

**TESTIMONY OF THE PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA (PhRMA)
BEFORE THE HOUSE ENERGY & COMMERCE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
APRIL 14, 2011**

Madame Chair, my name is Kendra Martello, Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am pleased to present this testimony on behalf of PhRMA, which 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. Industry-wide research and investment reached a record \$67.4 billion in 2010.

I. Introduction

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 Seven million Americans over age 12 reported using prescription drugs in the past month for non-medical reasons in 2009.² Among 12 to 17 year olds and 18 to 25 year olds, prescription drugs were the second most common drug of abuse in 2009, with 3.3% of 12 to 17 year olds and 6.3 % of 18 to 25 year olds reporting using prescription drugs non-medically in the past month.³ Of particular concern, there was an increase in recent nonmedical use of prescription drugs among 18 to 25 year olds between 2008 and 2009 from 5.9 to 6.3%--even more alarming when many are leaving college and entering the workforce with this dangerous behavior. According to treatment admissions data, opiates other than heroin increased from 1 percent of admissions aged 12 and older in 1998 to 6 percent in 2008, while other prescription medicines, such as tranquilizers and sedatives, each accounted for less than 1 percent of TEDS admissions between 1998 and 2008.⁴ In addition to the human toll on families, misuse and abuse of prescription drugs

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

² Substance Abuse and Mental Health Services Administration, *Results from the 2009 National Survey on Drug Use and Health: National Findings*, September 2010.

³ *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).

⁴ Treatment Episode Data Set 1998-2008, National Admissions to Substance Abuse Treatment Services, SAMHSA, April 2010.

result in higher costs to the health care system in terms of avoidable hospitalizations, increased emergency room visits, and costs related to addiction treatment.

PhRMA supports efforts to bring attention to this issue and recognizes the identified need for broad stakeholder engagement to help respond to this important public health matter. PhRMA and our member companies are actively engaged in a range of efforts to help ensure that prescription medicines are used appropriately and to reduce prescription drug abuse. At the same time, it must be recognized that national data on the abuse of prescription drugs reinforces the importance of improving communications between providers and patients as well as the need to improve patient monitoring among all health care stakeholders. According to the National Institute on Drug Abuse (NIDA), the three types of prescription drugs most commonly abused are opioids, central nervous system (CNS) depressants, and stimulants.⁵ While many of the medicines included in these categories are produced by brand name or innovator manufacturers, it is important to recognize that among these drugs, in 2010, 88.5% of prescriptions were for generic drugs with only 11.5% of the prescriptions for brand name medicines.⁶ For opioids, 92.4% of 2010 prescriptions were for generics; for CNS depressants, 93.4%, and for stimulants, 47.4%.⁷ These statistics reinforce that addressing the problem of non-medical use of prescription drugs is a shared responsibility and there is no single solution. Instead, collaborative efforts must be undertaken between the federal government, PhRMA, the Generic Pharmaceutical Association, American Medical Association, and other relevant associations and stakeholder groups – including healthcare providers, law enforcement, faith-based and other community organizations, schools and colleges, parents, pharmacists, and state and local governments – to address this public health issue.

II. Background

It is critical that policies aimed at preventing prescription drug abuse do not unintentionally create barriers to patient access to needed medicines. PhRMA and its members urge that any evaluation of policies to help reduce misuse and abuse of prescription medicines must also ensure continued patient access to needed prescription medicines. Potential barriers to patient access include poor or insufficient training of health care workers regarding appropriate prescribing practices, unnecessarily restrictive drug control regulations and practices which may impede good clinical care, and fear among health workers of the potential for legal sanctions for legitimate medical practice which may lead to undertreatment (see, for example, Gatchel 2010).⁸ Articles in medical literature and patient groups have raised concerns about increasing physician hesitancy to prescribe certain medications. As just one example, a survey of physicians regarding pain management found “that concerns of potential abuse or addiction often affect how pain is

⁵ National Institute on Drug Abuse, Prescription Drugs: Abuse and Addiction, August 2005; 2010 NSDUH Methodology Section.

⁶ 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.

⁷ 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.

⁸ Gatchel, R.J. Is fear of prescription drug abuse resulting in suffers of chronic pain being undertreated? Expert Rev. Neurotherapy 2010;10(5):637-39.

pharmacologically treated” by physicians.”⁹ The end result of such practices is that millions of Americans who suffer significant or chronic pain are likely being under-treated either due to inadequate training or concerns about the potential for prescription drug abuse.

