainers to use and a web-based interactive learning module.

DOJ, under the auspices of the IP Task Force Outreach and Education Working Group, is developing a public awareness campaign to educate the public about the risks associated with piracy and counterfeiting, including counterfeit pharmaceuticals. DOJ's Office of Justice Programs, through the Bureau of Justice Assistance, has engaged the National Crime Prevention Council ("NCPC") to research public perceptions of IP crime and develop the advertising campaign. To date, NCPC has completed several focus group sessions as well as a quantitative survey based on a number of preliminary sample ads. NCPC is also reviewing and analyzing current published research in this area to further inform the campaign. DOJ will share the results of NCPC's research with its agency partners to assist them in developing additional public awareness campaigns.

Commerce (USPTO and ITA) will conduct domestic Intellectual Property Awareness Campaign and outreach events in the United States to provide inventors, entrepreneurs, and small businesses with information regarding tools, resources and strategies for protecting and enforcing their intellectual property rights, including pharmaceuticals. Commerce also supports interagency efforts by providing resources and contact information to the public to address IPR enforcement issues.

5. Working Internationally to Address the Counterfeit Pharmaceutical Problem Through Public Awareness and Information Sharing

State Department's Campaign Against Counterfeits Public Diplomacy Program

In 2010, the State Department devoted $200,000 in public diplomacy funds to increase public awareness of the dangers of counterfeit medicines. Twenty-four U.S. embassies and consulates submitted proposals from which 14 were selected to be funded. Many of these projects have already been implemented and others will take place in the coming months. Programs range from TV and radio public service announcements in Bolivia to seminars with Brazilian pharmacy students to town hall meetings in Kenya. Also, as part of this Campaign Against Counterfeits, State has provided a grant to the World Intellectual Property Organization (WIPO) to produce a counterfeit medicines public diplomacy toolkit and to put on three pilot workshops to show how to use the toolkit to mount a nationwide public outreach campaign. The Department of State has a tentative FY2011 allotment of $100,000 for public diplomacy projects to build on the past two years of successful IP-related programming, although this funding may vary based on other budgetary requirements. State will evaluate the results of these workshops and collaborate with WIPO on additional workshops in the future. State will also look at other fora/organizations as possible partners for funding and venues to raise awareness of counterfeit medicines. FDA, USAID, and Commerce, including ITA, USPTO and overseas IPR attaches will work with the State Department to support the Campaign Against Counterfeit Medicines Public Awareness Program.

USAID's Promoting the Quality of Medicines Program

USAID funds the Promoting the Quality of Medicines (PQM) program implemented by the United States Pharmacopeia. Its purpose is to strengthen quality assurance mechanisms in developing countries, including efforts to detect counterfeit and substandard medicines. PQM strategically deploys sentinel sites to collect and test medicines circulating in the market or in the public sector. This surveillance strategy provides evidence for resource-constrained national medicine regulatory authorities (MRAs) to take regulatory action and support public service announcements. To date, PQM has worked closely with MRAs in more than 20 countries in Latin America, Southeast Asia, and Sub-Saharan Africa. For example, working with PQM, Cambodia has created public service announcements alerting its citizens to obtain medicines only at authorized pharmacies to ensure their quality and authenticity. Similarly, in Senegal, PQM participated in a high-profile communication campaign to raise public awareness about counterfeit medicines. Messages from government, social, and religious leaders were broadcast warning of the public health implications of counterfeit medicines. In FY2011, USAID shall share lessons learned with the FDA, State Department, and WHO on their surveillance and monitoring of counterfeit medicines program.

6. Working Internationally to Address the Counterfeit Pharmaceutical Problem Through Training

Government-to-Government Enforcement Training

The State Department, using foreign assistance anti-crime funds managed by the Bureau of International Narcotics and Law Enforcement Affairs, in collaboration with the Energy, Economic and Business Affairs Bureau, has a long-standing program to provide capacity-building training and technical assistance to foreign law enforcement to combat intellectual property rights crime. 2011 will bring a new focus to combating counterfeit medicines. The Department is using approximately $1.3 million—equal to about 31 percent of the total $4 million in anti-crime training and capacity building funds—in programs aimed squarely at combating counterfeit medicines. These programs were designed and will be implemented by DOJ and DHS and the U.S. Patent and Trademark Office in close cooperation with relevant U.S. Missions. Assuming positive outcomes, State will fund similar proposals in FY2011, which may focus on, but need not be limited to funding training programs that address infrastructure, regulatory framework, and adjudicating IP cases relating to counterfeit pharmaceuticals.

