TESTIMONY SUMMARY OF KENDRA A. MARTELLO, ASSISTANT GENERAL COUNSEL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY & COMMERCE,
SUBCOMMITTEE ON COMMERCE, MANUFACTURING & TRADE
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PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients live longer, healthier, and more productive lives.

The U.S. ensures prescription drug safety in part by maintaining a closed system for the distribution of prescription medicines. This closed U.S. prescription drug distribution system: (1) helps provide assurances regarding the quality, safety and integrity of the products lawfully sold in the U.S.; (2) helps reduce the potential for diversion from the regulated supply chain; and (3) minimizes the risks that a consumer receives a counterfeit medicine. This means that all entities engaged in the manufacture, distribution, and dispensing of pharmaceutical products, including controlled substances, must be licensed, registered, or approved by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), or the states. Further, the Controlled Substances Act and DEA regulations require entities handling these products to register, and to have in place effective controls and security measures to protect against the theft, loss, or diversion of controlled substances. The DEA also has authority over websites dispensing controlled substances and to supervise return of unused controlled substances for disposal.

Each entity in the regulated prescription drug supply must do their part to help prevent the diversion of medicines to help prevent inappropriate use or misuse.

PhRMA member companies engage in a variety of activities to help prevent the diversion of their products from the regulated supply chain. Our companies take these efforts seriously because, fundamentally and unequivocally, patient safety demands no less. A legitimate product could be compromised by diversion – resulting potentially in patient harm. Further, when a medicine is diverted, that product could be abused, potentially with devastating consequences. Efforts to prevent diversion by PhRMA members, both individually and through coalitions, include: (1) developing abuse-resistant products, (2) extensive facility and in-transit security measures; and (3) education, information sharing and consideration of best practices to help prevent and detect diversion from the regulated supply chain.

Finally, PhRMA supports increased use of and improvements to state prescription drug monitoring programs, the reauthorization of the National All Schedules Electronic Prescription Reporting Act, increased penalties for and enforcement against criminal cargo theft and rogue online drug sellers, implementation and enforcement of existing DEA authorities over online sales of controlled substances and responsible secure disposal of unused controlled substances, and increased licensure requirements for wholesale distributors, to prevent unscrupulous actors from moving their operations across state lines.

TESTIMONY OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

BEFORE THE HOUSE ENERGY & COMMERCE

SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

March 1, 2012

Chairman Bono Mack, my name is Kendra Martello, Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am pleased to appear before you again to provide information regarding the extensive efforts PhRMA member companies take to prevent diversion of their products from the domestic prescription drug supply chain. As you know, PhRMA represents the country's leading pharmaceutical research and biotechnology companies. Our members are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives, and are leading the way in the search for new cures and treatments. Our members alone invested an estimated $49.4 billion in 2010 in discovering and developing new medicines. PhRMA applauds your continued commitment to the issue of misuse and abuse of prescription drugs. Our members take seriously the importance of preventing diversion of prescription drugs, including controlled substances, to help prevent the patient safety and public health risks that could result if an authentic medicine is diverted and re-entered into the legitimate supply chain.

I. Introduction: Appropriate Use of Medicines and Role of Education in Helping to Reduce Misuse and Abuse of Prescription Drugs

The nation's leading pharmaceutical research and biotechnology companies are dedicated to developing safe and effective medicines to save and improve the lives of patients, including developing new medicines to treat addiction and new formulations with reduced abuse potential. Our companies are committed to helping to educate relevant stakeholders on the appropriate use of medicines and to preventing the abuse of prescription medicines, and we look forward to continuing to work with Congress, the Administration and other stakeholders on efforts to help reduce and prevent prescription drug misuse and abuse.

When used appropriately, under the direction and care of a licensed health care professional, prescription medicines can improve and save lives. However, when used inappropriately and not as intended, devastating consequences can result. According to the most recent national data, after marijuana, prescription medicines are the most abused substance.[1]

[1] *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings,* SAMHSA (2010).