Experts agree that appropriate use of medicines plays a central role in both the quality of health care patients receive and the quality of the lives they lead. Numerous studies have reported that appropriate prescribing of medication therapy and adherence to that therapy improves quality and outcomes, while often reducing total costs and use of other, often more expensive, health services.¹⁰ One study found that non-adherence has been shown to result in \$100 billion each year in excess hospitalizations alone.¹¹ Stakeholders from all sectors of health care, including researchers, payers, employers, patient advocates, and health care practitioners, agree that non-adherence is a serious problem that should be solved. Supporting better communication between providers and patients is a key step to improving adherence as well as enhancing the patient’s understanding about his or her disease or condition, its course, and its related target laboratory test values. Providers, when given support by the proper tools and systems, can play a central role in helping patients understand how to take their medicines properly. For instance, one main cause of preventable hospital readmissions is poor communication with patients during the discharge process, especially regarding medications.¹²

Public policy discussions about the appropriate role of prescription medicines in health care often assume that medicines are widely overused. The importance of ensuring appropriate use of medicines through appropriate training of health care providers cannot be overstated. As policies around prescription drug abuse are discussed, it is important to recognize that, while research indicating overuse of prescription drugs is limited, there is much evidence that large percentages of patients underuse needed medical care, including prescription medicines, for many serious health conditions. Efforts to stimulate better prescribing of and adherence to essential medications improves health, averting costly emergency department visits and hospitalizations, and improving quality of life and productivity.¹³

Long-term policy solutions to ensuring appropriate use and reducing the potential for abuse will require substantial ongoing education, training, and responsibility among a

9 McCarberg, BH et al. “The Impact of Pain on Quality of Life and the Unmet Needs of Pain Management: Results From Pain Sufferers and Physicians Participating in an Internet Survey,” *American Journal of Therapeutics* 2008;15(4): 312-20.,

¹⁰ Examples include, but are not limited to: W.H. Shrank, et al. “A Blueprint for Pharmacy Benefit Managers to Increase Value.” *American Journal of Managed Care*, February, 2009.; D. Cutler, et al., “The Value of Antihypertensive Drugs: A Perspective on Medical Innovation,” *Health Affairs*, January/ February 2007.; M. Cloutier, et al., “Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity,” *Pediatrics*, November 2006.; M. Sokol et al., “Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost,” *Medical Care*, June 2005.

¹¹ New England Healthcare Institute, “Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease.” A NEHI Research Brief, August 2009.

¹² B.W. Jack et al, “A Reengineered Hospital Discharge Program to Decrease Rehospitalization,” *Annals of Internal Medicine*, February 2009.

¹³ See, for example, M. Sokol et al., “Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost,” *Medical Care*, June 2005; B.W. Jack et al, “A Reengineered Hospital Discharge Program to Decrease Rehospitalization,” *Annals of Internal Medicine*, February 2009; New England Healthcare Institute, “Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease.” A NEHI Research Brief, August 2009.

broad range of stakeholders, including patients, physicians, nurses, pharmacists, insurers and others involved in health care delivery. Any policies to prevent prescription drug abuse must recognize and ensure that patients with a legitimate need continue to receive their medicines.

III. Selected Federal Activities

Overview of National Policy Related to Prescription Drug Abuse

The 2010 National Drug Control Strategy identifies a number of objectives related to the diversion, abuse, or misuse of, and addiction to, prescription drugs including:

- Regulating and monitoring the prescribing of drugs with potential for abuse;
- Shutting down illegal pharmacies and fraudulent clinics;
- Expanding prescription drug monitoring programs;
- Removing unused medications from the home;
- Informing the public of the risks of prescription drug abuse and overdose; and
- Working with physicians to achieve consensus standards on prescribing.¹⁴

PhRMA supports these efforts and a comprehensive approach involving a range of stakeholders to help address this public health issue.