DOS's Bureau of International Narcotics and Law Enforcement Affairs recently approved training programs specifically addressing counterfeit pharmaceuticals proposed by DOJ and HSI for Ecuador and Peru, a regional effort for Southern African nations, and to support INTERPOL training. INL also approved two regional seminars in Asia, which will include officials from China, Hong Kong, Malaysia, Japan, and Korea, and one training event in the Philippines. These programs, scheduled for 2011, will supplement more than 6 years of INL-funded training on intellectual property enforcement. Fostering joint U.S.-China criminal law enforcement efforts is a critical step in combating the manufacture and distribution of counterfeit drugs, and has been a positive area for engagement with China in recent years.

In addition, DOJ's training programs and supporting material are frequently modified to address the specific needs of particular countries and, where appropriate, to incorporate information and

experiences gained by USAID, World Bank, and other development entities, including in the area of counterfeit pharmaceuticals in the developing world. To this end, DOJ will develop a bench book for judges to use in adjudicating counterfeit pharmaceutical cases and a prosecutors' handbook for building counterfeit pharmaceutical cases for distribution to developing countries as appropriate.

In addition to DHS participation in DOS funded training, ICE HSI conducts significant outreach on anti-counterfeiting and piracy efforts with international customs administrations and law enforcement agencies. The IPR Center maintains a robust Outreach and Training unit, which coordinates and provides international IPR outreach and training to law enforcement, industry and the public.

7. Ensuring that U.S. Taxpayer Dollars Are Not Spent on Foreign Aid that Procures Counterfeit Pharmaceuticals

The USG addresses the threat of counterfeits in medicines that are procured using federal funds through various mechanisms. The particular mechanism used depends largely on whether the USG is purchasing drugs directly or indirectly.

Due diligence efforts by State and USAID's PEPFAR, Supply Chain Management Project, President's Malaria Initiative (PMI), and the Office of Population and Reproductive Health (PRH) have helped to prevent the procurement of counterfeit medicines while protecting the integrity of pharmaceuticals in the supply chain. To date, there has been no indication that USG dollars have been used to directly procure counterfeit medications.

The USG is a major contributor to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), having contributed close to one billion dollars in financial support to the Global Fund annually over the last three years. About 47 of Global Fund grant funding has been used by grant recipients to procure medicines, diagnostics, and other health products. Recognizing the importance of ensuring that Global Fund resources are not used to purchase counterfeit or sub-standard drugs, the Global Fund, with strong USG support and engagement, has established procurement and quality assurance policies and is actively monitoring compliance with these policies and ways to further strengthen Global Fund policies and oversight structures. The Global Fund's Office of the Inspector General (OIG) is currently investigating whether Global Fund monies have been spent on counterfeit anti-malarial drugs in Cambodia and elsewhere and whether appropriate controls exist to detect and deter counterfeits. The USG eagerly awaits the results of this work, and will take any appropriate and necessary action as a result of those findings. The USG takes all allegations of potential procurement of counterfeit drugs seriously and is working actively with the Global Fund, WHO, and other organizations to continually strengthen quality assurance and compliance policies and capacity.

8. Promoting Best Practices

The Asia-Pacific Economic Cooperation (APEC)

The existence of corruption and illicit trade challenge APEC's vision of free, open and prosperous economies, especially when it threatens human health and security as does the practice of selling counterfeit medicines. APEC has reaffirmed its commitment to meet these challenges, and APEC member

economies are working to combat corruption and illicit trade and to prevent the devastating human and economic costs of harmful counterfeit medicines to APEC communities by developing best practices and strengthening cooperation among all market actors to ensure greater supply chain integrity and public safety.

The APEC is of particular importance because the region is a leading source for counterfeit pharmaceuticals. The United States will hold the APEC presidency in 2011, offering a unique opportunity to increase awareness of trade in counterfeit pharmaceuticals. DOJ and DHS, along with FDA, State and Commerce, will take an active role in the 2011 APEC program, "Combating Corruption and Illicit Trade: Anti-Counterfeit Medicines and Strengthening Supply Chain Integrity," which is designed to increase cooperation among law enforcement officials and private industry to detect and disrupt the networks that produce and distribute counterfeit pharmaceuticals. Working closely and coordinating with numerous APEC sub-fora, the United States proposes to announce an APEC regional public-private partnership and law enforcement network against corruption and illicit trade that would include efforts to ensure integrity in the supply chain and stem the global flow of counterfeit medicines, a code of conduct related to counterfeit medicines, and innovative tools such as an Illicit Trade Unit (ITU).

