NASCSA
National Association of State Controlled Substances Authorities

NASCSA NEWS

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State Regulatory Developments

State Regulatory Developments is a monthly compilation by NASCSA of state regulatory actions related to pharmacy and controlled substances. State Regulatory Developments is located on the website at www.nascsa.org under "News".

The agenda for the annual NASCSA meeting is a testament to the extraordinary breadth and scope of the issues that controlled substances authorities address each day. For over 25 years, our conference seeks to provide the latest information on issues facing state regulatory and law enforcement officials as well as our federal and industry partners. We are excited about our upcoming conference and hope you are able to take the time to attend. You will have an opportunity to hear first-hand about the work of our committees, get involved with the organization as a volunteer and continue to have your voice heard as a vital member of this esteemed organization.

I am honored to have been given the opportunity to serve as your president, and as I finish up the year I can tell you that the organization is stronger than ever and growing. Last year we commissioned a "White Paper" on pseudoephedrine and co-hosted a webinar earlier this year to present our findings. We are hoping that this will be only the first of several to be commissioned in the coming years. We will continue to seek your input on ways that we can best support the important work you do each day and to provide a critical forum for the exchange of information and ideas.

Mark Keeley, President, NASCSA

Please Consider Volunteering

As a small nonprofit organization, NASCSA relies heavily on volunteers throughout the year and during the annual conference. There are many volunteer opportunities including assisting during the business meetings, serving on committees and serving as an officer or member of the Executive Committee. If you are interested in volunteering, please contact Kathy Keough at KathyKeough@nascsa.org or a member of the Executive Committee to learn how you can get involved.

NASCSA Forum

Members are strongly encouraged to take advantage of the "Forum" site for members and others interested in a variety of topics related to controlled substances, prescription monitoring programs, trends, legislation and other issues. The Forum, located at http://forum.nascsa.org is also accessible from the main website www.nascsa.org. The Forum requires a one-time initial registration to create a user name and password in order to post or subscribe and is moderated by volunteers. NASCSA has initially limited the number of "forums" included, however if you

Registration Now Open for NASCSA's Annual Conference Oct. 23-26, 2012

Hotel Deadline is October 1

Registration is now open for the 28th Annual Conference of the National Association of State Controlled Substances Authorities to take place at the Hotel Valley Ho in Scottsdale, Arizona October 23-26, 2012. This year's conference will continue to offer informative and diverse topics as well as an opportunity to network with colleagues and participate in several important business meetings throughout the conference. The Hotel Valley Ho is located in historic Scottsdale, Arizona and is within easy walking distance to many of the finest restaurants in the city as well as shopping and historic sites. The program, registration information, and hotel information can be found on our website here. Please note the room block is only being held until October 1, 2012 so it is important to reserve your room prior to that date.
The hotel features complimentary Wi-Fi access. You will need to make your own transportation arrangements (cab or super shuttle) from the airport to the hotel. Please note that there will be a luncheon on Thursday to provide an opportunity for attendees to stay on the property and network with their colleagues. For information on exhibitor or sponsorship opportunities please contact Kathy Keough at kathykeough@nascsa.org.

Please note that the Executive Committee of the Alliance of States With Prescription Monitoring Programs will be

would like to suggest a new forum subject please send your suggestion to KathyKeough@nascsa.org. Detailed instructions on how to use the Forum are also included on the site.

CDC Publishes Report Reviewing State Laws to Address Prescription Drug Abuse

The Centers for Disease Control and Prevention (CDC) has recently published a report that showcases state laws and strategies to address prescription drug abuse and diversion in the United States. The report can be found here.

Methadone Blamed For Nearly 33% Of Painkiller Overdose Deaths

The painkiller methadone accounts for nearly one-third of all prescription painkiller overdose deaths in the U.S., according to the Centers for Disease Control and Prevention. CDC researchers found that six times as many people died of methadone overdoses in 2009 as in 1999. For many years, the drug has been used to treat drug addiction, but in recent years has become increasingly popular as a pain reliever. CDC Press Release, Report

meeting on the morning of October 23, prior to the commencement of NASCSA's conference. Additional details will be posted on the Alliance and NASCSA websites for those who are interested in attending.

