Important Reminder

NASCSA's Annual Conference!

The 34th annual conference that takes place at the Hotel Valley Ho October 30-November 2, 2018 in Scottsdale, Arizona is less than a month away.

A few important reminders:

1. If you have not yet sent in your registration form please do so as soon as possible. A link to the registration form is found here.
2. October is a busy time in Arizona and the hotel is booking up quickly. Attendees are strongly encouraged to reserve your room asap as the deadline is 10/8/18 or the hotel may release the unused room block. Online registration is available here or you may call the hotel directly (hotel info is found here).

Please check the conference website periodically for any changes in the final program. The latest agenda is found here.

Important Items to be Discussed at the Annual Conference

There are two important items that will be discussed at this year's annual conference. All members are asked to review in advance of the meeting.

Proposed Bylaw Changes - Proposed Bylaw Changes will be voted on at the business meeting. Please see attached proposed changes here.
Follow NASCSA on Twitter

NASCSA is pleased to announce that it is now on Twitter and the number of followers continues to grow each month so please follow us at @NASCSA.

Proposed Resolutions - Proposed Resolutions to be voted on at the annual meeting are found here.

FDA Approves Final Opioid Analgesic REMS

In September 2018, FDA approved the final Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). The Opioid Analgesic REMS now applies to immediate-release opioid analgesics intended for outpatient use, as well as the extended-release and long-acting opioid analgesics, which have been subject to a REMS since 2012. The new Opioid Analgesic REMS also includes several measures to help better communicate the serious risks about the use of opioid pain medications to patients and health care professionals.

For the first time, the Opioid Analgesic REMS requires that training be made available to all health care providers who are involved in the management of patients with pain, including nurses and pharmacists. An FDA news release indicates the new Opioid Analgesic REMS also requires that the education cover broader information about appropriate pain management, including alternatives to opioids for the treatment of pain. In addition, FDA is approving new product labeling containing information about the health care provider education available through the new REMS.

FDA also approved the new FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (Blueprint), which includes updated educational content. The continuing education (CE) training under the modified REMS is expected to be available to health care providers by March 2019. Further, FDA’s web page states drug companies with approved opioid analgesics will provide unrestricted grants to accredited CE providers for the development of education courses for health care providers based on the September 2018 FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain (Blueprint). FDA maintains a website listing medications with approved REMS that are currently active and their associated materials at REMS@FDA.

Bipartisan Opioid Bill Nears President’s Desk
The House and Senate last week passed sweeping, bipartisan legislation to combat the opioid crisis. **H.R. 6, the SUPPORT for Patients and Communities Act** and now heads to the Senate for a final vote and then to the President's desk to be signed into law.

We encourage all of our members to take a look at this important legislation.

**FDA Approved Drug Epidiolex Placed in Schedule V**

The Department of Justice and Drug Enforcement Administration (DEA) today announced that Epidiolex, the newly approved medication by the Food & Drug Administration (FDA), is being placed in schedule V of the Controlled Substances Act (CSA), the least restrictive schedule of the CSA.

In June 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older.

Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana). The CBD in Epidiolex is extracted from the cannabis plant and is the first FDA-approved drug to contain a purified extract from the plant.

"DEA will continue to support sound and scientific research that promotes legitimate therapeutic uses for FDA-approved constituent components of cannabis, consistent with federal law," said Acting DEA Administrator Uttam Dhillon. "DEA is committed to continuing to work with our federal partners to seek ways to make the process for research more efficient and effective."

"The FDA is committed to advancing scientific research and drug development programs that properly evaluate the active ingredients contained in marijuana," said FDA Commissioner Scott Gottlieb, M.D. "Adequate and well-controlled clinical studies supported Epidiolex's approval, so prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes. The FDA will continue to support rigorous scientific research on the potential medical uses of marijuana-derived products and stand ready to work with
product developers who are interested in bringing patients safe and effective, high quality products."

Marijuana and CBD derived from marijuana remain against the law, except for the limited circumstances that it has been determined there is a medically approved benefit. In those instances, such as here, the drug will be made appropriately available to the public for medical use.