Overview of Select Provisions from PPACA

There are a number of provisions in the recently enacted Patient Protection and Affordable Health Care Act (PPACA) that may impact efforts to reduce prescription drug abuse and which should be taken into consideration in ensuring a comprehensive approach to preventing prescription drug abuse. For example, section 4305 of PPACA¹⁵ establishes three strategies to advance research and treatment in the field of pain care. First, it required the Secretary to enter into an agreement with the Institute of Medicine (IOM)¹⁶ to examine the state of pain research and treatment and to establish an agenda for action to improve the state of pain care research, education, and clinical care.¹⁷ We understand that IOM is about to hold its fifth meeting on its consensus study “Advancing Pain Research, Care, and Education”¹⁸ and look forward to findings and recommendations from the consensus study, which must be submitted to Congress no later than June 30, 2011. Second, PPACA added section 409J to the PHS Act to authorize the Pain Consortium of the National Institutes of Health (NIH) to enhance and coordinate basic and clinical research on the causes of and potential treatments for pain. Within one

¹⁴ONDCP. 2010 National Drug Control Strategy (<http://www.whitehousedrugpolicy.gov/strategy>).

¹⁵ The Reconciliation Amendments did not modify this provision.

¹⁶ If the Institute of Medicine declines to participate, the Secretary may enter into an agreement with another appropriate entity. Pub. L. No. 111-148 § 4305(a)(3).

¹⁷ This section authorizes Congress to appropriate sums necessary to carry out the Conference on Pain for each of fiscal years 2010 and 2011. Pub. L. No. 111-148 § 4305(a)(5).

¹⁸ IOM Consensus Study “Advancing Pain Research, Care, and Education,” <http://www.iom.edu/Activities/PublicHealth/PainResearch.aspx>

year of enactment, the Secretary also must establish an Interagency Pain Research Coordinating Committee to coordinate all efforts within the Department of Health and Human Services (HHS) and other federal agencies that relate to pain research. Third, PPACA added section 759 to the PHS Act to authorize the Secretary to make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.¹⁹

Other Relevant Federal Laws and Activities

Risk Evaluation and Mitigation Strategy (REMS) for Opioid Products: The Food and Drug Administration (FDA) has been considering the development of a REMS to reduce the abuse of long-acting and extended-release opioids, which are a critical treatment option for pain management. The proposed REMS has yet to be put in place but FDA is considering several elements such as prescriber training, information for patients, and periodic effectiveness assessments.

Prescription Drug Take-Back Programs: Some states and localities have organized a variety of different voluntary prescription drug take-back programs to help facilitate secure consumer disposal of unwanted or expired prescription medicines. These types of programs can take many forms: a one-day event with or without a law enforcement presence, a mail back program, or an ongoing collection event. The Drug Enforcement Administration (DEA) is currently drafting proposed regulations to permit an ultimate user to return a controlled substance for the purposes of disposal.

The DEA is planning a second voluntary national take-back day on April 30, 2011, which will consist of local events at which law enforcement officers will be present at all times to monitor the items collected, along with educational information on prescription drug abuse. Other voluntary one-day collection events exist as well, such as the America's Medicine Chest Challenge. That program, which occurred on November 13, 2010, also involved consumer education.

In addition, PhRMA believes that any prescription drug take-back program must adequately protect against the very real risks that prescription drugs, including controlled substances, could be diverted for abuse or misuse. Any take-back program must also be coupled with a comprehensive educational effort that instructs stakeholders on key issues regarding prescription drug abuse. Finally, we are concerned that ongoing collection events at local pharmacies could facilitate medicines fraud and abuse, particularly if a person who gained access to collected medicines, and then resold them to unscrupulous buyers, and/or attempted to bill government programs for collected and/or resold products.

¹⁹ This section authorizes Congress to appropriate sums necessary to carry out the award program for each of the fiscal years 2010 through 2012. Pub. L. No. 111-148 § 4305(c).

IV. Developing a Comprehensive and Balanced Approach to Prescription Drug Abuse: Discussion of Potential Policy Options

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. Our key goals are to promote health care access for all Americans, including a commitment to health care quality, increased emphasis on disease prevention, and continued medical progress through advances in research. Our industry is 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 working with Congress, the Administration and other stakeholders on efforts to help reduce and prevent prescription drug misuse and abuse. Public policy related to preventing prescription medicine abuse must:

- 1) Educate the public regarding the dangers of misusing and abusing prescription medicines while also educating and equipping youth influencers (including parents, grandparents, teachers, and health care providers) and all health care stakeholders with the necessary knowledge and skills to deter abuse of prescription medicines, identify those in need of treatment, and provide appropriate treatment options when appropriate.
- 2) Any policies to prevent prescription drug abuse must recognize and ensure that patients with a legitimate health need continue to receive the medicines they are prescribed.
- 3) Require a comprehensive approach and sustained commitment from all relevant health care stakeholders ranging from federal, state, and local governments to innovator and generic drug companies, to the broad range of health care providers that interact with patients, to educators, family members, and others across the community.