Travel Scholarships Announced

This year's travel scholarships have been awarded to the following individuals to attend the 2012 annual conference:

- Patricia D'Antonio, District of Columbia Department of Health
- Michael Baier, Maryland Board of Pharmacy
- Anne Rogers, Maine Office of Substance Abuse
- Devon Scott, North Carolina Controlled Substances Reporting System
- Steven Wheeler, Pennsylvania Office of the Attorney General
- David Wills, Wyoming Board of Pharmacy

We are pleased that NASCSA is able to offer this opportunity to member states that would not otherwise be able to have their representatives attend the conference.

It's Dues Renewal Time!

As a small nonprofit organization, NASCSA relies on dues from its members to help support its operations and to continue to provide valuable services to its members.

FDA Cracks Down On Unapproved Painkillers

FDA will begin cracking down on companies that market versions of the painkiller oxycodone that have not undergone agency review, according to a notice in the Federal Register. Companies selling unapproved versions have 45 days to cease manufacturing or face product seizure and court proceedings, according to the notice. The move is part of FDA's Unapproved Drug Initiative. F
DA Press Release, Federal Register Notice

NAMSDL Publishes New Compilation of Pain Laws

The National Association of Model State Drug Laws has recently published an updated compilation of state pain laws. The report is found here.

Citizens Petition for Change in Opioid Labeling

A group of physicians and public health officials petitioned the Food and Drug Administration (FDA) on July 25 to change the labeling directions on how and when medical professionals should

Dues statements for this year (July 1, 2012 through June 30, 2013) should have been received, however, there are still a number of states that have not yet paid their dues. If you have any questions please feel free to contact the office. If you need to update any information, please make sure to complete the membership application to ensure we have updated contact information. Please note that in order for states to be eligible for full participation in the organization, including voting, running for office, travel scholarships and the Prescription Drug Monitoring Program grant program, dues must be paid in full.

NASCSA's New Logo Takes Off

Over the last few months we have been hard at work incorporating our new logo. Over the next several months you will see our logo featured on new stationary, the electronic newsletter and other materials. The new logo represents the "heart of NASCSA" which is our membership and the many people involved in controlled substances regulation and enforcement. A special thanks to Bill Ward, our webmaster and Monica Simmons, our administrative assistant, as well as all of the members of the logo committee for their tireless efforts to ensure that the new logo truly represents the organization for many years to come.

NASCSA Committee News

NASCSA's committees have been

prescribe opioid pain relievers. The petition called for the FDA to limit the drugs' approved use to people with "severe" pain or cancer. If the FDA accept the proposed labeling changes, practitioners would be free to prescribe opioids "off label" in any way they choose, but pharmaceutical companies would face limitations in how they market the products. Per 21 CFR 10.30, the FDA has 180 days to respond. Congressional letter in support of citizen petition.

REMS for Certain Opioids Approved by FDA

As part of the federal initiative to address the prescription drug abuse, misuse, and overdose epidemic, the U.S. Food and Drug Administration (FDA) has approved a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioids. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER and LA opioids, while ensuring access to needed medications for patients in pain. FDA Commissioner Margaret A. Hamburg, MD, stated that the agency's goal "with this REMS approval is to ensure that health care professionals are educated on how to safely prescribe

activities to serve our members. Following is a brief summary of the work from the various committees. For a complete list of committee members click here.

Membership - The committee established travel scholarships to attend this year's conference, reviewed applicants and made recommendations on awards to the Executive Committee. As was the case in past years, a record number of applications were received for one of six travel scholarships. The committee will be working on a policy for placement of appropriate links on the website and will also be discussing the potential of creating a subject matter expert listing for members and others.
Special Projects - A record number of applications were received for the 2012 Prescription Drug Monitoring Program (PDMP) grants and the committee made a record number of awards. The committee has also spent the past several months monitoring progress reports and spending plans for each grantee. A representative from each state awarded a grant as part of this initiative will be attending the annual conference, and several grantees will be presenting details about their respective projects during the conference. In addition, each of the grantees will be presenting materials at a "showcase" in order to share their projects with all conference attendees. Finally, NASCSA has submitted a grant application to Purdue Pharma LLC to continue this project into 2013. More details about this initiative will be distributed to the membership as they become available.
Survey/Data - The committee continues to oversee the ongoing update of the "state profiles" page and completed a survey of states related to the issuance of state controlled substances registrations for ultimate publication. A compiled final report summarizing the results will be

opioids and that patients know how to safely use these drugs." The new REMS will affect more than 20 companies that manufacture these opioid analgesics, indicates FDA in a news release. FDA also indicates that affected companies will be required to make education programs available to prescribers based on an FDA Blueprint and to make available FDA-approved patient education materials on the safe use of these drugs.

