Federal Legislation Takes Aim at Prescription Counterfeits, Illegal Internet Drug Distribution

In 2011, counterfeit pharmaceuticals made up the largest portion of seized items in the Consumer Safety and Technology category, at 28% when ranked by domestic value, as reported by United States Customs and Border Protection. Through its own research, NABP has identified 3,845 Web sites selling drugs that have not been tested or approved by the US Food and Drug Administration and are illegal to sell in the US. Further, of the 8,789 Web sites reviewed by the NABP Internet Drug Outlet Identification program, 96.21% are operating out of compliance with pharmacy laws and practice standards established in the US to protect public health. In addition, NABP has found that of those 8,456 Not Recommended Web sites, 86% sell prescription medication without requiring a valid prescription.

With documented reports of US victims harmed by counterfeit drugs ordered online, and thousands of packages shipped from overseas direct to consumers, federal lawmakers are considering several pieces of legislation developed to address the issue from various angles. Two bills specifically target the distribution of medications online – one, targeting sites that sell non-controlled substances without requiring valid prescriptions, and the other targeting sites that peddle counterfeit drugs online. Three other bills currently under consideration by Congress are much broader in scope, aiming to clamp down on all counterfeited and pirated goods entering the US via the Internet. With the fate of these bills still unfolding in Congress, understanding the mechanisms proposed by each and how they may take shape if passed and implemented is of interest to all stakeholders, including boards of pharmacy, concerned about the health and safety of consumers who order medications online and the security of the US prescription drug supply chain.

Challenges Under Current Law

NABP and other organizations such as the Alliance for Safe Online Pharmacies (ASOP) and the Partnership for Safe Medicines have

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Internet Pharmacy Legislation
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pointed out that regulation of Internet drug outlets is difficult due to many factors. For example, many Internet drug outlets are foreign-based sites, making the process of tracking down the operators difficult and lengthy. It is worthy of note that many foreign-based sites use US-based registrars and other Internet service providers. Some enforcement strategies target these enabling service providers. In addition, if law enforcement agents are able to shut down such a site, often the operators are able to set up shop again, using a different domain name, using a different Web site server, and/or setting up in a different country with weaker regulations.

While not directly related to Internet drug outlets, the recent shut down of the site Megaupload.com, a site allegedly providing pirated US-created music and movies, serves as a good example of the difficulty of stopping these operations. The site’s owner, Kim Schmitz, also known as Kim Dotcom, a German citizen, was arrested in New Zealand and the Web site was shut down by seizing servers that hosted the site’s content. Within 24 hours of the arrest, other sites claiming to be associated with Megaupload.com posted remnants of its content or the company’s logo and graphics without content; these sites were reportedly hosted on servers in the Netherlands and Belize.

While US agents in partnership with international law enforcement were able to orchestrate an arrest relating to the Megaupload.com case, a New Zealand court will determine whether Schmitz is extradited to face charges in the US. Many times the operators of Internet sites peddling prescription drugs are located in foreign countries where US law enforcement has no jurisdiction. And many industry experts have also pointed out that when arrests and convictions are made for selling counterfeits, the penalties are not strong enough to deter others from engaging in counterfeit manufacture or distribution. Bryan Liang, MD, PhD, JD, vice president of the Partnership for Safe Medicines, has also noted that it is “difficult to attribute patient death or injury to online drug consumption or purchase.”

Bill Focused on Internet Drug Distribution

The Online Pharmacy Safety Act (S 2002), a bill developed to protect consumers from Internet drug outlets that distribute drugs without requiring a valid prescription, was introduced to the US Senate on December 15, 2011, by Senators Jeff Sessions (R-AL) and Dianne Feinstein (D-CA). The legislation builds on the Ryan Haight Online Pharmacy Consumer Protection Act which, by amending the Controlled Substances Act with a definition of “valid prescription,” allowed for the prosecution of individual-drug outlets. The proposed law would amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to use the Ryan Haight definition of valid prescription so that non-controlled substance prescription drugs may only be ordered and dispensed from an Internet pharmacy pursuant to a valid prescription. Specifically, the bill would amend the FD&C Act to define valid prescription as “a prescription issued for a legitimate medical purpose in the usual course of professional practice,” and to specify that a prescription must be issued by “a licensed practitioner who has conducted at least one in-person medical evaluation of the patient,” except under certain circumstances, such as the issuance of a prescription under an Expedited Partner Therapy program or pursuant to a state health authority order, as allowed by law.

The Online Pharmacy Safety Act also includes a provision that would help to protect consumers from sites illegally marketing prescription drugs and peddling counterfeit drugs. The legislation would amend the FD&C Act to require the establishment of a registry of legitimate online pharmacy Web sites, that would include Internet pharmacies accredited by the NABP VIPPS® (Verified Internet Pharmacy Practice Sites®) accreditation program, and other Internet pharmacies approved by the Secretary of Health and
2012-2013 NAPLEX Review Committee Announced
Twenty-Five Dedicated Members Return to Safeguard the Integrity and Validity of the Examination

NABP is pleased to announce the members of the 2012-2013 North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee, commending 25 returning members.

This group of dedicated volunteers is composed of faculty and pharmacists who are representative of the diversity of pharmacy practice, and is responsible for reviewing the examination questions, attending and participating in meetings, and writing new test questions. Acting under the policy and planning guidance of the Advisory Committee on Examinations and the NABP Executive Committee, the committee shares the task of safeguarding the integrity and validity of the Association’s examination. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements, which, in essence, determine the question pool. The NAPLEX Review Committee members began their terms on February 1, 2012.

NAPLEX Review Committee Members

- Marie A. Abate, West Virginia University
- Loyd V. Allen, Jr, Edmond, OK
- Jennifer Beall, Samford University
- Christopher Betz, Sullivan University
- Michael Cockerham, University of Louisiana at Monroe
- Mark Decerbo, University of Southern Nevada
- Betty Dong, University of California, San Francisco
- Darla Gallo, Philadelphia, PA
- W. Franklin Gilmore, Montana Tech of The University of Montana
- Robert P. Henderson, Samford University
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- Tom M. Houchens, London, KY
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- William Kehoe, Jr, University of the Pacific
- Susan C. Lutz, Altoona, IA
- David W. Newton, Shenandoah University
- Stephen M. Ouellette, Oakland, ME
- Roy Parish, University of Louisiana at Monroe
- David B. Roll, Granbury, TX
- Theresa Salazar, Indianapolis, IN
- Eric F. Schneider, University of Waterloo
- Cindy Sieck, Vancouver, WA
- John L. Szarek, The Commonwealth Medical College
- Neal F. Walker, Hibbing, MN
- Siu-Fun Wong, Loma Linda University

NAPLEX Review Committee Members Convene to Discuss Examination Items

North American Pharmacist Licensure Examination* (NAPLEX®) Review Committee members Siu-Fun Wong, PharmD, FASHP, FCSHP, Loma Linda University School of Pharmacy, and Neal F. Walker, RPh, of Hibbing, MN, analyze and discuss examination items for the NAPLEX. *

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Chairperson
One-year term

Malcolm J. Broussard
President
One-year term

Michael A. Burleson
President-elect
One-year term

Karen M. Ryle
Treasurer
One-year term

James T. DeVita
Member, District 1
Serving second year of a three-year term

Edward G. McGinley
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Mark T. Conradi
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Lloyd K. Jessen
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Cathryn J. Lew
Member, District 7
Serving third year of a three-year term

Hal Wand
Member, District 8
Serving first year of a three-year term

NABP Executive Committee elections are held each year at the Association’s Annual Meeting.
Burden May Be Burdensome
By Dale J. Atkinson, JD

When undertaking an administrative disciplinary action, the burden of proof necessary to substantiate a finding of guilt is essential to sustaining such board action. Boards of pharmacy are encouraged to understand what burden of proof is necessary to support administrative disciplinary action. In many jurisdictions, a preponderance of the evidence standard is the burden of proof necessary to sustain an administrative prosecution. A preponderance of the evidence is defined as “more likely than not” and is the same burden of proof used to assess civil cases.

Some jurisdictions require a clear and convincing evidentiary standard in administrative actions. Clear and convincing evidence calls for a “more highly probable to be true than not” standard to be met to sustain a decision. A clear and convincing standard requires a greater degree of believability than the preponderance standard.