PhRMA offers the following policy ideas for consideration as part of a comprehensive national strategy aimed at reducing and preventing prescription drug abuse.

Expand existing and develop additional educational and awareness efforts for the public, health care stakeholders, and others.

Existing educational efforts could be expanded and the development and implementation of additional outreach campaigns to educate all relevant stakeholders about prescription drug abuse should be considered. Framing the issue as one that implicates the public health could also help educate Americans about the dangers of abuse of prescription medicines. While education is an important first step, it must be sustained and consistent, and reach a multitude of audiences, to be truly effective. And, while education is of critical importance, we must not stop there.

As background, the 2010 National Drug Control Strategy identifies several targets for education: (1) the public about the risks of prescription drug abuse and overdose, (2)

physicians via consensus standards to inform prescribing practices, and (3) those involved in prescribing via prescription drug monitoring programs (PDMPs). While these are important groups, there are many more stakeholders who have a role to play in preventing and reducing prescription drug abuse.²⁰ Regarding physicians as an educational target, we expect that the results of the IOM consensus study will help inform potential revisions to quality standards in treatment guidelines by various physician specialties. We also recognize that a wide range of coalitions and collaborative efforts have been developed that focus on preventing prescription drug abuse. Additionally, use of measurable performance outcomes could also help facilitate the development of a robust national network of organizations with prevention of prescription drug abuse as their core mission, and could help facilitate the expansion of existing collaborative efforts among various stakeholders.

These efforts should be complemented by educational activities related to the appropriate use of medicines with the goal of all patients monitored and supported effectively across the health care system. All health care stakeholders – not just physicians and pharmacists – who have access to patients or patient data have a responsibility to promote appropriate use of medicines and help identify and prevent inappropriate prescribing and abuse.

Enhance efforts to promote prevention, screening, brief intervention and referral for treatment of prescription drug abuse throughout the health care system.

There are four key stages at which the problem of prescription drug abuse can be impacted: prevention, screening, early intervention, and treatment. Through PPACA, Congress recognized the importance of ensuring addiction and mental health benefits. This is an important first step that could be enhanced by the assessment of the adequacy of current screening efforts across health care stakeholders. Such an assessment could inform the development of more robust screening and intervention efforts. The development of a cross-cutting strategy to address prescription drug abuse could help ensure adequate resources and attention are devoted to prevention, screening, early intervention, and treatment. Adequate infrastructure investments in the health care system could help connect Americans to prevention, early screening, intervention and treatment options. At the same time, it is also critical to ensure that such efforts do not unintentionally reduce patient access to medicines or negatively impact their medical treatment.

Working with relevant stakeholders, Congress could also explore incentives for ensuring that screening for prescription drug abuse is incorporated into routine interactions in the health care system, e.g., screening could be incorporated into medical and dental visits by asking about substance abuse history, current prescription drug use, and reasons. In

²⁰ For example, in a Drug Benefit News article representatives of pharmacy benefit plans acknowledged that payers and plans have a large responsibility in addressing prescription drug abuse, and identified a number of potential areas for payers to focus on, including increasing the frequency of monitoring of patients using controlled prescription medicines, promoting the use of consensus guidelines, developing additional educational and awareness efforts, and making better use of medication history to identify potential prescription drug abuse. Drug Benefit News. PBMs, Payers Need More Focus on Curbing Spike in Rx Pain Med Abuse, July 30, 2010 (vol. 11, no. 15).

addition, all health care providers should be educated regarding the signs of addiction and to be alert to drug seeking behaviors, including "doctor shopping." As another example, the Centers for Medicaid and Medicare Services (CMS) could explore incentives for the use of electronic health records (EHRs) to allow pharmacy medication data to auto-populate EHRs to ensure that the use of EHR technology improves the quality of patient care. Identifying new ways to facilitate electronic exchange of pharmacy claims data, as well as other medical data, would facilitate a more accurate picture of the patient's medication history by allowing providers to view a patient's active medication list and history within the EHR, resolve any identified discrepancies, compare any new medications with the list, receive prompts about medication interactions or allergies, and easily share the updated and verified information with the patient and other appropriate providers.