As highlighted in my testimony before this Subcommittee on April 14, 2011, we believe preventing and responding to prescription drug misuse and abuse is a shared responsibility, and that education – of health care providers, pharmacists, patients, and the public -- is critical to helping stem the growing tide of prescription drug misuse and abuse. The importance of education is highlighted by the Food and Drug Administration's (FDA's) recently released draft blueprint for prescriber education for long-acting opioid products.[2] Additionally, and consistent with the Administration's strategy to reduce prescription drug abuse, PhRMA supports a range of efforts to help educate health care providers, including revising educational curricula in health professional schools (e.g., medical nursing, pharmacy, and dental) and continuing medical education (CME) units to help ensure health care providers have specific knowledge and skills associated with appropriate prescribing while minimizing the risk of addiction. CME courses such as those developed by the Center for Substance Abuse Treatment (CSAT) provide valuable training to physicians and other health care professionals as they face the challenge of minimizing the potential for misuse of medications without impeding patients' access to needed medical care.[3]

One critical aspect of any educational effort is to assess their impact and effectiveness. As the Government Accountability Office (GAO) found in a December 2011 report, only two of the nine federal agencies conducting prescription drug misuse educational campaigns measure effectiveness outcomes.[4] We believe that these federal educational efforts, which include federally-funded CME programs, would be enhanced by the incorporation of specific outcomes metrics and assessments, as GAO recommended, assessing the impact of the educational messages on behavior.

As highlighted in my testimony last April, PhRMA's educational efforts have focused on four simple messages: (1) patients should take their medicines exactly as prescribed; (2) all prescription medicines, including controlled substances, are intended only for the person named in the physician's prescription, and thus, should not be shared with anyone, including family members or friends; (3) all prescription medicines, including controlled substances, should be stored out of the sight and reach of others; and (4) any unused, unwanted, or expired medicines should be disposed of properly, either immediately through the household trash or through an organized, secure disposal program with law enforcement supervision.

With respect to disposal programs, PhRMA supports the American Medicine Chest Challenge, a national, periodic collection event and also looks forward to continuing to work with the Drug Enforcement Administration (DEA) as it develops regulations to allow ultimate users and long-term care facilities to

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[2] FDA, "Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide REMS," Nov. 4, 2011, available at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>. In 2010, 92.4% of the opioid prescriptions dispensed were for generic medicines. (PhRMA analysis of retail claims data for January-December 2010 for the classes of most commonly abused prescription drugs based on SDI Health's Vector One National Audit (VONA), April 8, 2011).

[3] Office of National Drug Control Policy, "The Administration's Response to the Prescription Drug Epidemic: Action Items," available at: <http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/action_items_response_to_the_prescription_drug_epidemic.pdf>.

[4] Government Accountability Office, "Prescription Pain Reliever Abuse, Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness," GAO-12-115, Dec 22, 2011, available at: <http://www.gao.gov/assets/590/587301.pdf>.

return controlled substances for disposal under the Secure and Responsible Drug Disposal Act of 2010. It is important to note, however, that for a very limited set of products, including most opioids, current FDA recommendations are to flush such products.

II. The Domestic Prescription Drug Supply Chain and DEA Regulation of the Distribution of Controlled Substances

A. FDA Oversight and the U.S. Closed Distribution System Helps Prevent Against Diversion of Prescription Drugs Generally

The U.S. ensures prescription drug safety in part by maintaining a closed system for the distribution of prescription medicines. In addition to the existing standards that require FDA approval of a New Drug Approval (NDA) application for new drugs, an Abbreviated New Drug Application (ANDA) for generic drugs, or a Biologics License Application (BLA) for biologic medicines and maintenance of current Good Manufacturing Practices (cGMPs) for biopharmaceutical manufacturing, the closed U.S. prescription drug distribution system: (1) helps provide assurances regarding the quality, safety and integrity of the products lawfully sold in the U.S.; (2) helps reduce the potential for diversion from the regulated supply chain; and (3) minimizes the risks that a consumer receives a counterfeit medicine. Our prescription drug supply system was closed in 1987 after the passage of the Prescription Drug Marketing Act (PDMA), championed by Reps. John Dingell and Henry Waxman.