Finally, beyond a reasonable doubt standard is used in criminal matters. Beyond a reasonable doubt is described as that no other logical explanation can be derived from the facts except that the defendant committed the crime, thereby overcoming the presumption that a person is innocent until proven guilty. Beyond a reasonable doubt is the most difficult standard to meet from the prosecution perspective, based upon the fact that a person’s liberties are at stake. That is, criminally convicted defendants can be incarcerated and lose certain civil rights.

Further complicating legal issues involving burden of proof questions is the impact of using a civil or criminal conviction as a basis for subsequent administrative action. For instance, if a licensee is convicted in a civil matter by a preponderance standard, can such civil conviction form the basis for subsequent administrative action by the regulatory board? To enhance judicial efficiencies, the legal doctrines of res judicata and/or collateral estoppel may apply. Res judicata and collateral estoppel prevent the re-litigation of matters between the same parties based upon the same material facts under circumstances where all applicable due process and other rights were afforded to the parties. In short, the previous judicial determinations are conclusive of the issues (collateral estoppel) or entire litigation (res judicata) and eliminate the need to re-litigate the facts. When differing burdens of proof apply, the application of these principles becomes complicated. Consider the following.

An employee (licensee) of a real estate brokerage firm represented both buyers and sellers in a residential transaction. The deal fell through and the sellers refused to return the buyers' deposit. The buyers sued the licensee, the brokerage firm, and the sellers in a civil action. The jury by a preponderance of the evidence found in favor of the buyers against the licensee holding that they breached their fiduciary responsibilities and made misrepresentations. However, the jury also held that the buyers did not prove by a clear and convincing standard that the licensee acted with malice, fraud, or oppression. Interestingly, the jury did find by clear and convincing evidence that the additional defendant (the sellers) did indeed commit fraud and deceit.

The misrepresentation and breach of fiduciary counts in the civil action formed the basis for an administrative complaint against the licensee before the California Real Estate Commissioner (Commissioner). The applicable California law authorizes discipline based upon a civil
Judgment against a real estate licensee for misrepresentation, fraud, or deceit in connection with a transaction for which a license is required. After a hearing, the administrative law judge recommended that no discipline be imposed. The Commissioner rejected this recommendation and imposed administrative discipline. The licensee appealed and the trial court denied his request. He thereafter appealed to the appellate court.

On appeal, the licensee argued that the Commissioner cannot discipline a licensee premised upon a civil judgment that used a preponderance of the evidence standard rather than a clear and convincing standard. Under the California Constitution, administrative discipline against a professional license must be based upon a clear and convincing standard. The Commissioner acknowledged the clear and convincing standard in administrative actions, but argued that the only fact that must be proven by a clear and convincing standard is the existence of a civil judgment based upon fraud, misrepresentation, or deceit with reference to a transaction for which a license is required. Specifically, the statute states:

When a final judgment is obtained in a civil action against any real estate licensee upon grounds of fraud, misrepresentation, or deceit with reference to a transaction for which a license is required under this division, the commissioner may, after hearing, suspend or revoke the license of such real estate licensee.

Under California law, the Commissioner is permitted to discipline a licensee based solely upon the entry of a judgment against a licensee for fraud, misrepresentation, or deceit with reference to a transaction for which a license is required. No reference to the facts related to the entry of the judgment is necessary. Thus, the court narrowed the issue to whether the use of a civil conviction determined under a preponderance of evidence standard in a subsequent administrative action violates the principle, under the California Constitution, that the suspension or revocation of a professional license must be based upon misconduct proven by clear and convincing evidence. The court noted the unusual circumstances in the present case in that the licensee in the civil matter was found by a preponderance of the evidence to have acted negligently and to have made false representations. In that same civil matter, the jury held that clear and convincing evidence did not establish that the licensee acted with malice, oppression, or fraud for purposes of imposing punitive damages.

In agreeing with the licensee, the court noted that the doctrine of collateral estoppel was inapplicable to the current case. This conclusion was based upon the fact that the proceedings operate under different burdens of proof (preponderance in the civil case and clear and convincing in the administrative case). In ruling in favor of the licensee, the court reversed the argument of the board that the civil judgment is the operative fact upon which the licensee is subject to discipline, not the acts or omissions of the licensee that led to that judgment.

The court also noted that rather than applying collateral estoppel principles to the case, the actual argument is “whether the legislature can constitutionally authorize the imposition of professional discipline based only on clear and convincing evidence that a judgment has been entered against the professional for license-related misconduct, without requiring that the judgment itself have been based on clear and convincing evidence.” Citing cases dealing with attorneys, the court held that the law is settled and findings made by a preponderance of the evidence standard in civil cases cannot be given binding effect in a subsequent administrative proceeding because clear and convincing evidence is required.

Accordingly, the court reversed the imposition of administrative sanction against the licensee and directed that the Commissioner’s order be set aside. The court also awarded costs in favor of the licensee.

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FDA Takes Action to Mitigate, Prevent Drug Shortages

With the rise in drug shortages climbing dramatically in the last several years, more and more patients have faced delays in treatment or treatment with suboptimal alternative drug therapies. Drug shortages are affecting patients with life-threatening and chronic illnesses including cancers, various strains of pneumonia, attention deficit hyperactivity disorder (ADHD), and asthma, among other serious diagnoses.

President Obama has stressed that “shortages of pharmaceutical drugs pose a serious and growing threat to public health,” with the number of prescription drug shortages reported to Food and Drug Administration (FDA) having tripled from 61 in 2005 to 178 in 2010. Data from the University of Utah Drug Information Service showed 211 shortages in 2010 with a 27% increase to 267 drug shortages in 2011. To meet patient demand, pharmacists at some hospitals spend at least 40 hours a week managing drugs in shortage, up 50% from a few years ago, according to one hospital pharmacy director. Hospital pharmacists also continue to field unsolicited inquiries from gray market wholesalers who often market drugs in shortage at greatly increased prices. Community pharmacists have also been affected and face difficulties in filling prescriptions for ADHD drugs.

In October 2011, FDA released a report on the issue, including an analysis of drug shortage causes and steps the agency will take to address shortages. Further, with the support of a presidential executive order issued on October 31, 2011, FDA has expanded efforts to work with manufacturers to help mitigate drug shortages.

Possible Causes of Shortages

A recent study on shortages of anti-infective medications examined the scope and causes of shortages of these life-saving treatments and concluded that the shortage amounts to a public health emergency. As of February 2011, anti-infectives represented 13% of the 193 unavailable drugs. The shortage of these drugs becomes more problematic when combined with increasing rates of drug resistance, and a reduction in the approval of new anti-infective agents, according to the study, published in the March 1, 2012 Clinical Infectious Diseases. The study indicates that while patient-outcome data due to shortages is limited, it has been documented that delayed treatment with an appropriate anti-infective has resulted in increased mortality for patients with bacterial sepsis, bloodstream infections, and three strains of pneumonia. The authors cite several causes for anti-infective shortages, including an increase in demand due to epidemics, new therapeutic indications, or perceived shortages, and – from the supply standpoint – a shortage of raw materials, regulatory compliance issues, and capacity issues.