We support related efforts by the Substance Abuse and Mental Health Services Administration (SAMHSA) to consider how health information technology can be incorporated into a broad range of activities that include but are not limited to exploring the use of pharmacy and medical provider information from individual State PDMPs, and NASPER to inform state and community treatment and prevention programs, including community coalitions, to identify and provide local, real time information regarding questionable prescribing practices.

Assess the effectiveness of PDMPs and explore enhancements.

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. According to the National Alliance for Model State Drug Laws, as of July 15, 2010, 43 states have enacted legislation enabling the establishment of a PDMP, of which, 33 states have operational programs.²¹

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. For PDMPs applying for federal funding, the Bureau of Justice Assistance has identified the principal impact measure as simply a reduction in the rate at which members of the general population use prescription drugs inappropriately to be based on National Survey on Drug Use and Health prevalence data.²² Other PDMPs may identify as desired outcomes (1) an increase in the number of referrals to treatment, and (2) a reduction in the number of prescribers who engage in inappropriate behavior.

²¹ National Alliance for Model State Drug Laws. Status of State Prescription Drug Monitoring Programs. <http://www.namsdl.org/documents/StatusofStatesJuly152010.pdf>.

²² Bureau of Justice Assistance. Guidance for Harold Rogers Prescription Drug Monitoring Program (PDMP) Grantees on Responding to Performance Measures (<http://www.ojp.usdoj.gov/BJA/pdf/PDMPPerfMeasureGuide.pdf>).

Programs and initiatives to promote removal of unused and expired medicines from the home are generally implemented with the goal of reducing the misuse and abuse of pharmaceuticals by reducing the access to such medicines in the home and/or preventing accidental overdoses. To fully assess the benefit of a program and, by extension, its cost-effectiveness, we continue to urge evaluations of their efficacy relative to its stated goal. As such, any discussion of program outcomes should be augmented with a consideration of the programs' goals and their relationship with those measurable outcomes.

As part of a comprehensive strategy designed to reduce and/or prevent prescription drug abuse, the utility and effectiveness of PDMPs to assist in the identification of inappropriate prescribing practices and the identification of prescription drug abusers should be assessed. Key considerations with respect to assessing the utility of PDMPs in reducing or preventing prescription drug abuse include:

- Interoperability across state lines,
- Appropriately populated with data from prescribers,
- Adequate funding and routine updating to serve as a reliable data source,
- Operate as “real-time” databases or static data files,
- Outcome measures tracked by the state that are appropriately matched to identifiable policy goals such as increasing the number of referrals for treatment,
- Assessment of extent to which PDMPs are incorporated into health care providers' clinical practices,
- Assessment of provider perspectives on PDMP effectiveness and administrative burden;
- Detailed outcome assessments for providers using PDMPs versus those not using PDMPs, that is, how patient-level outcomes differ,²³
- An understanding regarding whether and to what extent PDMPs have impacted fraud and related criminal investigations, and
- Understanding any gaps in PDMP data resulting from mail-order and internet purchases.

Address challenges related to research and development of new medicines to treat addiction and medicines with reduced potential for abuse.

Congress could promote efforts, both in the public and private sector, to address challenges in the research, development and approval of new medicines that can treat addiction and medicines with a reduced potential for abuse. The federal agencies with key roles in the approval and oversight of prescription drugs could be regularly convened to share ideas and perspectives on their relevant roles in helping prevent prescription drug abuse and to help promote comprehensive policies that could help further the Administration's goal of reducing prescription drug abuse.

²³ Possible outcome measures could include, of those identified as abusing prescription medicines, what percentage are prosecuted and sentenced and do they have access to treatment, what percentage are referred to treatment, is there adequate treatment capacity in the community, do those identified have better treatment outcomes due to earlier intervention in the drug abuse cycle, do those identified have fewer emergency department visits and hospitalizations.

Another potential way to address challenges related to medication development would be for the FDA to provide additional guidance to sponsors on the clinical trial and approval requirements for products with abuse-resistant formulations/dosing regimens. At the same time, however, any new policies should not present potential barriers to patient access to needed medicines.

