National Association of State Controlled Substances Authorities

NASCSA NEWS

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Did You Know NASCSA is on Twitter?

If you have a Twitter account, please make sure to follow us @NASCSA. Our followers are growing by leaps and bounds so spread the word and stay connected!

Long-time NASCA Liaison Nick Reuter Retires from SAMHSA

Nicholas (Nick) Reuter, Senior Public Health Analyst at the Substance Abuse and Mental Health Services Administration (SAMHSA) and long-time friend of NASCSA, recently announced his retirement. Nick was a past recipient of NASCSA's prestigious President's Award and frequently spoke at NASCSA's annual conference. We wish him well in his retirement and look forward to our continued working relationship with SAMHSA.

Revised Dates Announced for NASCSA's Fall Conference

October 22-24, 2013

Responding to attendee feedback at this year's conference, the Program Committee with the approval of the Executive Committee, is making a few changes in this year's conference to take place at the Westin Hotel Crown Center in Kansas City, Missouri.

This year's NASCSA conference will begin on Tuesday, October 22 at 8 a.m. and conclude on Thursday, October 24 at 5 p.m. The Alliance of States With Prescription Drug Monitoring Programs will hold their annual meeting on Monday, October 21, 2013. Additional details will be provided but please mark your calendars accordingly.

NASCSA Launches Our New Website

Thanks to our webmaster Bill Ward, NASCSA is rolling out our new website effective February 2013. The site will now be viewable on a wider array of portable devices such as tablets and smart phones. Additionally, the most immediate change you will notice is the integration of our new logo colors into the overall theme of the website.

What difference does this make to you? You can now view all elements of the NASCSA website on any device with full functionality. Items such as the events calendar, state profile map, rotating photo displays were previously not visible on tablets and smart phones because they required an Adobe Flash plugin. Many tablets and phones including all devices manufactured by Apple, could not utilize this software. As a result, these aspects of the website could not be viewed on these portable devices.

The use of new html5 coding has eliminated this issue and now allows all elements of the NASCSA website to be viewed on all devices including those made by Apple. This re-design will provide for a better user experience when viewing our site, whether on a desktop, laptop, or any portable touch-screen device. Please take time to visit us at www.nascsa.org

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NASCSA PDMP Grants Awarded

NASCSA is pleased to announce that the 2013 Prescription Drug Monitoring Program (PDMP) grants have been awarded. This solicitation is part of the $200,000 grant for FY2013 from Purdue Pharma, LP to assist states with funding PDMPs for the purpose of operating and expanding such programs, and promoting the ability of state PDMPs to address the abuse and diversion of controlled substances. The maximum amount of each grant was $20,000 however given the record number of applicants (13) the maximum amount was not awarded. This was the third year that were grants awarded. Grants were reviewed by the Special Projects Committee members

Recent NIDA Report Shows Reduction in Abuse When Early Education Takes Place

Middle school students from small towns and rural communities who received any of three community-based prevention programs were less likely to abuse prescription medications in late adolescence and young adulthood. The research, published late last week in the American Journal of Public Health, was funded by the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Mental Health, all components of the National Institutes of Health. A copy of the report is found here.

FDA Holds Public Hearing on Opioid Medicatons

As the Food & Drug Administration (FDA) continues to seek a balance between minimizing opioid drug abuse and enabling the appropriate treatment of pain, the agency held a two-day public hearing February 7-8, 2013 to obtain information, such as scientific evidence and study data, on issues related to opioid use. FDA sought input from expert members of the public on the following topics:

- Diagnosis and Understanding of Patient Pain

and approved by the Executive Committee. Members of the Special Projects Committee include: Peg Clifford (NH), Brian Howes (AK) and Danna Droz (OH).

2013 PDMP awardees include: Alaska, Arkansas, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, South Dakota, Virginia, Washington, West Virginia, Wisconsin and Wyoming.

From the States

Florida - Florida Attorney General Pam Bondi has released the Final Report of her Statewide Task Force on Prescription Drug Abuse and Newborns; the report contains the task force's findings and policy recommendations. The task force, developed during the 2012 legislative session, has examined the scope of prescription drug abuse by expectant mothers, the costs associated with caring for babies with Neonatal Abstinence Syndrome, the long-term effects of the syndrome, and prevention strategies.

Montana - William Sybrant is now serving as the acting Executive Director of the Montana Board of Pharmacy.