The FDA report, A Review of FDA’s Approach to Medical Product Shortages, found that of 127 shortages studied, 80% of the drugs were sterile injectable medications. Such drugs are “more complex and require more specialized processes and equipment to manufacture, leading to a higher likelihood of manufacturing problems,” reports FDA. Of all drug shortages, most were due to quality problems that delayed manufacturing, with injectable drugs having a higher instance of quality problems compared with non-injectables. The report also notes that there are fewer companies producing these drugs, and that delays in manufacturing take
longer to resolve due to complexity of the process. Since 2011, pharmacists have experienced a greater demand for the ADHD medications Adderall® and Ritalin® due to shortages in the generic versions of these drugs. Lack of generics can mean patients pay out of pocket for brand-name medications or pharmacies or insurers absorb the cost. When unable to afford the brand-name medication, many patients choose to wait until a pharmacist can dispense the generic product. FDA has indicated that manufacturers are seeing a shortage of the active pharmaceutical ingredients (API) used in these drugs. Drug Enforcement Administration (DEA) is aware that quotas limiting the amounts of controlled substance API released to drug companies is cited as an issue, but indicated that there is enough API to meet the demand for ADHD medications, and DEA spokesman Rusty Payne told Pharmalot.com that the agency increased the quota for the amphetamine salt by 30% for 2012. DEA stated that drug manufacturers have made decisions to produce more of the brand-name versions of these drugs, rather than the generics, possibly leading to the shortage. Further, in regard to releasing additional API, DEA is concerned about rising levels of Ritalin and Adderall abuse, which has seen a particularly dramatic increase among college students. While FDA and manufacturers have indicated that releasing additional API could help address the shortage of these drugs, DEA remains concerned about rates of abuse and helping to ensure legitimate use of ADHD medications. Others note that there has been an increase in demand for ADHD drug treatments in part due to new guidelines for diagnosis of ADHD that increased the number of children diagnosed with the disorder from 7.8% in 2003 to 9.5% in 2007. In 2010, more than 18 million prescriptions were written for Adderall, a 13.4% increase from 2009.

**Executive Order & FDA Actions**

The most common actions FDA takes when working with manufacturers to address drug shortages are:

- expediting review of new manufacturing sites, new suppliers, and specification changes,
- exercising regulatory flexibility and discretion, and
- asking other firms to increase production.

FDA has also worked with manufacturers to identify means to mitigate the dangers of products with quality issues, and has expedited review of regulatory submissions. In 5% of the shortages recently reviewed by FDA, controlled importation of similar products approved abroad was authorized by the agency.

On October 31, 2011, President Obama issued an executive order that directs FDA to take additional steps to prevent and reduce current and future disruptions in the supply of lifesaving medicines. The order directs FDA to:

- require manufacturers to provide adequate advance notice of manufacturing discontinuances that could lead to shortages of drugs that are life supporting or life sustaining, or that prevent debilitating disease;
- expand current efforts to expedite regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes, whenever the agency determines that expedited review would help to avoid or mitigate existing or potential drug shortages; and
- communicate to the Department of Justice (DOJ) any findings that shortages have led market participants to stockpile the affected drugs or sell them at exorbitant prices. The DOJ will determine whether such activities are consistent with applicable law, and take action as appropriate.

In conjunction with the executive order, FDA sent a letter to drug manufacturers reminding them of their responsibility to report the discontinuation (continued on page 80)
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of certain drugs to the agency and encouraging companies to voluntarily disclose to FDA potential shortages in cases where disclosure is not currently required by law. In addition, plans were initiated to increase staffing resources for FDA’s Drug Shortage Program. FDA also initiated the implementation of a database that will track and analyze the characteristics of drug shortages. FDA’s report notes a number of additional long-term actions that the agency has planned.

FDA Rule to Improve Manufacturer Notifications

According to FDA, “The federal Food, Drug, and Cosmetic (FD&C Act) does not grant the Agency legal authority to require companies to continue manufacturing medications that are in shortage. However, manufacturers of certain drugs are required to provide advance notification to FDA of a discontinuance in manufacture under section 506C of the FD&C Act and in the implementing section of the Code of Federal Regulations.”

A new rule issued by FDA modifies the requirements for reporting drug shortages to the agency with the aim of obtaining information about more potential shortages and obtaining it sooner. The FDA interim final rule, issued December 19, 2011, and effective January 18, 2012, requires manufacturers that are the only producer of certain drug products to report to FDA all interruptions in manufacturing that could lead to drug shortages. This rule applies to products that are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition. Whereas in the past only permanent shortages were required to be reported to FDA, the new rule modifies the definition of “discontinuance” to include temporary and permanent shortages of affected drugs. The new rule also clarifies the definition of “sole manufacturer” to mean the only manufacturer actually producing the product must meet the reporting requirements, regardless of whether another manufacturer holds the Abbreviated New Drug Application or New Drug Application for the drug. Affected manufacturers should report anticipated shortages to FDA six months in advance of the shortage whenever possible, and otherwise, under certain circumstances, as soon as possible. In February 2012, FDA released a draft guidance for industry on requirements for notification to FDA of drug discontinuance or issues that may lead to a drug shortage.

As explained in a US Department of Health and Human Services (HHS) fact sheet, early notification of potential drug shortages is an essential tool in helping FDA work with drug manufacturers, hospitals, health care providers, and patients to prevent or mitigate drug shortages. HHS reports that FDA prevented 233 shortages in the past two years, and that awareness raised by the President’s executive order “When informed of the possibility of a shortage in advance, FDA has increasingly been able to prevent potential drug shortages from occurring” (GAO Report December 15, 2011) and the FDA letter to manufacturers resulted in a six-fold increase in voluntary notifications in November 2011, compared with prior months.

FDA actions are consistent with recommendations of the Government Accountability Office (GAO). GAO’s report, Drug Shortages: FDA’s Ability to Respond Should Be Strengthened, issued December 15, 2011, recommended that “Congress should consider establishing a requirement for manufacturers to report to FDA any changes that could affect the supply of their drugs.” The report also supported the creation of an information system for managing data about drug shortages and concluded that “[w]hen informed of the possibility of a shortage in advance, FDA has increasingly been able to prevent potential drug shortages from occurring,” but that lack of authority to require manufacturers to report actual or potential shortages has made this task a challenge.

Legislation Introduced

Recognizing this issue, federal lawmakers have introduced legislation that would amend the FD&C Act to authorize FDA to require broader reporting from drug manufacturers. The Preserving Access to Life-Saving Medications Act of 2011 is under consideration in the US House of Representatives (HR 2245) and the US Senate (S 296), and would amend the FD&C definitions of “drug shortage” and “discontinuance,” along with other revisions to the act that would effectively require a prescription drug manufacturer to notify FDA of a discontinuance, interruption, or other adjustment of the manufacture of the drug that would likely result in a shortage of such drug.

At the same time, while FDA has “taken on the task of working with manufacturers to help prevent and mitigate these shortages,” and has been successful in mitigating and managing numerous shortages, the agency notes that “many of the root causes and potential solutions to the shortage problem lie beyond its purview.”

The drug shortage issue will be further discussed at the NABP 108th Annual Meeting during the session “Where Have All the Drugs Gone? – Who’s Responsible for Drug Shortages and Quotas?” (See page 89 for more details.)
Human Services. In addition, the legislation would allow Internet service providers – such as domain name registrars, financial transaction providers, and Internet advertising services – to cease or refuse to provide services to Internet drug outlets not included on the registry. A House version of the bill was introduced by Representative Bill Cassidy (R-LA) on February 28, 2012.

NABP recently issued a letter to Senators Sessions and Feinstein indicating the Association’s support of the Senate bill.

Deterring Counterfeit Distributors

Other legislation has been drafted to specifically target the trafficking of counterfeit drugs and was introduced by Senator Patrick Leahy (D-VT) to the Senate on November 17, 2011. The Counterfeit Drug Penalty Enhancement Act of 2011 (S 1886) would increase penalties for trafficking counterfeit drugs, with convicted individuals facing penalties of up to $4 million and 20 years imprisonment, and up to $8 million for multiple offenses. Entities convicted of trafficking counterfeit drugs could face fines as high as $10 million for a single offense or as much as $20 million if convicted of multiple offenses. One supporter of the bill stated that under current US law, individuals convicted of trafficking counterfeit drugs typically face prison sentences of three years, while the products they peddle can cause serious long-term health issues for unsuspecting purchasers.

Fighting Intellectual Property Infringers

As a variety of counterfeited products – from pirated movies and music, to fake baby formula, military goods, and pharmaceuticals – are distributed through Internet channels, some legislators have introduced bills focused on protecting American intellectual property (IP) rights. Two of three such bills include provisions specifically related to counterfeit goods that endanger lives, such as counterfeited pharmaceuticals. Such bills have met with much debate, with supporters aiming to protect American innovation, jobs, and safety, and critics voicing concerns over freedom of speech, policing of the Internet, and the security of the Internet. While debates have not focused on the provisions related to the online distribution of prescription drugs and counterfeits, understanding how each proposed law could impact Internet drug outlets is pertinent.