Medications to Treat Addictions

A number of promising medicines are in the pipeline to treat addiction ranging from vaccines for nicotine and cocaine addiction to medicines to treat alcoholism and opioid dependence, as well as combination medicines and personalized medicines. However, research and development of medicines remains costly, risky, and very challenging, and clinical trials are becoming more complex.²⁴ The complexities related to developing medicines to treat addiction are compounded by challenges related to clinical trial recruitment and retention, ensuring patient access to addiction medicines, and obtaining adequate reimbursement and coverage of addiction medicines. While it is important for the public and private sector to continue to explore ways to develop new medicines to treat addiction, it is equally important to ensure access to these medicines and other treatment services, including via education of the health care community regarding how to screen for and treat drug abuse. We urge an increased emphasis within HHS and with private payers to address this ongoing challenge and to continue to explore how to further incentivize research and development of medicines to treat addiction.

Medications with Reduced Potential for Abuse

The biopharmaceutical industry faces similar issues in the development of medicines that are abuse resistant or deterrent. Reformulations, for example, can decrease abuse potential but require substantial research and development investment to demonstrate safety and efficacy with no guarantee of approval by the FDA. The lack of clear standards for assessing tamper-resistance has resulted in an unpredictable regulatory process. In addition, once approved, there is no guarantee that pharmacy benefit managers will favorably place or include these products in their formularies. In developing a comprehensive prescription drug abuse policy, resolution of potential barriers to research and development in this area is an important element.

Promote the enforcement of existing laws that can help deter abuse of prescription drugs as a key law enforcement priority.

Congress is uniquely positioned to encourage state, local, and federal law enforcement officials to use their full arsenal of existing enforcement authorities to deter prescription drug abuse. By increasing the emphasis on the enforcement of existing laws, financial incentives for illegal activities will be reduced, and the risks for those seeking to divert and profit from the illegal sale of prescription medicines will be increased. Areas of focus could include:

²⁴ See, for example, J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007.

- Increased enforcement of existing prohibitions on sales of prescription drugs without a doctor’s prescription or without an in-person medical evaluation could be encouraged.
- Consider limiting online sales of prescription medicines only to those Internet sites operating in compliance with all state pharmacy laws, per a recent report from the Joint Strategic Plan on Intellectual Property Enforcement, which references ongoing U.S. government efforts to prohibit paid advertising for illegal on-line pharmaceutical vendors and to explore means to ensure those operating in violation of relevant laws can be subject “to the full reach of law enforcement jurisdiction.”²⁵
- Ensure adequate resources for training law enforcement in pursuing investigations in this area and promoting information-sharing across jurisdictions as appropriate to ensure successful investigation and prosecution of health care fraud.

Expand educational efforts related to the proper disposal of unused and expired prescription medicines and secure storage of prescription medicines.

As discussed previously, PhRMA believes that prompt and proper disposal of unused and expired medicines is an important tool to help prevent the diversion and abuse of prescription medicines. Equally important is the secure storage of prescription medicines for a number of reasons, including to help consumers organize and keep track of their prescription medicines and to ensure that a child, teenager, or even a stranger does not gain inappropriate access to prescription medicines. In addition, ensuring medicines are stored properly will prevent damage to medicines and help reduce the potential for accidental injury. Efforts such as the SMAR_xT DISPOSAL campaign, a partnership between PhRMA, the U.S. Fish and Wildlife Service and the American Pharmacists Association, educate consumers on how to quickly and easily dispose of any unused medicines in a safe and environmentally protective manner in their household trash.

V. Spotlight on Select Activities by PhRMA Related to Preventing Prescription Drug Abuse

As stated, PhRMA views increasing awareness and education as fundamental to the prevention of prescription drug abuse. We have worked collaboratively with the medical community, drug abuse prevention organizations, and others on educational efforts to prevent the misuse and abuse of prescription drugs. Select examples of PhRMA initiatives include those described below.