A drug is restricted by FDA to prescription use only after it concludes that the medicine may only be used safely under the professional supervision of a practitioner licensed by law to administer such drug.[5] In the U.S., prescription medicines, including controlled substances, typically are sold by a manufacturer to a wholesale distributor, who may in turn sell the product to one or more wholesale distributors, or to an independent or chain pharmacy, at which point the medicine may be dispensed to a patient upon the pharmacy's receipt of a physician prescription for an individual patient. Each of these actors in the supply chain are separate legal entities who take ownership of the medicine as it travels through the supply chain until it is dispensed to a patient, and they are licensed and overseen by the relevant state licensing authority. Further, a patient may not legally obtain a prescription medicine, including a controlled substance, without a prescription from a health care practitioner authorized to write a prescription. Thus, each entity in the prescription drug supply chain – from primary and secondary wholesalers, to licensed pharmacists working in licensed independent and chain pharmacies, to physicians and other licensed health care prescribers – must do their part to help prevent the diversion of medicines to help prevent inappropriate use or misuse. The responsibility to prevent diversion must be equally shared.

[5] 21 U.S.C. § 353(b).

B. The Role of DEA Registration, Effective Controls, and Security Requirements to Prevent Controlled Substances Diversion

Entities handling controlled substances – whether they are manufacturers, distributors, or dispensers -- must register with the DEA to handle controlled substances.[6] Through its Diversion Control Program, DEA regulates more than 1.3 million registrants.[7] All DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances.[8] During manufacturing activities involving controlled substances, all substances must be stored in a secure area at the end of the workday unless manufacturing operations are continuous and must occur in an area with limited employee access.[9] Before distributing a controlled substance, DEA registrants are expected to determine if the person ordering a controlled substance from them is appropriately registered with DEA.[10] Registrants must also have in place a system to disclose suspicious orders of controlled substances to the relevant DEA Field Office.[11] Suspicious orders can include orders of unusual size, unusual frequency, or orders that deviate substantially from a normal pattern.[12] Further, as a condition of registration, DEA registrants must report thefts or losses of controlled substances within one business day of such theft or loss.[13] DEA registrants are also responsible, when shipping controlled substances, to select contract carriers that provide adequate security to guard against losses in storage and in transit.[14] The requirement to maintain adequate security for controlled substances in storage and transit also extends to agents of a DEA registrant.[15] As will be described more fully below, PhRMA, along with many of its member companies, is part of a Coalition effort to modernize our nation's criminal laws to increase penalties for criminal networks targeting large scale shipments of medical products for theft and reintroduction into the supply chain.

As the GAO highlighted in an August 2011 report, the DEA recently expanded its resources and targeted its diversion control investigations to collaborate more with state and local law enforcement agencies and to enhance the effectiveness of the diversion control investigations it conducts. GAO also recommended that DEA should determine the extent to which these efforts have reduced prescription drug diversion.[16] Most recently, the Administration's FY 2013 budget request would increase funding

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[6] 21 U.S.C. § 822. Controlled substances are placed into one of five schedules by DEA, based on the substance's abuse potential. Schedule I controlled substances have no legitimate medical use. See generally 21 U.S.C. § 812.
[7] DEA FY 2013 Budget Summary, available at: <http://www.justice.gov/jmd/2013summary/pdf/fy13-dea-bud-summary.pdf>.
[8] 21 U.S.C. § 823 and 21 C.F.R. § 1301.71.
[9] 21 C.F.R. § 1301.73.
[10] 21 C.F.R. § 1301.74(a).
[11] 21 C.F.R. § 1301.74(b).
[12] Id.
[13] 21 C.F.R. § 1301.74(c).
[14] 21 C.F.R. § 1301.74(e).
[15] 21 C.F.R. § 1301.74(f).
[16] Government Accountability Office, "Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results," available at: < http://www.gao.gov/new.items/d11744.pdf>.

for DEA's Office of Diversion Control by more than $30 million over FY 2012 levels.[17] We support these efforts to enhance the operations and effectiveness of the DEA's diversion control investigations, and agree with the GAO recommendation regarding the need for enhanced efforts to assess the effectiveness of these investigations in reducing prescription drug diversion.