In the 112th Congress, the three bills being considered to address Internet distribution of counterfeited products are as follows:

- Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act of 2011 (PROTECT IP Act or PIPA), (S 968), introduced to the US Senate, May 12, 2011
- Online Protection and Enforcement of Digital Trade Act (OPEN Act), (S 2029), introduced to the US Senate, December 17, 2011

PROTECT IP Act

The PROTECT IP Act, or PIPA, was developed with the intention of targeting the worst-of-the-worst Internet intellectual property infringers by eliminating financial viability of a site, rather than blocking access. Concerns voiced by various parties over similar intellectual property legislation introduced in 2010 were considered as the bill was drafted, yet, it has also faced much criticism. PIPA was pulled from the legislative calendar on January 23, 2012, but the bill’s sponsor, Senator Leahy, hopes to bring it to the Senate floor again later in 2012.

SOPA

Under SOPA, a court order could authorize the Attorney General to require domain name system (DNS) providers to block infringing foreign sites. In addition, entities such as Internet Service Providers and search engines would be required “to remove the link to an illegal site so that it doesn’t come up as part of the search results,” as summarized by the bill’s author, Representative Lamar Smith (R-TX).

Of particular interest to boards of pharmacy and other stakeholders concerned about the security and safety of pharmaceuticals that reach US patients, SOPA includes provisions that would provide immunity from liability to entities refusing to do business with foreign infringing Internet sites distributing counterfeit products causing harm or death, such as pharmaceuticals and military goods. Further, individuals convicted of trafficking in counterfeit drugs or intentionally participating in or knowingly aiding drug counterfeiting could face up to $2 million in fines and a 10-year prison term, or up to $5 million in fines and 20 years for multiple offenses. Convicted entities could be fined up to $5 million, or up to $15 million for multiple offenses. Offenders convicted of knowingly or recklessly causing bodily injury through trafficking in counterfeit drugs or other goods, could face up to life imprisonment under the bill.

SOPA Supporters

Organizations focused on Internet pharmacy safety and consumer safety are among the supporters of SOPA. ASOP, in which NABP participates as an observer, issued a letter of support for the bill, noting that it gives Internet commerce companies “incentive to shut down illegal online drug operations that endanger the public health.” ASOP also supported the provision that provides immunity, or a “safe harbor,” for entities taking voluntary action against illegal online sellers. The International AntiCounterfeiting Coalition also issued a letter supporting the bill and specifically the provisions that would increase penalties for trafficking in goods, such as counterfeit pharmaceuticals, that endanger the lives and health of consumers. Other supporters included Pharmaceutical Re-

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search and Manufacturers of America, the National Sheriffs’ Association, the National Governors Association, and several organizations representing the entertainment industry.

SOPA Critics

Some critics of the bill claim its language could allow the government or copyright owners to block access to sites allegedly infringing on copyright and possibly without due process. Senator Ron Wyden (D-OR) has argued against SOPA and PIPA, as one of many critics who believes that both bills would make the Internet vulnerable to risks. Wyden explained in a Washington Post blog interview that if domain names are blocked, people could use work-arounds and third-party tools that use foreign or other domain-name servers to access the sites, placing the Internet at risk to hackers. Both Wyden and Representative Darrell Issa (R-CA) also criticize SOPA because it requires US businesses to enforce the actions against the infringing foreign entities, which Issa states is unconstitutional. Issa also believes that SOPA does not allow due process and could be used to block access to a site before it is clear that the site is in violation of copyright law.

OPEN Act

Wyden and Issa are the sponsors of the OPEN Act, which aims to protect intellectual property rights by authorizing the US International Trade Commission (ITC) to cut off the money to infringing sites. According to a press release from Wyden, if an ITC investigation “finds that a foreign registered website is ‘primarily’ and ‘willfully’ infringing on the IP rights of a U.S. rights holder, the commission would issue a cease and desist order that would compel payment processors (like Visa and Paypal) and online advertising providers to cease doing business with the foreign sites in question. This would cut off financial incentives for illicit activity and deter these unfair imports from reaching the U.S. market.” Wyden and Issa believe this approach will be more effective than an approach that requires DNS blocking.

White House Response

On January 14, 2012, the White House issued a response to two online petitions urging the Obama administration to “veto” the SOPA and PIPA bills. The response, authored by Victoria Espinel, Intellectual Property Enforcement Coordinator at Office of Management and Budget; Aneesh Chopra, US Chief Technology Officer; and Howard Schmidt, special assistant to the president and cybersecurity coordinator for National Security Staff stresses that “the important task of protecting intellectual property online must not threaten an open and innovative internet.”

The response indicated that analysis of some legislative efforts showed that proposed provisions would be a threat to cyber security, and that measures driving users to unreliable DNS servers should be avoided. Further, the statement emphasized that legislation addressing the issue of copyright infringement on the Internet should be targeted at sites out of reach of US law engaged in activity clearly prohibited by US law, and called upon the Internet technology industry to offer ideas for clamping down on foreign rogue sites selling counterfeit goods.

At Press Time . . .

Both the Online Pharmacy Safety Act and the Counterfeit Drug Penalty Enhancement Act had been referred to committees, with the latter scheduled to be placed on the Senate calendar. SOPA had been referred to the Senate Committee on the Judiciary. PIPA was pulled from the legislative calendar, but Senator Leahy intends to bring it to the Senate again this year. The OPEN Act was referred to committees in the Senate and House.

Of interest to boards of pharmacy and other stakeholders concerned about the safety of medications that reach US patients, it appears that each bill, if signed into law, could assist federal law enforcement in investigating rogue Internet drug outlets and related counterfeit drug trafficking schemes. Further, provisions regarding tougher penalties for involvement in counterfeit drug trafficking seemingly should serve as a stronger deterrent to these crimes.

NABP convened the Task Force on Internet Pharmacy Practice, March 6-7, 2012, and as part of its charge to review and determine whether additional action should be taken by boards of pharmacy and the Association to address the illegal distribution of drugs via Internet sites, the task force discussed many issues also relevant to the pending legislation. The report of the task force is forthcoming.

Further Resources

In addition to www.thomas.gov, which provides the status on each bill, the following online resources may be of interest for further reading on the topic:

State Boards of Pharmacy Report 4,324 Disciplinary Actions to the NABP Clearinghouse in 2011

State boards of pharmacy continue to demonstrate consistent efforts in disciplinary action reporting to the NABP Clearinghouse. Year-end totals for 2011 showed a total of approximately 4,324 records reported to the database, 65% of which were actions taken on pharmacists and 35% of which were actions taken on pharmacy technicians. The total number of records entered into the Clearinghouse for 2011 decreased by 16% when compared to actions reported in 2010; however, in 2010, the number of submissions may have increased as some states worked to catch up on any backlogs in disciplinary reporting.

Overall, findings in 2011 reporting appeared consistent with annual results in 2009 and 2010. Administrative or publicly available fines/monetary penalties (14.8%) and revocation of license (12.5%) remained in the top three disciplinary actions taken against pharmacists and pharmacy technicians; however, at 19.7%, probation of license was the highest reported action taken, which is a slight change from 2010 when this action fell to 14.6% of the total reported actions. Probation of license was also the highest reported action in 2009 at 20.4%. (See Figure A.)

Of all the actions taken in 2011, Clearinghouse data indicates that 19.5% were taken due to a violation of federal or state statutes, regulations, or rules. The miscellaneous category, which consists of several smaller categories, held the actual highest percentage overall with 20.2%. These findings are consistent with results in 2010. Disciplinary actions related to diversion of a controlled substance rose to 10.4% in 2011, compared to 8.6% in 2010. (See Figure B.)

The NABP Clearinghouse is regularly updated to serve as a comprehensive resource for the boards of pharmacy. Housing a tremendous amount of disciplinary data provided by the boards, the Clearinghouse is an important resource for the license transfer process as it tracks everything from the actions taken against pharmacists and pharmacy technicians to the basis for these actions. NABP also offers its services as a reporting agent for the Healthcare Integrity and Protection Data Bank (HIPDB).