Development of a school curriculum to prevent abuse of prescription and over-the-counter drugs. The curriculum is comprised of components for students (in grades 5 through 12) as well as presentations for parents (information available at <http://www.dare-america.com/home/features/documents/RxOTCInfoFlyer.pdf>). This curriculum was created by D.A.R.E. America (Drug Abuse Resistance Education), with

²⁵ “2010 Joint Strategic Plan on Intellectual Property Enforcement,” (June 2010), available at: < http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf >, at 17.

the support and expertise of law enforcement officials; PhRMA; Abbott; the Consumer Healthcare Products Association (CHPA); and a number of other organizations, including the White House Office of National Drug Control Policy (ONDCP), the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), NIDA, the Substance Abuse and Mental Health Services Administrations' Center for Substance Abuse Treatment (SAMHSA/CSAT) and the Partnership for a Drugfree.org.

A tool kit and brochure to raise awareness of the dangers of abusing over-the-counter cough medicines, alcohol, and prescription drugs. In collaboration with the Community Anti-Drug Coalitions of America (CADCA) and CHPA, PhRMA developed a 16-page newspaper supplement distributed nationwide as well as online, entitled "Stay Smart, Don't Start: The Truth About Drugs and Alcohol" (available at <http://www.nieteacher.org/staysmart.pdf>) to educate youth and parents about the dangers of abusing over-the-counter cough medicine and prescription drugs as well as a brochure targeting teenagers entitled "The Real Truth About Rx and OTC Medicine Abuse" (available at <http://www.otcsafety.org/Media/129096000527317246.pdf>).

Study of health care provider attitudes in collaboration with Partnership for a Drug-Free America (PDFA). PhRMA and PDFA (now Partnership at Drug Free.org) assessed healthcare provider attitudes as to their need for more information on prescription drug abuse for their patients. Many specialties stated they received information through their journals or their respective professional associations but several groups expressed the need for more patient-friendly materials for use in the emergency room, dental offices, orthopedic offices, nurse practitioner locations, etc. Through these interviews, we were able to assess the need for additional materials and educational opportunities, as well as guide them to valuable resources within the prevention and treatment community.

Educational tools and guidelines to prevent the misuse and abuse of prescription medicines targeting undergraduate and graduate students. In collaboration with the Washington Health Foundation, a program to improve health for the people of Washington state, PhRMA along with a diverse group of stakeholders recently unveiled a new initiative that will help educate college students in Washington state about the proper use of medicines and provide resources to help prevent the abuse and misuse of prescription drugs and over-the-counter products. The tools and guidelines available online (available at <http://www.whf.org/my-health>) were developed by other young people and the site is exclusively maintained by current undergraduate and graduate student interns from across the state. Key elements of the Washington state initiative include the use of resident assistants in college dormitories to conduct peer-to-peer education and the use of university healthcare clinic staff to increase awareness of the misuse or abuse of prescription drugs.

Educational efforts related to the proper disposal of unused and expired prescription medicines and secure storage of prescription medicines. According to the 2009 National Household Survey on Drug Use and Health, 55.3 percent of those who reported non-medical use of prescription pain relievers reported that they obtained them

from a friend or relative for free, if you also include the number who reported buying them from a friend or relative, or taking them from a friend or relative without asking the percentage increases to 70.2 percent in 2008.²⁶ PhRMA supports educational efforts to promote prompt and responsible disposal of unused and expired prescription medicines. As a practical matter, any medicine that appears damaged, discolored, or otherwise different from when the prescription was initially filled should be disposed of promptly and properly. PhRMA partnered with the U.S. Fish and Wildlife Service and the American Pharmacists Association to create the SMAR_xT 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 promptly, safely, quickly and easily dispose of any unused or expired medicines in their home.

VI. Conclusion

In conclusion, tackling the increasing problem of prescription drug abuse is a shared responsibility. There is no single solution that will effectively reduce or eliminate the rates of prescription drug misuse or abuse. PhRMA stands ready to engage in the dialogue around this public health issue and to work with relevant stakeholders to help address the problem.

Prescription medicines save and improve lives every day but when used inappropriately, devastating consequences can result. At the same time, patients need continued, uninterrupted access to the prescription medicines that allow them to live longer, healthier lives. Any policies in this area should not unintentionally create barriers to patient access to needed medicines. Appropriate use of medicines is an important issue to all of our member companies, and we look forward to working with the Subcommittee, members of Congress, and other stakeholders on these important issues.

²⁶ *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).

²⁶ Substance Abuse and Mental Health Services Administration, *Results from the 2009 National Survey on Drug Use and Health: National Findings*, September 2010; table 6.47B.