C. DEA Authority Over Internet Sites Distributing Controlled Substances Can Help Prevent Diversion

In 2008, Congress recognized the need for additional oversight of Internet sites distributing controlled substances, and DEA received additional statutory authority to regulate online sales of these products. The Ryan Haight Online Pharmacy Act of 2008 contained new provisions to prevent the illegal distribution of controlled substances by means of the Internet, including:

- New definitions, such as "online pharmacy" and "deliver, distribute, or dispense by means of the Internet";
- A requirement of at least one face-to-face patient medical evaluation prior to issuance of a controlled substance prescription;
- Registration requirements for online pharmacies;
- Internet pharmacy website disclosure information requirements; and
- Prescription reporting requirements for online pharmacies.[18]

An update on DEA's registration and enforcement activities would help assess the effectiveness of these recent measures in combatting illegal online sales of controlled substances.

D. DEA Authority Relating to Disposal of Controlled Substances, When Fully Implemented, Can Help Prevent Diversion

As stated above, in 2010, DEA received new authorities to establish secure disposal programs that would enable ultimate users and long-term care facilities to return controlled substances for disposal.[19] Since a public meeting with widespread participation in January 2011, no proposed regulations have been issued to date regarding secure disposal.

All of these measures, once fully implemented by DEA to the extent they have not been to date, will further reinforce the "closed system" in place to help prevent the diversion of prescription drugs that are also controlled substances.

[17] DEA FY 2013 Budget Summary, available at: <http://www.justice.gov/jmd/2013summary/pdf/fy13-dea-bud-summary.pdf>.
[18] Pub. L. 110−425, 122 Stat. 4820, Oct. 15, 2008.
[19] Secure and Responsible Drug Disposal Act of 2010, Public Law 111–273, Oct. 12, 2010.

III. PhRMA and Member Company Efforts to Prevent Diversion of Prescription Drugs From the Regulated Supply Chain

PhRMA member companies place a high priority on their responsibility for helping ensure that the medicines patients receive are authentic and meet the established quality specifications set out in the FDA-approved application. These activities focus on working to help prevent diversion of legitimate products from the regulated supply chain, as well as to help prevent counterfeiting of prescription medicines. The patient safety risks presented by both criminal acts require nothing less. The resulting risks to patients are equally unacceptable – a legitimate product could be compromised by diversion, resulting potentially in patient harm -- or, a counterfeit could contain a deadly ingredient or no active ingredient at all – again resulting potentially in patient harm. When medicines are diverted, a second real risk exists, that the product could be misused or abused, potentially with devastating consequences. Member companies routinely assess information about issues and trends related to both diversion from the regulated supply chain and counterfeiting, because the lessons learned from one setting often helps inform the other.

Because of the number of independent actors that make up the regulated prescription drug supply chain, it is clear that preventing pharmaceutical product diversion is a shared responsibility. And PhRMA member companies are committed to doing our part. Through individual member company efforts and participation in a variety of third-party organizations and coalitions, PhRMA and its member companies are extremely proactive in helping to protect the security of their manufacturing facilities, warehouses, and the shipment of their prescription medicines in transit. At the same time, PhRMA member companies engage in robust activities to prevent the counterfeiting of their medicines, whether they are controlled or non-controlled substances. Relevant member company and coalition activities are summarized below.

A. Anti-Diversion Activities

Anti-diversion activities by PhRMA member companies are ongoing, but can best be categorized as occurring at four key points: (1) during a product's research and development lifecycle; (2) during manufacturing and storage; (3) during transit to a customer, typically a wholesale distributor; and (4) after a product has been dispensed to patients.