To further enhance the systems usability, in 2011, NABP launched an electronic reporting tool allowing boards to submit disciplinary actions taken against pharmacies and facilities directly to HIPDB if they have designated the Association as their reporting agent. This online tool was developed to assist the boards in meeting HIPDB reporting requirements set forth by the United States Department of Health and Human Services, Health Resources (continued on page 84)

![Figure A: Disciplinary Actions Reported in 2011](image)

* The miscellaneous category includes denial of initial license; denial of license renewal; extension of previous action; license restoration or reinstatement denied; limitation or restriction on license; other licensure action – not classified; and reduction of previous action.
NABP, FSMB, NCSBN to Hold First Ever Tri-Regulator Symposium

Members from NABP, the Federation of State Medical Boards (FSMB), and the National Council of State Boards of Nursing (NCSBN) will have the opportunity to meet at the first ever Tri-Regulator Symposium to be held October 17-18, 2012, in Washington, DC. The focus of the meeting will be on the history of state-based medical, nursing, and pharmacy regulation in the United States, as well as a discussion of current and future opportunities for interprofessional cooperation and collective challenges faced by these three groups.

Attendance is limited among the three organizations. NABP will be represented by the NABP Executive Committee as well as additional representatives from member boards of pharmacy. Attendance will be on a first-come, first-served basis. More information about the opportunity to attend the symposium will be provided in the NABP Electronic Mailbag, which is sent to the board of pharmacy executive officers each week.

The Tri-Regulator Symposium is being sponsored by the Tri-Regulator Collaborative, which is composed of NABP, FSMB, and NCSBN. While each organization is autonomous with its own constituent membership, common values about public protections through state-based licensure unite the organizations for dialogue and consensus building. The members recognize that there are potential benefits to be gained by collaborating to better protect the public health, safety, and welfare. Tri-Regulator Collaborative members also recognize the value of involving a broader constituency as issues emerge and, therefore, encourage other health care regulatory representatives to participate in relevant and pertinent issues.

Clearinghouse 2011

(continued from page 83)

and Services Administration, Division of Practitioner Data Banks. NABP also plans to launch a similar reporting tool in late 2012 to accommodate online reporting of actions taken against pharmacists and pharmacy technicians. Additional information about the NABP Clearinghouse and designating NABP as a reporting agent is available at www.nabp.net/programs/member-services/nabp-clearinghouse.

Figure B: Basis for Disciplinary Actions Reported in 2011

*The miscellaneous category includes default on health education loan or scholarship obligations; failure to obtain informed consent; failure to provide medically reasonable and/or necessary items or services; filing false reports or falsifying records; immediate threat to health or safety; improper or inadequate supervision or delegation; malpractice; misleading, false, or deceptive advertising or marketing; negligence; nolo contendere plea; other – not classified; practicing beyond the scope of practice; submitting false claims; substandard or inadequate care; unable to practice safely; and unauthorized administration of medication.
2012 PCOA Administered to More Than 4,000 Students Across the Nation; Computer-Based Assessment Delivered with Success

The 2012 Pharmacy Curriculum Outcomes Assessment® (PCOA®) took place January 23 to February 4, 2012, with more than 4,000 students participating from 28 different schools and colleges of pharmacy. With involvement from all 19 schools that administered the PCOA in 2011, plus nine additional schools, the PCOA witnessed its highest numbers since the assessment was launched in 2008.

This year also marked the first administration of the PCOA as a computer-based assessment in addition to the paper-based format. Of the 28 schools, seven chose to participate in the computer-based PCOA. NABP worked with these participating schools to ready their systems and ensure that all the necessary technical functionalities were in place prior to the administration date. The computer-based assessments were delivered through a special lockdown Web browser that disables all nonessential functions on the user’s computer for the duration of the assessment. Overall, the computer-based assessment was delivered successfully. A handful of students experienced difficulty accessing the assessment on the day of the administration; however, NABP was able to quickly resolve these issues. The PCOA was created as a response to the need expressed by the United States Department of Education, the Accreditation Council for Pharmacy Education, and some US schools and colleges of pharmacy for a tool to assist with curriculum development and review. More information regarding the dates for the 2013 PCOA will be forthcoming. Schools and colleges of pharmacy will receive registration packets for the 2013 administration in late summer 2012.

FPGEE Review Committee Evaluates Examination Items

Earlier this year, members of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) Review Committee met to discuss and evaluate items for the examination. Pictured above from left to right: Karen J. Kopacek, RPh, University of Wisconsin-Madison, School of Pharmacy; Kelly M. Shields, PharmD, Ohio Northern University; Sheldon Holstad, PharmD, St Louis College of Pharmacy; and Ralph Raasch, PharmD, University of North Carolina at Chapel Hill Eshelman School of Pharmacy.
Licensees Encouraged to Create their NABP e-Profiles to Receive Valuable CPE Credit in the Future

With more than 124,000 pharmacists and 54,000 pharmacy technicians having set up their NABP e-Profiles, preparation for the switch to electronic transmission of continuing pharmacy education (CPE) credits is well underway. This electronic data exchange – available through CPE Monitor – will provide pharmacists and technicians with a way to more easily monitor their compliance with CPE requirements. In addition, the CPE Monitor service will eventually enable state boards of pharmacy to access an online registry of their licensees’ completed CPE contact hours, allowing them to conduct audits electronically if they so desire.

Through various means of communication, NABP continues to encourage licensees to set up their e-Profiles if they have not done so already. The Association has worked closely with state boards of pharmacy, state and national pharmacy associations, and other organizations to get the word out, utilizing such publications as the NABP Newsletter and the National Pharmacy Compliance News, which is located in the center section of the State Newsletters and is distributed to pharmacists in 34 states. Likewise, several boards of pharmacy have included information in their own print and/or electronic State Newsletters. In addition, the NABP Government Affairs Department continues its efforts to reach out to those boards of pharmacy with higher numbers of licensed pharmacists, offering assistance and providing messaging when requested to ensure that licensees are aware of the importance of setting up an NABP e-Profile and obtaining an e-Profile ID.

NABP has also participated in various meetings, distributing CPE Monitor informational materials and in some instances, providing convenient on-site registration for licensees to create their NABP e-Profiles.

Through these joint efforts, it is NABP’s hope that all pharmacists and pharmacy technicians will be prepared when the final switch to complete electronic tracking of all Accreditation Council for Pharmacy Education (ACPE)-accredited CPE activity occurs. Soon, all ACPE-accredited providers will begin requiring that licensees provide their NABP e-Profile ID, obtained when the e-Profile is created, as well as their date of birth (MMDD) in order to obtain CPE credit. Without this information, pharmacists and pharmacy technicians risk missing out on valuable CPE credit.

Launched in March 2011, CPE Monitor is a collaborative effort by NABP, ACPE, and ACPE providers. To create a NABP e-Profile and obtain more information about the service, visit www.MyCPEmonitor.net.

Annual Meeting Travel Grants Still Available to Boards

Annual Meeting Travel Grant opportunities are still available for active member boards of pharmacy to attend the 108th Annual Meeting to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA. New this year, the travel grant is no longer restricted to the board’s voting delegate. Now, a grant may be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board’s administrative officer regardless of whether or not he or she is a voting delegate. In the past, only the voting delegate of each board was qualified to apply for the grant.

One individual per active member board of pharmacy is eligible to receive the grant. Though the individual applying for the travel grant need not be the voting delegate, his or her board of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

The NABP Annual Meeting Travel Grant program lessens the costs for qualified individuals by providing funds for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. Eligible individuals can receive up to $1,500 in grant monies to attend the NABP 108th Annual Meeting. The grant may not be applied to Annual Meeting registration fees.

Grant applications may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. Applications can be submitted by mail to Sarah Fowle, at NABP Headquarters or via fax at 847/391-4500. NABP requests that applications be submitted prior to the Annual Meeting. All applicants will be informed of whether or not they have qualified for the grant.