DEA to Hold Fifth National Prescription Drug Take-Back Day, Sept 29, 2012

The US Drug Enforcement Administration will conduct its fifth national prescription drug "take back" day on September 29, 2012. Consumers may safely dispose of unwanted medications at one of thousands of collection sites coordinated by DEA and provided by law enforcement agencies and community organizations in all 50 states and United States jurisdictions. The DEA online collection site locator will be available in August 2012. The DEA online collection site locator is found here..

committee recently issued a survey of state members in order to provide an update on such items as what drugs are scheduled differently than DEA, electronic prescribing of controlled substances, quantity limits on Schedule II prescriptions and "doctor shopping" statutes to name a few. Please feel free to submit any ideas you might have for future surveys as the organization moves to fulfill its mission of becoming the central repository of information related to controlled substances on behalf of its members.

Resolutions/Bylaws - The committee has drafted three resolutions for consideration at this year's conference, which will be distributed electronically to the membership prior to the conference and then will be discussed and voted on by the membership at the annual conference. Please note that pursuant to the bylaws, the deadline for resolutions to be considered is September 8, 2012. Any member is permitted to submit a resolution for consideration, so we encourage members who wish to submit a resolution idea to contact Ralph Orr, chair of the committee. Please note resolutions can still be considered at the annual conference but must receive a 2/3 vote of the membership in order to be considered. Thus far, the committee has not identified any needed changes to the bylaws, however, members are encouraged to review the bylaws and offer any suggested changes for consideration. A copy of the bylaws is found here.

Policies and Procedures - Members of the committee are in the final stages of completing a huge undertaking - the preparation of a complete Policy & Procedures document in order to ensure that NASCSA office operations are documented. The document is expected to be finalized prior to the October conference and has been underway for over a year. Following completion of the

conducted to ensure the document remains up to date.

Program - The committee began work on this year's conference almost immediately after last year's successful program and strove to ensure that the most timely and pertinent topics are presented at the 2012 conference. The committee finalized the program agenda last month and in the next month will be reviewing the format to ensure that it provides the best opportunities for presentations and exchanges of information as well as plenty of opportunity for questions and answers. The program is now available on the website. Please note that there may be periodic changes to the program, so please refer to the website periodically for updates.

From the States

Alabama - Congratulations to Charles Thomas, State Pharmacy Director from the Alabama Department of Public Health who was recently inducted into the Alabama Healthcare Hall of Fame.

California - California's prescription drug monitoring system could run out of funding by the end of the year as a result of budget cuts, according to the state attorney general's office. Officials indicate they are seeking other sources of funding. California Watch

California - A nationally unprecedented law telling the pharmaceutical industry it must pay to get rid of prescription drugs won approval from Alameda County lawmakers last month. The county's Board of Supervisors cast their final votes, 5-0, on the Safe Drug Disposal Ordinance, which requires producers of drugs sold or distributed in the county to pay for the safe collection and disposal of unused medications. Failure to comply will cost drug makers $1,000 a day in

fines. The law, based on a British Columbia program, shifts the cost of disposal from taxpayers to drug companies. Currently, residents can discard pills they no longer need at 28 publicly funded drop-off locations, which cost an estimated $330,000 to run annually. See the press release here.

Iowa - New legislation in Iowa allows the Board of Pharmacy to provide annual funding for the administration of the pharmaceutical collection and disposal program - the TakeAway Environmental Return System. The program provides a total of $125,000 each year for the management and disposal of unused, expired pharmaceuticals.

Michigan - Michigan Governor Rick Snyder signed a package of bills banning the sale of K2, Spice and similar synthetic drugs. The new measures crack down on chemicals used to make the products and also give state health officials power to temporarily ban substances deemed an imminent danger to people's health.