New York - New York City public hospitals will begin following new voluntary guidelines on prescribing. Recommended by Mayor Michael Bloomberg's Task Force on Prescription Painkiller Abuse, the guidelines limit prescriptions for opioid painkillers written by emergency department providers to a three-day supply for the treatment of acute pain. In addition, the guidelines advise providers to avoid prescribing prescription painkillers for chronic non-cancer pain unless other treatments have been demonstrated to be ineffective. The task force summarized the voluntary guidelines, which were developed by the New York City Health Department, in a January 2013 report. The guidelines will be implemented in all of New York's public hospitals.

Emergency Department Visits Due to Misuse of ADHD Medications Tripled in Five Years

A new study released by the Substance Abuse and Mental Health Services Administration (SAMHSA) shows that emergency department visits due to misuse of attention deficit hyperactivity disorder (ADHD) medications tripled from 5,212 in 2005 to 15,585 in 2010. In 2010, 50% of emergency department visits related to ADHD medications were due to non-medical use of the drug, according to the study.

A SAMHSA news release indicates further that in 2010 there were 2.3 million emergency department visits related to the misuse of all drugs. SAMHSA Administrator Pamela S. Hyde stated that "ADHD medications, when properly prescribed and used, can be of enormous benefit to those suffering from ADHD, but like any other medication they can pose serious risks - particularly when they are misused." Hyde explains that these study results show the need to raise awareness among "all segments of society - not just the young - that misuse of these medications is extremely dangerous."

FDA Advisory Committee Votes 19 to10 In Favor of Rescheduling Combination Hydrocdone

By Delia A. Stubbs
Courtesy of NASCSA Associate Member Hyman, Phelps & McNamara

On January 25, 2012, after two days of discussion and deliberation, an FDA Advisory

Understanding and Adhering to the Labels of Pain-Treating Products
- Limiting Opioid Prescription and Use

Additional details about the hearing are found in a *Federal Register* *Notice*. NASCSA will be closely monitoring developments related to this hearing in the coming months.

New Study Focuses on the Value of Interstate Sharing of Prescription Data

A new study released last week in the journal Health Affairs focused on the value of states sharing data amongst state Prescription Drug Monitoring Programs (PDMPs) to combat prescription drug abuse. A copy of the full article is found here.

State Regulatory Developments

Did you know that NASCSA publishes a monthly compilation of state regulatory actions related to pharmacy and controlled substances. State Regulatory Developments is located on the website here.

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

Committee voted 19 to 10 in favor of rescheduling combination hydrocodone from its current placement in Schedule III to Schedule II.

The decision was informed by presentations from various perspectives, including high ranking government officials from FDA and DEA, professional societies, practitioners, industry representatives, and family members who lost loved ones to prescription drug abuse. What began as a conversation about abuse-ratios (FDA and DEA had competing views), soon developed into a conference about prescription drug abuse generally; the practical impact of rescheduling on prescribing practices, patient access, drug distribution, opioid abuse and misuse; and alternatives to rescheduling that would equally or more effectively reduce hydrocodone misuse and abuse.

Industry representatives argued that up-scheduling hydrocodone would impose huge costs on pharmacies, distributors, and patients with no discernible reduction on abuse and diversion. While some committee members gave little weight to these increased costs, they also shared a concern about the change's overall effectiveness, noting the widespread abuse of opioids currently placed in Schedule II. Patient representatives remarked that rescheduling would increase patient (and payer) costs and impede patient access because Schedule II controlled substances, versus Schedule III controlled substances, may not be refilled. Thus, patients who currently see their physicians twice-a-year would be required to do so as often as once a month. To avoid the need for monthly visits, they explained, prescribers may react by increasing prescription volume, which, in turn, raises the risks of abuse and diversion, by increasing the number of pills available inside the home.
Advocating for the change from Schedule III to II, DEA Deputy Assistant Administrator, Joseph Rannazzisi, argued that tightening security and control of combination hydrocodone products by pharmacies and distributors, and increasing DEA's enforcement tools, would reduce abuse and diversion of combination hydrocodone. See DEA Slides, here.

He argued that many individuals start abusing combination hydrocodone due to its ease of availability, build a tolerance, and consequently move on to stronger opioids such as oxycodone and heroin. However, he recognized that, "I am not going to be able to provide you with clear evidence [that rescheduling will work to reduce prescription opioid abuse] because there is no clear evidence until the drug actually gets rescheduled." In response to patient access concerns, he asked, "Is it really that bad to have to see a patient every 3 months?," and identified a rule DEA promulgated in 2008 that allows prescribers to issue up to three post-dated 30-day prescriptions for the same Schedule II substance at one time. He recognized, however, that many prescribers do not avail themselves of the rule.

The Committee discussed other activities that might address misuse and diversion of hydrocodone, including interoperable Prescription Drug Monitoring Programs, drug disposal initiatives, provider and patient education, and Risk Evaluation and Mitigation Strategies ("REMS"). One Committee member who voted in favor of rescheduling stated that placing hydrocodone combination products in Schedule II is the best way to educate providers on the drug's abuse potential.