Commerce's International Trade Administration and FDA will work with other agencies to hold APEC funded anti-counterfeit medical product seminars to endorse and implement the APEC Anti-counterfeit Medicines and Product Safety Action Plan. In 2011, these will include an APEC project focusing on the use of detection technologies for drug safety, an APEC anti-counterfeit workshop and discussion of an APEC economy anti-counterfeit medical product and safety "Single Point of Contacts" (SPOCs) system for cooperation on criminal investigations and public awareness.

In addition, CBP will introduce a proposal to the APEC Sub-Committee on Customs Procedures on development of a set of model practices for enforcing IPR in the international mail and express carrier environments, with a particular focus on counterfeit pharmaceuticals, and on conducting a joint enforcement operation targeting counterfeit pharmaceuticals in these environments.

WHO's International Medical Products Anti-Counterfeiting Task Force

FDA is a key player in WHO's efforts to combat counterfeits around the world, including leading the work of the International Medical Product Anti-counterfeiting Task Force (IMPACT). IMPACT brings together private and public sector experts to address public health aspects of drug counterfeiting and is developing technical tools for countries to use and adopt to fight drug counterfeiting. These tools can be used to strengthen legislative, regulatory, technological, enforcement and communication infrastructure and build capacity for surveillance, identification, and prevention of counterfeit drugs from reaching patients. The USG will continue to support complementary partnerships, including continued development and implementation of IMPACT.

The USG will also engage substantively in the process underway at the WHO to define the Organization's role in mitigating the public health impacts of counterfeit drugs. The WHO and FDA are collaborating to build global rapid alert surveillance/monitoring system(s) for combating counterfeit/falsified medicines and risks in the supply chain security. The goals of this effort are to: 1) generate sound and reliable evidence of where incidence of falsified medicines is most serious; 2) promote exchange of information

(e.g. case reports and description of actions taken) and expertise between countries, to stimulate action (including alerts); and 3) make available a system to be used for collecting and disseminating information based upon requirements shared by all partners. FDA will share this information with ICE, the IPR Center and Interpol, which could be used to guide outreach efforts and government-to-government training programs.

9. Suggested Legislative Fixes

Notification When Importers and Manufacturers Discover Counterfeit Drugs and Medical Products

Counterfeit drugs threaten public health and, when they are discovered by importers or manufacturers, the importers or manufacturers should notify the FDA and other relevant agencies of any known potential health risks, thereby allowing the FDA or other agencies to take action. Members of the Pharmaceutical Research and Manufacturers of America (PhRMA) Association have already voluntarily agreed to provide notification to the FDA. That disclosure, however, does not include all manufacturers, nor does it necessarily include importers. In the Joint Strategic Plan, the Administration recognized the need for such notification and the Administration recommends adopting legislation providing for such notification.

> ***Recommendation:*** The Administration recommends that Congress require importers and manufacturers to notify the FDA and other relevant agencies when they discover counterfeit drugs or medical products, including the known health risks associated with them.

Extend the Ryan Haight Act's Definition of "Valid Prescription" (and Telemedicine Exemption) to the FFDCA to Apply to Drugs that Do Not Contain Controlled Substances

Online pharmacies that are least likely to enforce prescription requirements are also generally most likely to sell counterfeit drugs. The Controlled Substances Act prohibits the distribution of controlled substances without a valid prescription and, significantly, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act) provides, for the first time, a Federal definition of "valid prescription." Public Law 110-425, 122 Stat. 4820, § 2 (2008). Under that definition, a prescription is only valid if it has been issued by a practitioner who has conducted an "in-person medical evaluation" or by a covering practitioner (although an exemption is included in the Ryan Haight Act for prescriptions issued by a practitioner engaged in the legitimate practice of telemedicine). The Ryan Haight Act also codified regulatory language (21 C.F.R. § 1306.04(a)) that requires the prescription to be issued for a "legitimate medical purpose in the usual course of professional practice." The definition was designed to address the practice of online pharmacies that dispensed controlled substances without a prior prescription or on the basis of a purported review by a physician who reviewed a questionnaire.

Many online pharmacies sell prescription drugs that do not contain controlled substances. The FFDCA regulates such sales, requiring a "practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1). There is, however, no definition of what constitutes a valid prescription under this Act and,

thus, no definition that applies to prescription drugs that do not contain controlled substances. The Administration recommends amending the FFDCA (21 U.S.C. § 353(b)(1)) to use the definition of valid prescription in the Ryan Haight Act (and also to use its exemption for prescriptions issued through the legitimate practice of telemedicine). By making that amendment, Congress can help reduce the number of online pharmacies evading prescription requirements and, in turn, selling counterfeit drugs.