1. Research & Development of Abuse-Resistant Formulations: PhRMA member companies are committed to continuing to research and develop abuse-resistant formulations to reduce the potential that even if they are diverted, it will be much more difficult to extract the active ingredient for the purposes of misuse. Additional guidance from FDA to sponsors on the clinical trial and approval requirements for products with abuse-resistant formulations/dosing regimens could help facilitate the continued research and development of these products.
2. Manufacturing and Warehousing Operations: PhRMA member companies routinely employ technologically advanced measures to protect the security of both their facilities and their operations. Manufacturing sites and warehouses are commonly secured by guards, fences

and extensive electronic access control and video surveillance systems. Pharmaceutical products, and their active ingredients, are securely stored in locked cages and/or vaults. Many companies utilize background checks to qualify employees, as well as third-party vendor services. Employee access to in-process manufacturing areas, as well as those used for storage and distribution, is limited to those with the requisite education, experience and necessary security training to carry out required tasks. Visitors, and in many cases contractors, are always accompanied when travelling through or working in sensitive areas.

3. In-Transit: PhRMA member companies conduct vulnerability assessments on third party carriers, freight-forwarders, warehousemen and third party logistic providers, striving to utilize only trusted and proven vendors. As with the security of facilities, in-transit security also can involve the use of advanced electronic security measures such as GPS tracking systems to monitor carrier shipments. Actual shipper cases are commonly sealed with tamper-evident tape. A "layered" security approach is applied to the trip itself, which includes: avoiding weekend and holiday deliveries; the use of two person driver teams, secreting proprietary, portable GPS devices within the shipment itself; sealing the trailer with hardened, tamper evident devices; and never leaving the shipment unattended during a trip.
4. After Dispensing: Once products have been dispensed to patients, PhRMA and its member companies help educate on the need to use medicines exactly as prescribed, the dangers of sharing medicines with anyone, the need to store medicines where they cannot be accessed by others, and how to immediately and properly dispose of any unwanted or expired medicines in the household trash or through a secure disposal program with law enforcement oversight. Along with U.S. Fish and Wildlife and the American Pharmacists Association, PhRMA established the SMARXT DISPOSAL program (see, for example, www.SMARxTDISPOSAL.net) to help educate consumers about how to properly and safely dispose of medicines in an environmentally-friendly manner. This educational program outlines how in just a few small steps, consumers can safely, quickly and easily dispose of any unused, unwanted, or expired medicines in their home. We also note that the FDA requires, for a limited set of products, including many opioids, that the products be disposed of by flushing.

B. Anti-Counterfeiting Measures

PhRMA member companies also employ a variety of overt and covert anti-counterfeiting technologies to help prevent counterfeiters who intentionally copy our products and packaging for their own financial gain to the detriment of patients. These anti-counterfeiting measures can also help deter those who may seek to divert our products from the regulated supply chain. In addition to the use of tamper-evident features on prescription product packaging, PhRMA member companies use holograms, color-shifting inks, and other mechanisms to help protect their products. These anti-counterfeiting measures are frequently updated, sometimes as often as every 12-18 months, to stay one step ahead of increasingly sophisticated criminals. PhRMA member companies engage in these activities because the consequences of a patient receiving a counterfeit medicine can also be potentially devastating. As

stated, the use of these overt and covert anti-counterfeiting measures can also help deter those who may be seeking to divert our products from the regulated supply chain.

C. Pedigree/Track and Trace Systems

Many stakeholders focus on the use of electronic technologies such as pedigree or track and trace systems to help secure our finished product supply chain and to electronically track products from the manufacturer through each change of ownership to the final point at which a medicine is dispensed to patients. We are concerned about the possibility of a patchwork of potentially conflicting state laws addressing pedigree systems. Thus, we believe that a uniform national approach to any electronic system to track finished prescription drugs in the regulated pharmaceutical distribution chain is of primary importance. As described more fully below, we currently are actively engaged in a coalition effort that includes every sector in the finished product distribution chain – manufacturers (brand and generic), wholesalers (primary and secondary), and pharmacies (chain and independent) – and we remain committed to working with that group to help develop a potential solution to a complex technological and operational issue for the prescription drug supply chain overall. While electronic systems or technologies may serve a deterrent effect, there is no one single technology or electronic system that would be a "silver bullet" to prevent diversion from the regulated supply chain.