New Mexico - New Mexico has added a rule that will allow participating practitioners and clinics in the state to accept by donation certain previously dispensed medications and redistribute them to patients. Only eligible medications, defined as unused prescription drugs stored in a tamper-evident container, or by a tamper-evident process preventing unauthorized access, and has an expiration date of six months or greater listed on the packaging, may be accepted. More details are available in the New Mexico Drug Donation Guide, available at www.rld.state.nm.us/pharmacy

New York - The state issued new regulations aimed at cracking down on the illegal sale of bath salts and other synthetic drugs. The rules expand the list of prohibited synthetic drugs as well as the chemicals used to make them. For more information click here.

North Dakota - During the North Dakota Legislative Session, SB2119 was enacted

into law, which added Soma and propofol to the list of controlled substances. The law took effect last year.

Texas - The Texas Department of Public Safety (DPS) has launched an online prescription monitoring program (PMP) to provide controlled substance prescription dispensing history to authorized health care providers and law enforcement. The PMP, known as Prescription Access in Texas (PAT), has been available to a select group of health care providers, including pharmacists, as well as law enforcement professionals since June 2012, and access has now been expanded to include additional physicians and law enforcement, mid-level practitioners, and medical board and nursing board investigators, as noted in a DPS press release. DPS indicates that additional users will continue to be phased in over the next two months, and that pharmacists and pharmacy board investigators are on track to acquire access to the system in mid-August. The original Texas PMP was launched in 1982 and provided authorized users with access to PMP information through a manual paper process. The new PAT online version of the database allows instant, 24/7 access to authorized users. Texas law requires that the PAT database includes Schedule II-Schedule V drugs for the last 12 months only.

Utah - we were saddened to hear of the passing of Steve Davis, a longtime NASCSA member and Controlled Substances Administrator of the Division of Occupational and Professional Licensing who died late last year.

Study Finds Abuse of Other Opioids Increased Following Oxycontin

Reformulation

Since the introduction of tamper-resistant OxyContin in 2010, abuse of other prescription opioids, as well as heroin, has increased, report researchers from Washington University in St Louis. The reformulated pill is more difficult to crush or dissolve, helping to prevent ingestion by inhalation or injection of dissolved medicine, means used by some abusers to get around the time-release effect of the drug. Researchers found that the change did result in a significant reduction in abuse of OxyContin. However, abuse of prescription opioids including fentanyl (Duragesic®), hydromorphone (Dilaudid®), and oxymorphone (Opana), as well as abuse of heroin, has climbed from about 20% to 32% from July 1, 2009 to March 31, 2012. Researchers surveyed 2,566 patients entering treatment for opioid-dependency, and found that the number of patients abusing OxyContin fell from 35% to about 13% during the same period when comparing time periods before and after the introduction of the new formulation. More information about the study is available in the *New England Journal of Medicine* article here.

US Senate Efforts To Reclassify Hydrocodone Fails; Executive Branch Continues to Consider

Legislation proposed in the US Senate related to FDA user fees, S. 3187, passed May 24 with a provision to place greater restrictions on access to hydrocodone drugs. A version passed by the House of Representatives, H.R. 5156, did not contain any such language. The

conference committee that worked out the differences in the bills removed the hydrocodone-reclassification language. Nevertheless, a Food and Drug Administration (FDA) advisory committee will meet in October to discuss the risks and benefits of hydrocodone medications. The Drug Enforcement Administration (DEA) has been taking a closer look at rules for hydrocodone products since 1999. Full story on Senate measure. Full story on Executive Branch measures.

Endo Transitions OPANA ER To Crush Resistant Formulation

Endo Health Solutions completed its transition of its OPANA ER franchise to a new formulation designed to be crush resistant. In connection with the completion of this transition, the Food and Drug Administration moved the old formulation of OPANA ER to the Orange Book Discontinued List. Endo Health Solutions Press Release.

We hope you enjoyed this latest edition of NASCSA News. We strongly encourage members and others to share information from their respective agencies for consideration for our newsletter. Please email KathyKeough@nascsa.org with your articles and ideas.
Sincerely,

Kathy Keough
Executive Director

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