For more information on the Annual Meeting Travel Grant, contact the NABP Executive Office at exec-office@nabp.net.
Meeting Program

May 19-22, 2012        Sheraton Philadelphia Downtown Hotel        Philadelphia, PA

Saturday, May 19, 2012

9 AM - 7 PM
Registration/Information Desk Open

2 - 4 PM
Pre-Meeting CPE
ONDCP - National Drug Plan to Combat Prescription Drug Abuse
Sponsored by CVS Caremark
ACPE #205-000-12-001-L03-P
(0.2 CEUs - 2 contact hours)

5 - 6 PM
Annual Meeting and District Meeting Orientation

7 - 10 PM
President's Welcome Reception
Sponsored by Medco Health Solutions, Inc
Honoring NABP President
Malcolm J. Broussard, RPh
Buffet dinner will be served.
Dress: business casual

Sunday, May 20, 2012

6:30 AM - 5 PM
Registration/Information Desk Open

7:30 - 8:30 AM
NABP AWARE Fun Run/Walk
Sponsored by Rite Aid Corporation

8 - 11:30 AM
Hospitality Brunch
Sponsored by Omnicare, Inc
Educational Table Top Displays

8 - 11:30 AM
Joint CPE
Educational Poster Session - Embracing Knowledge for Public Protection
Sponsored by Pearson VUE
ACPE #205-000-12-002-L04-P
(0.1 CEU - 1 contact hour)

3:30 - 4:30 PM
Joint CPE
Where Have All the Drugs Gone? - Who's Responsible for Drug Shortages and Quotas?
Sponsored by Walgreen Co
ACPE #205-000-12-003-L03-P
(0.1 CEU - 1 contact hour)

Monday, May 21, 2012

7 AM - 2 PM
Registration/Information Desk Open

7 - 8:15 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention

8:15 - 10:15 AM
Joint CPE
Advancing Online Drug Safety: How Public-Private Partnerships Thwart Illicit Online Drug Sales
Sponsored by Walgreen Co
ACPE #205-000-12-004-L03-P
(0.2 CEUs - 2 contact hours)

10:30 AM - noon
Second Business Session
Presiding: Malcolm J. Broussard, RPh, NABP President

• Report of the Executive Director/Secretary
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
• Report of the Treasurer
  Karen M. Ryle, MS, RPh, NABP Treasurer
• Recognition of Sponsors
• President’s Address
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
• Greetings from the Host State
  Edward J. Bechtel, RPh, Chairperson, Pennsylvania State Board of Pharmacy
• Report of the Executive Committee
  William T. Winsley, M S, RPh, Chairperson, NABP Executive Committee
• Report of the Treasurer
  Karen M. Ryle, MS, RPh, NABP Treasurer
• A nnouncement of Candidates for Open Executive Committee Officer and Member Positions
• Open Microphone Session
  (Time permitting.)

Noon - 12:30 PM
Informal Member/Candidate Discussion

(continued on page 88)
108th Annual Meeting

Monday, May 21, 2012 (cont)

1:30 - 5:15 PM
Optional Tour
Philadelphia History and Architecture
Reservation required.

Tuesday, May 22, 2012

7:30 AM - 4:15 PM
Registration/Information Desk Open
7:45 - 8:45 AM
NABP Breakfast
8:45 - 10:15 AM
Executive Officer and Board Member CPE
OIG, NPDB, and HIPDB - What Everyone Should Know
ACPE #205-000-12-006-L03-P
(0.15 CEUs - 1.5 contact hours)
8:45 - 10:15 AM
Compliance Officer CPE
CSI Philadelphia - How to Conduct a Pharmacy Investigation
ACPE #205-000-12-006-L03-P
(0.15 CEUs - 1.5 contact hours)
10:30 AM - noon
Joint CPE
Freedom for Consumers or Freedom from Meth - Point-Counterpoint
ACPE #205-000-12-007-L03-P
(0.15 CEUs - 1.5 contact hours)
1:30 - 4 PM
Final Business Session
Presiding: Malcolm J. Broussard, RPh, NABP President
• Election of 2012-2013 Executive Committee Officers and Members
• Remarks of the Incoming President
  Michael A. Burleson, RPh, NABP President-elect
• Installation of 2012-2013 Executive Committee Officers and Members
• Final Report of the Committee on Constitution and Bylaws
  Ronald J. Klein, RPh, Chairperson, Committee on Constitution and Bylaws
• Final Report of the Committee on Resolutions
  Michael A. Burleson, RPh, NABP President-elect and Chairperson, Committee on Resolutions
  - Discuss and Vote on Resolutions

5:45 - 6:45 PM
Awards Dinner Reception
7 - 11 PM
Annual Awards Dinner
Presiding: Michael A. Burleson, RPh, 2012-2013 NABP President
• Presentation to 2012 Honorary President
• Presentation to Malcolm J. Broussard, RPh, 2012-2013 Chairperson, NABP Executive Committee
• Presentation of the 2012 Fred T. Mahaffey Award
• Presentation of the 2012 Henry Cade Memorial Award
• Presentation of the 2012 John F. Atkinson Service Award
• Presentation of the 2012 Lester E. Hosto Distinguished Service Award
  Award Dress: semiformal

NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). ACPE Provider Number: 205. Participants may earn ACPE-accredited CPE credit by completing a Statement of Continuing Pharmacy Education Participation online and submitting it to NABP. Full attendance and completion of the program evaluation and learning assessment for each session are required to receive CPE credit and a Statement of Continuing Pharmacy Education Credit.

Continuing Legal Education (CLE) Policy: NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending CPE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.
Exciting, Timely Topics Offer Attendees Up to Nine Contact Hours of CPE Credit at NABP 108th Annual Meeting

The NABP 108th Annual Meeting, themed “State Boards of Pharmacy and NABP – Empowering Liberty with Knowledge and Responsibility,” to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA, offers attendees the chance to earn up to 9 contact hours (0.9 continuing education units) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit. The CPE is designed to address current issues affecting the regulation of pharmacy practice. All Annual Meeting participants will have the opportunity to attend four joint CPE sessions as well as one of two concurrent sessions: one geared for state board of pharmacy executive officers and members, and the other for compliance staff. In addition, there will be one pre-meeting CPE session.

Saturday, May 19

Pre-Meeting CPE
ONDPC – National Drug Plan to Combat Prescription Drug Abuse

During this special pre-meeting session, a representative from the Office of National Drug Control Policy (ONDPC) will provide attendees with the most up-to-date information regarding how they coordinate all aspects of federal drug control programs and implement the President’s National Drug Control Strategy as it relates to combating the prescription drug abuse epidemic that is sweeping our nation. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit. This session is sponsored by CVS Caremark.

Sunday, May 20

Joint CPE
Educational Poster Session – Embracing Knowledge for Public Protection

Becoming an annual favorite, this CPE session will offer the boards of pharmacy and schools and colleges of pharmacy the unique opportunity to present various poster displays as they relate to this year’s Poster Session theme, “Embracing Knowledge for Public Protection.” CPE is earned in this session by interacting with presenters for one hour during the three and one-half hour offering and completing a post-session test. Participants will earn 1 contact hour (0.1 CEU) of CPE credit. This session is sponsored by Pearson VUE.

Joint CPE
Where Have All the Drugs Gone? – Who’s Responsible for Drug Shortages and Quotas?

It seems as if every day the drug products shortage notification list grows longer and increasingly includes controlled substances. During this joint CPE session, meeting attendees will hear from a Drug Enforcement Administration expert about how quotas are determined and enforced and a pharmaceutical manufacturer representative will discuss how and why they allocate their active pharmaceutical ingredients. Participants will earn 1 contact hour (0.1 CEU) of CPE credit. This session is sponsored by Walgreen Co.

Monday, May 21

Joint CPE
Advancing Online Drug Safety: How Public-Private Partnerships Thwart Illicit Online Drug Sales

Whether selling controlled substances without requiring a prescription or peddling counterfeit medications, there is no doubt that rogue Internet pharmacies continue to place the public health at risk and can be extremely difficult for regulators to police. During this joint CPE session, experts from various public and private sectors will provide meeting attendees ways in which partnerships can stop these illegal operations. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit. This session is sponsored by Walgreen Co.