D. Coalition Activities

Pharmaceutical Security Institute: Established in 2002, the Pharmaceutical Security Institute (PSI) is a non-profit membership organization composed of the corporate security directors from 25 global pharmaceutical manufacturers. PSI maintains the Counterfeiting Incident System (CIS), which is used to record incidents of counterfeiting, theft and illegal diversion of pharmaceutical products worldwide. CIS incidents come from a variety of sources, including open media reports, PSI member company submissions, and public-private sector partnerships. PSI and its members also help educate and train federal, state, local and international law enforcement personnel on both counterfeit and drug diversion incidents, using information in the CIS, and counterfeit and drug diversion investigation techniques. PSI members have most recently developed and distributed to all PSI members a set of best practices for pharmaceutical warehouse security.

Coalition for Patient Safety and Medicine Integrity: PhRMA and several of its members are part of this coalition of pharmaceutical, medical device and medical products companies focused on patient safety. The Coalition's purpose is to protect patients from the risks posed by stolen and inappropriately handled medical products re-entering the legitimate supply chain. The Coalition is asking Congress to modernize the U.S. criminal code to increase criminal penalties for medical product cargo theft in order to deter this criminal behavior and prosecute the organizations that perpetrate it.

Pharmaceutical Cargo Security Coalition (PCSC): PCSC is an organization comprised of pharmaceutical industry professionals, law enforcement and government entities, cargo insurers, carriers and risk management advocates dedicated to preventing theft of pharmaceutical products in transit. Created and managed daily by a PhRMA member company, the PCSC regularly shares information about law

enforcement investigations, trends, and best practices related to securing pharmaceutical and other medical products in distribution, along with offering training, intelligence and relevant information.

Pharmaceutical Distribution Security Alliance (PDSA): PhRMA and 10 of its member companies are active participants in this informal coalition of more than 27 member organizations representing all sectors of the regulated domestic finished prescription drug supply chain, including 6 trade associations. The PDSA is developing legislative specifications addressing increasing licensure requirements for wholesale distributors, increasing criminal penalties for counterfeit drugs, enacting controls over online drug sellers, and establishing the building blocks for an electronic tracking system for finished prescription drugs, all of which could help enhance patient safety by minimizing the risk of a patient receiving a counterfeit or diverted prescription drug product.

Partnership for Safe Medicines (PSM): The Partnership for Safe Medicines is a group of not-for-profit organizations and individuals that have policies, procedures, or programs to protect consumers from counterfeit or contraband medicines. PSM regularly engages in consumer and stakeholder outreach and education designed to help educate about the dangers of counterfeit medicines, purchasing medicines online, and drug diversion. PhRMA and its member companies actively support PSM.

IV. Recommendations for Additional Finished Product Supply Chain Security and Prescription Drug Misuse/Abuse Measures

PhRMA and its member companies support a variety of additional measures that could help strengthen the domestic prescription drug supply chain against diversion and counterfeiting and that could help prevent inappropriate use or misuse of prescription drugs. Several of these efforts are summarized below.

Increased Licensure Requirements for Wholesale Distributors: We support increasing the federal licensure requirements for wholesale distributors, who are currently licensed by the states, under minimum guidelines created under the PDMA. Weaknesses or gaps in state licensing requirements can facilitate individuals obtaining wholesaler licenses for operations that could potentially deal in diverted and counterfeit drug products. As an example, H.R. 3026 sponsored by Reps. Bilbray and Matheson would prohibit persons with felony convictions related to wholesale distribution from being licensed as wholesale distributors, and would also require additional security measures such as payment of substantial performance bonds and background checks and fingerprinting for key facility managers.