Recommendation: The Administration recommends that Congress apply the Ryan Haight Act's definition of "valid prescription" to the FFDCA to drugs that do not contain controlled substances (and incorporate an exemption for prescriptions issued through the legitimate practice of telemedicine).

Adoption of a Track-and-Trace System

Effective track-and-trace systems can make it more difficult to introduce counterfeit drugs into the U.S. market, make it easier to identify those responsible for making a product unsafe, and facilitate the recall of unsafe products by more quickly identifying where a product is located. In the Joint Strategic Plan, the Administration recommended the adoption of a track-and-trace system. We note the importance of addressing privacy concerns, such as deciding where the information resulting from this system will be housed and who will have access to it.

Recommendation: The Administration recommends that Congress adopt a track-and-trace system for pharmaceuticals and related products.

Provide for Forfeiture under FFDCA

Title 18, United States Code, Section 2320(b) provides for civil and criminal forfeiture for counterfeit trademark offenses, as provided in 18 U.S.C. § 2323. The FFDCA also prohibits, among other offenses, counterfeit trademark offenses involving pharmaceuticals, 21 U.S.C. § 331(i), but no such forfeiture authority exists under the FFDCA. To make the FFDCA consistent with other criminal statutes, particularly counterfeit trademark offenses under 18 U.S.C. § 2320, the Administration recommends providing forfeiture authority.

Recommendation: The Administration recommends that Congress give civil and criminal forfeiture authority under the FFDCA.

Increase the Statutory Maxima under the FFDCA

The FFDCA prohibits, among other offenses, adulterated, misbranded, and counterfeit pharmaceuticals. Most criminal violations of the FFDCA, however, are subject to a statutory maxima sentence of no more than three years in prison. For example, counterfeit pharmaceutical cases prosecuted under 21 U.S.C. § 331(i) are generally misdemeanors, 21 U.S.C. § 333(a)(1), unless the government proves that the defendant committed the offense with the intent to defraud or mislead, 21 U.S.C. § 333(a)(2). In such circumstances, the offense becomes a felony, but one subject only to a statutory maximum sentence

of three years in prison. Id. This contrasts with the 10-year statutory maximum for the sale of products with counterfeit trademarks (including for drugs) under 18 U.S.C. § 2320. The Administration recommends that Congress increase the statutory maxima for drug offense under the FFDCA, particularly for counterfeit drug offenses.

Recommendation: The Administration recommends that Congress increase the statutory maxima under the FFDCA, particularly for counterfeit drugs.

Increases in the Offense Level for Counterfeit Drug Cases and Cases Presenting a Serious Risk to Health

The sale of counterfeit pharmaceuticals is a significant problem, including the sale of counterfeit drugs containing potentially dangerous chemicals or lacking the ingredients needed to treat serious medical conditions. U.S. Sentencing Guideline Section 2B5.3(b)(5) provides: "If the offense involved (A) the conscious or reckless risk of death or serious bodily injury; or (B) possession of a dangerous weapon (including a firearm) in connection with the offense, increase by 2 levels. If the resulting offense level is less than level 14, increase to level 14." The Administration recommends two changes to this existing Guideline.

First, where there is a "conscious or reckless risk of death or serious bodily injury," that significantly aggravated conduct should warrant a significantly increased sentence. The Administration, thus, recommends increasing the current enhancement by two levels when there is "conscious or reckless risk of death or serious bodily injury," such that there would be a four-level enhancement. The Administration recommends retaining the current minimum offense level of 14.

Second, there are inherent risks associated with counterfeit drugs that are not accounted for under this Guideline and that warrant an enhanced sentence even where a defendant does not recklessly risk serious bodily injury. Accordingly, a defendant selling counterfeit pharmaceuticals should automatically receive a two-level enhancement (even where there is no conscious or reckless risk of death or serious bodily injury). Where a defendant has no other aggravated conduct (taking into account a reduction for acceptance of responsibility), this two-level increase does not actually raise the Guideline range: It is 0-6 months in prison with a base offense level of 8 (minus two points for acceptance of responsibility) and after the two-level enhancement (10 minus those same two points). Accordingly, the Administration recommends that the U.S. Sentencing Commission consider a minimum offense level of 12 for offenses involving counterfeit drugs. With that minimum offense level, a first-time offender with no criminal history will face at least a 6-12 month Guideline range without any other aggravated conduct (taking into account a reduction for acceptance of responsibility).

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider providing: (1) a four-level enhancement for offenses involving the conscious or reckless risk of death or serious bodily injury; and (2) a two-level enhancement, and a minimum offense level of 12, for offenses involving counterfeit pharmaceuticals (where there is no conscious or reckless risk of death or serious bodily injury).