Joint CPE
CSI Philadelphia – How to Conduct a Pharmacy Investigation

Being savvy with the ins and outs of how to conduct a pharmacy investigation is of paramount importance to board compliance officers in their efforts to protect the public. During this CPE session geared toward compliance officers, attendees will learn from pharmacy inspectors, who are also police officers, how to go about conducting an official pharmacy investigation – from collecting evidence to interviewing respondents and witnesses to drafting reports and testifying at hearings. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Tuesday, May 22

Executive Officer and Board Member CPE
OIG, NPDB, and HIPDB – What Everyone Should Know

As questions still remain about the Office of Inspector General (OIG) Exclusion List and the National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HIPDB) reporting, meeting attendees will be provided with the information about how board disciplinary actions relate to the OIG Exclusion List during this CPE session geared toward executive officers and board members. Attendees will also learn about the NPDB and HIPDB reporting requirements and utilizing reporting agents. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Joint CPE
Freedom for Consumers or Freedom from Meth – Point-Counterpoint

As the ravages of methamphetamine abuse in our country continue to rise so (continued on page 95)
Five States Prepare to Deploy NABP InterConnect; NABP to Participate in National Project to Enhance Access to PMP Data

Five more prescription monitoring programs (PMPs) are preparing to deploy the NABP PMP InterConnect℠, the system that facilitates the secure sharing of data between state PMPs, which will bring the total number of live participants to 10. The North Dakota Prescription Drug Monitoring Program, the South Carolina Reporting & Identification Prescription Tracking System, and the West Virginia Controlled Substance Monitoring Program plan to go live by end of first quarter 2012, and will join PMPs in Connecticut, Michigan, Ohio, Indiana, and Virginia, which have implemented use of the NABP InterConnect, giving authorized PMP users the ability to request and share program data across state lines. PMPs in Arizona and Kansas plan to go live by early second quarter 2012. It is anticipated that more than 20 states will be sharing data using the NABP InterConnect by the end of 2012.

NABP Participates in National PMP Project

The Association is participating in the Enhancing Access to Prescription Drug Monitoring Programs Project, a national effort initiated to determine how health information technology can be used to increase timely access to prescription drug monitoring program data with the goal of reducing prescription drug misuse, abuse, and overdose. The project is managed by the Office of the National Coordinator for Health Information Technology in collaboration with the Substance Abuse and Mental Health Services Administration, the Centers for Disease Control and Prevention, and the Office of National Drug Control Policy. NABP will participate in several workgroups that will make recommendations relating to this national effort.

Register Online for the NABP 108th Annual Meeting at NABP.net

Reduced Rate for Early Registration Ends April 9


Individuals may register by visiting the Meetings section of the NABP Web site at www.nabp.net/meetings. To maintain the accuracy of attendee information and streamline the registration process, all registration will be handled electronically.

NABP offers attendees three payment options:
1. Mailing in the payment
2. Using a credit card (American Express, MasterCard, or Visa)
3. Paying in Philadelphia

Attendees who do not have access to a computer may contact the NABP Customer Service Department at 847/391-4406. More information about the 108th Annual Meeting is available in the Meetings section of the NABP Web site at www.nabp.net/meetings.
AWARxE Continues to Support DEA Take-Back Events, Encourages Participation in Medication Disposal Programs

With a fourth Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day planned for April 28, 2012, DEA Administrator Michele M. Leonhart emphasized that the last three events “dramatically reduced the risk of prescription drug diversion and abuse, and increased awareness of this critical public health issue.” The AWARxE® consumer protection program continues to inform consumers about the importance of safely disposing of unused medications and securely storing needed medications. AWARxE national advertising will raise awareness about this DEA-coordinated opportunity for a convenient, legal means of medication disposal, as well as alerting readers to AWARxE resources. The “Does a Drug Dealer Lurk in Your Medicine Cabinet?” ad will appear in the April 2012 issue of the AARP Bulletin (circulation 22 million), raising awareness among seniors and other AARP readers about how to protect loved ones from medication misuse and abuse. (See sample of AARP ad at right.)

Additional information about the DEA National Prescription Drug Take-Back Day is available on www.AWARErx.org by clicking on the link from the home page. For the previous take-back event, DEA partnered with local law enforcement and other organizations to provide 5,327 take-back locations across the country.

Boards of pharmacy continue to partner with the Association to share AWARxE resources and to educate the public. For example, the Connecticut Commission of Pharmacy presented an educational display at a community wellness expo. NABP staff also continue AWARxE outreach efforts at expos and conventions. Staff hosted an AWARxE booth at the American Pharmacists Association Annual Meeting and Convention, March 9-12, 2012, sharing resources with attendees, and passing out AWARxE bookmarks and flyers, as well as AWARxE airline carry-on travel pouches for liquids and prescriptions.

To find out how you can help share AWARxE information in board mailings, meetings, or other events, you may send an e-mail to AWAREx@nabp.net.

Connecticut Commission of Pharmacy Presents AWARxE Educational Display

Sporting an AWARxE hat, Edith G. Goodmaster, member, Connecticut Commission of Pharmacy, hosted an AWARxE educational display at the Congregation Or Shalom Wellness Expo in Orange, CT, on January 29, 2012. Goodmaster shared information about prescription drug misuse and abuse trends, how to safely order medication online, and other medication safety topics. She encouraged attendees to take steps to prevent medication misuse, such as securely storing medications, and properly disposing of unneeded medications through local disposal programs, or by visiting a DEA-approved drug take-back location in April. The display included AWARxE bookmarks and flyers alerting attendees to visit the AWARxE Web site for more information.
Certain Endo Opioids Should be Verified as Correct Medication

Food and Drug Administration (FDA) and Endo Pharmaceuticals (Endo) advised health care providers and patients to check certain prescription Endo opioid products to ensure that the correct medication is received, as a result of product manufacturing issues. Specifically, at a Novartis Consumer Health (NCH) facility in Lincoln, NE, where certain opioid products are manufactured and packaged for Endo, manufacturing problems were discovered that could result in tablets from one product type being carried over into packaging of another product. FDA estimates that the likelihood of a patient receiving a stray pill of another medicine in their dispensed prescription medication is low, but to ensure patient safety, the agency advises that affected pills be examined. FDA advises that pharmacists visually inspect and verify the identity of all affected medications including “tablets counted out for dispensing in a separate container from the manufacturer’s bottle” and the contents of “bottles that have never been opened when the entire bottle is being dispensed.” Patients prescribed the affected medications should also examine all pills in their bottles, making sure the size, shape, and color of each pill is the same.

For example, if a patient discovers that one or more tablets in their dispensed medication looks different from the others, the medication should be returned to his or her pharmacist. The following drugs are affected:
- Opana® ER (oxymorphone hydrochloride) Extended-Release Tablets CII
- Opana® (oxymorphone hydrochloride) CII
- Oxymorphone hydrochloride Tablets CII
- Percocet® (oxycodone hydrochloride and acetaminophen USP) Tablets CII
- Percodan® (oxycodone hydrochloride and aspirin, USP) Tablets CII
- Endocet® (oxycodone hydrochloride and acetaminophen USP) Tablets CII
- Endodan® (oxycodone hydrochloride and aspirin, USP) Tablets CII
- Morphine Sulfate Extended-Release Tablets CII
- Zydone® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII

A list of the affected medications including descriptions and images of each pill are posted on the Endo Web site at www.endo.com/Supply_disruption.aspx. FDA advises that patients discuss any related questions with their health care providers and that they may also contact Endo at 800/462-3636. The FDA Drug Safety Communication issued January 9, 2012, is available at www.fda.gov/Drugs/DrugSafety/ucm286226.htm.

Endo and FDA are also advising pharmacists that while manufacturing process improvements are implemented by Endo, there may be a short-term disruption in the supply of the affected products to patients. Information for pharmacists regarding potential supply disruption is posted on the Endo Web Site at www.endo.com/pdf/Supply_disruption/Dear_Pharmacist_Letter.pdf.

Novartis Recalls Certain OTC Medications

As a precautionary measure, Novartis Consumer Health (NCH) initiated a voluntary recall of certain over-the-counter (OTC) medications manufactured at a Lincoln, NE, facility. This recall includes all lots of select bottle packaging configurations of the following medications:
- Excedrin® (expiration December 20, 2014, or earlier)
- NoDoz® (expiration December 20, 2014, or earlier)
- Bufferin® (expiration December 20, 2013, or earlier)
- Gas-X Prevention® (expiration December 20, 2013, or earlier)

NCH initiated the recall because the products may contain stray tablets, capsules, or caplets from other NCH products, or contain broken or chipped tablets, as indicated in a news release available at www.fda.gov/Safety/Recalls/ucm286240.htm. Additional consumer information including details on the specific product lots recalled and instructions on returning affected medications for a refund are available on the Novartis Web site at www.novartis-otc.com/otc/index.html.