Internet Drug Sellers: The prevalence of online drug sellers offering frequently counterfeit medicines, including controlled substances, without a valid prescription, is a gap that must be closed. We note that the passage of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 gave DEA new authorities over online sales of prescription drugs that are also controlled substances, and we encourage DEA to continue to exercise that authority to help protect the public and prevent diversion of controlled substances.[20] Additionally, in many instances, consumers face a very real risk of receiving a counterfeit drug from an online drug seller. Several PhRMA member companies are also active in the Alliance for

[20] Pub. L. 110−425, 122 Stat. 4820, Oct. 15, 2008.

Safe Online Pharmacies, an informal international alliance of stakeholders dedicated to protecting patient safety globally and to helping ensure patient access to safe and legitimate online pharmacies in accordance with applicable laws.

Increased Oversight of Repackaging Operations: Repackaging has been an identified weak spot in the drug distribution system that can be used as an entry point and distribution center for diverted and counterfeit drug products. Repackagers remove drug products from their original packaging and labeling, thereby destroying any counterfeit resistant technologies employed by the original manufacturer. Consequently, additional oversight is necessary to ensure that repackaged drug products are authentic and are not compromised by repackaging operations. PhRMA believes FDA could better regulate the authenticity and quality of repackaged drug products if it had authority to require prior approval of repackaging operations. At a minimum, FDA should increase its inspections of repackagers and, where appropriate, initiate enforcement action. In addition, repackagers should be subject to the same requirements regarding overt and covert counterfeit resistant technologies as original manufacturers.

Increased Criminal Penalties for Counterfeit Drugs: We support increased criminal penalties for those who counterfeit our drugs. The current criminal penalties for counterfeiting a prescription drug are less than selling illicit drugs or counterfeiting U.S. currency, and must be increased to reflect the significant negative public health impact of the crime of pharmaceutical counterfeiting.

Support Increased Funding for DEA's Office of Diversion Control: As stated above, we support the Administration's proposed FY 2013 increased funding requests for the DEA's Office of Diversion Control.

Continue to Work with DEA to Implement Regulations for Secure Disposal of Prescription Drugs: As stated above, we look forward to continuing to work with the DEA as it implements regulations under the Secure and Responsible Drug Disposal Act of 2010 to allow ultimate users and long-term care facilities to safely return for disposal controlled substances without increased risks of diversion.

Support for NASPER reauthorization: PhRMA continues to support reauthorization of the National All Schedules Prescription Electronic Reporting Act, or NASPER, which would provide and improve patient access with quality care, and protect patients and physicians from deleterious effects of controlled substance misuse, abuse and trafficking.

Support for Prescription Drug Monitoring Programs: Federal law provides grants to the states to create prescription drug monitoring programs (PDMPs), which are databases in which medical professionals enter information related to prescription medicines identified as controlled substances by the DEA. PDMPs can help prevent abusers from obtaining prescriptions from multiple doctors and help identify inappropriate prescribing patterns. While federal law sets out certain parameters for states to receive grants for PDMPs, the specific attributes of PDMPs vary widely across the states. In addition, PDMPs vary in terms of the outcome measures of interest. PhRMA continues to believe that PDMPs can play a vital role in identifying inappropriate prescribing patterns, help identify signals of prescription drug misuse or abuse and prompt enhanced referral of patients for treatment for prescription drug abuse. A key component of effective PDMP programs is to establish interoperability across state lines, and

PhRMA has supported the PDMP Interconnect program, which facilitates the transfer of PDMP data across state laws for access by authorized users.[21]

V. Conclusion

In conclusion, PhRMA and its member companies are dedicated to improving the lives of patients. This emphasis on the patient extends throughout the life cycle of the product -- from researching and developing new medicines, to helping ensure medicines are used appropriately, to helping prevent the diversion of pharmaceutical products from the regulated supply chain. At the same time, addressing the growing problem of prescription drug abuse is a shared responsibility, and patients need continued, uninterrupted access to the prescription medicines that allow them to live longer, healthier lives. PhRMA remains committed to the issues of prescription drug diversion and inappropriate use of prescription medicines. We look forward to continuing to work with the Subcommittee, members of Congress, and other stakeholders on these important issues.

[21] See <http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect/index.php>.