Overall, in recommending rescheduling, many Committee members were persuaded by evidence showing combination hydrocodone acts similar to other Schedule II controlled substances, such as morphine and oxycodone. Sharon Walsh, Ph.D., from the Center on Drug and Alcohol Research, University of Kentucky, presented evidence from human studies showing no significant difference between combination hydrocodone and combination oxycodone drugs on pupil diameter and drug "likeability." See S. Walsh Slides, here. When asked by committee members for her opinion as to whether there was a meaningful difference in those drugs' abuse potential, she opined that the drugs' abuse potential was indeed the same. Many Committee members later referenced Ms. Walsh's presentation when casting their vote in favor of rescheduling.

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.

New Drug Approved to Treat ADD/ADHD

The Food and Drug Administration (FDA) recently approved a new drug for the treatment of ADHD in patients ages 6 year and older. The drug Quillivant XR, (methylphenidate hydrochloride) oral suspension is manufactured by Pfizer.

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 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.

The Advisory Committee's recommendation is not binding on FDA and there is no statutory time-limit on when FDA must respond to DEA's request for a scheduling recommendation. Because there is a pending petition before DEA to reschedule these drugs, when FDA provides its recommendation to DEA, DEA will then likely proceed with a notice and comment rulemaking proposing to reschedule the drug.

Western States Has the Highest Rate of Prescription Drug Abuse

The Substance Abuse and Mental Health Services Administration (SAMHSA) released "The NSDUH Report: State Estimates of Nonmedical Use of Prescription Pain Relievers: 2010-2011." The report is based on data from the SAMHSA National Survey on Drug Use and Health, which is a scientific annual survey of approximately 67,500 people ages 12 and older throughout the country. This NSDUH report is available here.

The study shows prescription drug misuse is second only to marijuana as the nation's most prevalent illegal drug problem, with approximately 22 million people nationwide starting non-medical pain reliever use since 2002. With the 2010 and 2011 data combined, rates of past year misuse ranged from 3.6 percent in Iowa to 6.4 percent in Oregon.
"Addressing prescription drug misuse remains a top public health priority, as we've seen inconsistent progress in addressing the issue across the states," said SAMHSA Administrator Pamela S. Hyde. "Data from this report helps up better understand geographic variations in use, and should help with the development of more targeted and effective prevention and treatment programs. The key is educating the public on the serious health risks involved, and ensuring that we are providing the necessary treatment to those who need it."

FDA Issues Draft Guidance on Abuse-Deterrent Opioids

Jan. 9, 2013 - The U.S. Food and Drug Administration (FDA) last month issued a draft guidance document to assist industry in developing new formulations of opioid drugs with abuse-deterrent properties.

The document "Guidance for Industry: Abuse-Deterrent Opioids - Evaluation and Labeling," explains the FDA's current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated by the agency, and what labeling claims may be approved based on the results of those studies.
"The FDA is extremely concerned about the inappropriate use of prescription opioids, which is a major public health challenge for our nation," said FDA Commissioner Margaret A. Hamburg, M.D. "This draft guidance is an important part of a larger effort by FDA aimed at preventing prescription drug abuse and misuse."

Opioids can be abused in a number of ways. Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject, for the specific opioid drug substance in that formulation. The science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. In working with industry, the FDA will take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products.

"While prescription opioids are an important component of pain management, abuse and misuse of these products have resulted in too many injuries and deaths across the United States," said Douglas Throckmorton, M.D., deputy director for regulatory programs in the FDA's Center for Drug Evaluation and Research. "An important step towards the goal of creating safer opioids is the development of products that are specifically formulated to deter abuse."
The FDA continues to encourage the development of abuse-deterrent formulations of opioids and believes that these products have promise to help reduce prescription drug abuse. At the same time, the FDA remains committed to ensuring that patients with pain have appropriate access to opioid analgesics.

This draft guidance fulfills mandates under the Food and Drug Administration Safety and Innovation Act (FDASIA) and the Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan.

FDA is seeking public comment on the draft guidance for 60 days and encourages additional scientific and clinical research that will advance the development and assessment of abuse-deterrent technologies. Instructions on how to submit comments will be announced in an upcoming Federal Register notice. The FDA will also hold a public meeting to discuss and receive feedback on the draft guidance. In finalizing the guidance document, the agency will consider the information received from the public.
For more information:

- FDA: Draft Guidance for Industry: Abuse-Deterrent Opioids - Evaluation and Labeling
- ONDCP: Prescription Drug Abuse

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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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