FDA Advice on New Liquid Acetaminophen Dose for Infants

In late December 2011, FDA advised consumers to ensure that infants administered liquid acetaminophen products are given the correct dose, as an additional concentration for infants became available. The new product is less concentrated (160 mg/5 mL) than the prior available concentration of 80 mg/0.8 mL. This change in the concentration will affect the amount of liquid given to an infant, and should be especially noted if someone is accustomed to using the 80 mg/0.8 mL concentrations of liquid acetaminophen. An FDA Drug Safety Communication reviews the steps that consumers should take to ensure that infants are administered the correct dose including reading the Drug Facts on the label; following dosing instructions; using the dosing device provided; and discussing any questions about dosing with a pharmacist or appropriate health care provider. The Drug Safety Communication is available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/ucm284741.htm.
MT Implements PMP

To help fight prescription drug misuse and abuse, the state of Montana approved the “Montana Patient Safety Act” (HB 83) calling for the establishment of a prescription monitoring program (PMP). Montana’s PMP, known as the Montana Prescription Drug Registry (MPDR), was implemented in January 2012, and Montana joins 34 other states actively running PMPs.

Every licensed pharmacy in the state of Montana as well as every out-of-state mail-order pharmacy that dispenses scheduled medications within Montana must submit weekly records to the registry. Upon submission, the information will be available to authorized users within hours.

The Montana Board of Pharmacy notes that potential diversion or misuse/abuse will be monitored by a designated official appointed by the Board. A patient will have a letter sent to his or her practitioner(s) and pharmacy/pharmacies if he or she obtains controlled substances from four or more prescribers within a 60-day time period or if he or she fills controlled medications at four or more pharmacies within a 60-day time window.

The registry is funded by a four-year $400,000 grant provided by the Department of Justice as well as a $15 annual fee paid by practitioners who prescribe controlled substances, pharmacists, pharmacies, and wholesalers. In 2016 the annual fee will be reassessed and changed as deemed necessary.

The Board notes that MPDR is intended to be used as a tool to enhance patient safety by increasing a provider’s insight into a patient’s medication profile, thus promoting proper pharmaceutical care of dangerous drugs.

Additional information about MPDR, including the state’s reporting requirements, is available in the January 2012 Montana State Board of Pharmacy Newsletter, available at www.nabp.net/publications/assets/MT012012.pdf. More information about MPDR is also available on the Board’s Web site under Drug Registry, at http://bsd.dli.mt.gov/license/bsd_boards/pharmacy/board_page.asp.

OK Board Reports PMP Updates

As of January 1, 2012, all controlled prescriptions must be submitted to the Oklahoma State Board of Pharmacy’s PMP within five minutes of selling (not filling) them to the customer. The Board also notes that the pharmacy must submit the ID information of both the recipient and the recipient’s agent, if someone other than the patient is picking up the prescription. The Board clarifies that if a patient is a resident of a nursing home or a hospice patient and does not have an ID card, the pharmacy may use the Social Security number for the patient. Further information is available on the Oklahoma Bureau of Narcotics and Dangerous Drugs Web site at www.ok.gov/obn/dd/Prescription_Monitoring_Program/index.html.

IL Law Allows Medication Disposal Boxes

Effective January 1, 2012, a new Illinois law allows any city, village, or municipality to authorize the use of its city hall or police department to provide a secured and locked container for the disposal of used, expired, or unwanted pharmaceuticals including prescription drugs. The law specifies that the container must be accessible to the public with clearly legible signage that indicates the instructions for disposing of expired or unwanted prescription drugs in the container. The full text of the law (HB3090; PA 97-0546) is available at http://ilga.gov/legislation/publicacts/fulltext.asp?Name=097-0546. A list of existing medication disposal programs in Illinois, including police department drop-off boxes that can accept unwanted controlled substance prescription drugs, is available in the Get Local section, on the Illinois page, of the AWARERx® Web site at www.AWARERx.ORG.

WA Board Implements NPLEx to Fight Meth

On October 15, 2011, the Washington State Department of Health, Board of Pharmacy, announced the implementation of National Precursor Log Exchange (NPLEx), an electronic tracking system that monitors the purchase of over-the-counter medicines containing pseudoephedrine (PSE), a key ingredient in methamphetamine. It replaces the mandatory paper transac-

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State Board News
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nabp newsletter

Lora Williams, JD, has been reappointed a public member of the Indiana Board of Pharmacy. Williams’ reappointment will expire on July 1, 2014.

Martin Castleberry has been reappointed a public member of the West Virginia Board of Pharmacy. Castleberry’s reappointment will expire on June 30, 2013.

Carl Hedrick, Jr, RPh, has been reappointed a member of the West Virginia Board of Pharmacy. Hedrick’s reappointment will expire on June 30, 2015.

Sam Kapourales, RPh, has been reappointed a member of the West Virginia Board of Pharmacy. Kapourales’s reappointment will expire on June 30, 2014.

Charles Woolcock has been reappointed a public member of the West Virginia Board of Pharmacy. Woolcock’s reappointment will expire on June 30, 2014.

Board Officer Changes
The Alabama State Board of Pharmacy has elected the following officers to the Board:
- Donnie Calhoun, RPh, President
- Kenny Sanders, RPh, Vice President
- Mark T. Conradi, RPh, JD, Treasurer

The Kentucky Board of Pharmacy has elected the following officer to the Board:
- Joel Thornbury, RPh, President
- Brian DeWire, DC, Vice President

The Minnesota Board of Pharmacy has elected the following officer to the Board:
- Laura Schwartzwald, RPh, Vice President

The Nevada State Board of Pharmacy has elected the following officer to the Board:
- Kirk Wentworth, RPh, Treasurer

Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson Creek Pharmacy</td>
<td>Spring Lake, NC</td>
</tr>
<tr>
<td>Ave J Royal Care Pharmacy</td>
<td>Brooklyn, NY</td>
</tr>
<tr>
<td>Eaton Apothecary</td>
<td>Beverly, MA</td>
</tr>
<tr>
<td>Sterling Grocery Mart Pharmacy, Inc</td>
<td>Sterling, CO</td>
</tr>
<tr>
<td>Santo Domingo Pharmacy, Inc</td>
<td>Jackson Heights, NY</td>
</tr>
<tr>
<td>U.N. Plaza Pharmacy</td>
<td>New York, NY</td>
</tr>
</tbody>
</table>

A full listing of the over 1,000 accredited DMEPOS companies representing more than 29,000 facilities is available on the NABP Web site at www.nabp.net.
While an efficient means of administrative prosecutions, the use of previous civil judgments against licensees is dependant upon consistent burdens of proof. In many jurisdictions, the preponderance standard applies to both civil and administrative matters and will provide a basis for the application of the doctrine of collateral estoppel and eliminate the need to re-litigate matters. In jurisdictions where a clear and convincing standard applies in administrative prosecutions, reliance upon a previous civil judgment alone will not suffice and the facts may have to be established using this heightened scrutiny.


Newly Accredited VIPPS Facility

The following Internet pharmacy was accredited through the NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) program:

**Wal-Mart Stores, Inc**

www.wal-mart.com/pharmacy

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies are available on the NABP Web site at www.nabp.net.
Newly Accredited VAWD Facilities

The following facilities were accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

- Apothecary Shop Wholesale, Inc
  Phoenix, AZ
- Becton, Dickinson and Company dba BD Distribution Center
  Four Oaks, NC
- Legacy Pharmaceutical Packaging
  Earth City, MO
- Medline Industries, Inc
  Libertyville, IL
- Merz Pharmaceuticals, LLC
  Greensboro, NC
- Nephron Pharmaceuticals Corporation
  Murray, KY
- RGH Enterprises, Inc dba Independence Medical
  Elgin, IL
- Fort Worth, TX
- Twinsburg, OH
- Schering Corporation
  Kenilworth, NJ
- TAGI Pharma, Inc dba TAGI Pharma
  South Beloit, IL
- Technomed, Inc dba National Hospital Specialties
  Hackensack, NJ

A full listing of more than 510 accredited VAWD facilities is available on the NABP Web site at www.nabp.net.