President’s Message

Greetings to all. Spring has finally arrived in the Land of 10,000 Lakes with the ice finally out on a major fishing lake just this past weekend.

It has been a busy 6 months since our annual meeting and is bound to continue at the same brisk pace for the next 6 months. All of the NASCSA committees have met at least once, with a majority of them meeting monthly as they continue to develop new resources for the membership, update resources currently available and prepare for the next annual conference.

This year’s annual conference agenda is shaping up and looks like there will be a lot of good information shared as a result. Please plan to join us to exchange ideas, information, and network with like-minded individuals working in the controlled substances arena.

I look forward to seeing you at the 34th NASCSA Annual Conference scheduled October 30 - November 2 in sunny Scottsdale, Arizona.

Barbara Carter, President

Save the Date for our Annual Conference

The 34th annual conference will take place at the Hotel Valley Ho October 30-November 2, 2018 in Scottsdale,
are open. If you are interested in serving please email Ralph Orr at ralph.orr@dhp.virginia.gov, indicate the position you are interested in running for and submit a copy of your resume.

Consider Donating to NASCSA

Did you know that you can contribute to NASCSA online? As a 501(C)(3) nonprofit is a great organization to consider donating to.

To donate please click 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.

Follow NASCSA on Twitter

NASCSA is pleased to announce that it is now on Twitter and the number of followers continues to

Arizona. Registration information as well as information on hotel accommodations is available on our website here. We strongly urge members to book your hotel early as this is a particularly busy time of year and the hotel is extremely popular. Check the website on a regular basis for updates.

Travel Scholarships to Attend Our 2018 Conference Announced!

The Executive Committee has authorized the awarding of six (6) travel scholarships to attend this year's annual conference. Travel scholarship criteria as well as the application form and instructions have already been posted here. The deadline for submitting applications is June 22, 2018.

NASCSA Committees Hard at Work

NASCSA President Barb Carter created a number of committees that have been meeting throughout the year on a variety of projects. Committee members, comprised of volunteers from member states as well as associate members are the backbone of the organization. We encourage all members to consider volunteering. For a list of committee members click here.

Membership - In addition to developing the criteria for this year's travel scholarship, members of the committee will review the applications and make recommendations to the Executive Committee. Travel Scholarship applications and instructions will be available later this spring. The committee also recently updated its communication policy to reflect current operations. The committee will be identifying other individuals and organizations to expand its membership and sponsorship base to continually ensure that NASCSA continues to be self-sustaining in the future. If you are aware of potential organizations please contact us!
Program Committee - Members of the committee are hard at work on the 2018 conference, taking into consideration feedback from last year’s conference evaluation to ensure yet another successful conference. It is not too late to provide suggestions for conference speakers and/or topics for consideration. The program should be finalized in the next month.

Survey/Data/IT - The committee has begun its work of developing potential surveys of the membership. We ask that state agencies check the state profile page here for their respective states and let us know whether any information needs updating. If there is information you feel would be helpful, please forward those suggestions.

Prescription Monitoring Program - The committee is meeting on a monthly basis and has a number of important tasks. Several subcommittees (conference program, Resolutions/Bylaws, Data and data integrity) have been formed. The committee is also evaluating the current Model PMP Act for potential modifications.

Policy and Procedures - A committee has been formed to review NASCSA's written policies and procedures to ensure that these documents are up to date. These policies ensure the smooth operation of the organization and provide a roadmap for overall operations of the organization.

Finance Committee - A committee has been formed to review NASCSA's finances on an ongoing basis and to make recommendations to the Executive Committee.

Education Committee - The committee recently organized NASCSA's first webinar on May 8th "The Impact of the Opioid Crisis - An Insurers Perspective: Claims, Liabilities and Control Considerations" featuring Mike Warren, ARM, PHST, Risk Manager for Pharmacists Mutual. Based on the terrific response the committee is already planning additional webinars later this year. We welcome any suggestions for the committee to consider.

Nominating Committee - In order to streamline the nominating process for election of officers, a formal committee has been formed.

Resolutions/Bylaws - The committee is in the process of reviewing the bylaws for any revisions at this year's annual business meeting. Bylaw changes must be distributed 60 days in advance of the meeting. In addition,
Monitoring Program Director following the retirement of Dana Crenshaw. In addition, Frank Gammill, Executive Director of the Board of Pharmacy retired May 31, 2018.

HHS Provides Second Round of Funding to States and Territories Affected by the Opioid Crisis

As part of the 21st Century Cures Act, the Department of Health and Human Services (HHS) is releasing the second installment of the Opioid State Targeted Response grants to 50 states, four United States territories, and the free-associated states of Palau and Micronesia, totaling $485 million. This funding is one more step in implementing HHS’ comprehensive five-pronged strategy to address the opioid crisis. Administered by the Substance Abuse and Mental Health Services Administration, the first round of grants was announced in April 2017. Grantees have used the funding from the first year to implement effective medication-assisted treatment, promote the

the committee will be reviewing potential resolutions for consideration at the annual conference. All members are strongly encouraged to provide their suggestions on possible resolutions and proposed language as soon as possible. All members are permitted to submit proposed resolutions in accordance with our Bylaws, found at Article XI. Draft resolutions will be distributed in early September (45 days prior to the annual meeting). The committee will also be developing guidelines for voting on resolutions and election of officers at this year’s meeting.

State Regulatory Developments

On a monthly basis NASCSA compiles a listing of state regulatory updates related to controlled substances including scheduling actions, Prescription Drug Monitoring Program requirements and registration information related to state requirements of interest to our members. These updates are posted on our website here. Below are recent actions:

**Alabama** - Proposed rule of the Board of Dental Examiners would amend regulations under AAC 270-X-2 to require dentists who are authorized by the board to write controlled substances to be registered with and have access to the controlled substances prescription database program maintained by the Department of Public Health. A meeting is scheduled for June 15, 2018, in Hoover. Comments are due June 15, 2018. Contact: Matthew Hart; BDE; 205-985-7267

**Florida** - Proposed rule of the Department of Health, Board of Medicine, would amend regulations under FAC 64B8-13 to require physicians registered with the U.S. Drug Enforcement Agency and authorized to prescribe controlled substances to complete a course on prescribing such substances. The rule also would exempt licensed physician assistants from this requirement. In addition, the rule would approve the Florida Medical Association, the Florida Academy of Family Physicians, and the Florida College of Emergency Physicians as entities authorized to provide the course. Comments are due May 30, 2018. Contact: Claudia Kemp; DOH, Board of Medicine; 850-245-4588
use of naloxone and key prevention strategies, and build sustainable systems of recovery support services across the country. Prevention efforts include communications campaigns along with use of proven community-based strategies. Details of the funding amounts for each state and territory can be found in HHS’ news release.

DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant

WASHINGTON, DC - May 22, 2018 - In 2004, the U.S. Court of Appeals for the Ninth Circuit enjoined DEA from enforcing certain regulations with respect to tetrahydrocannabinols (THC). See Hemp Industries Ass’n v. DEA, 357 F.3d 1012 (9th Cir. 2004). The government did not seek Supreme Court review of that decision. In response to various inquiries, DEA hereby issues to DEA personnel the following internal directive on how to carry out their duties in Missouri - Final rule of the Department of Insurance, Financial Institutions and Professional Registration, State Board of Pharmacy, amends regulations under 20 MCSR 2220-2 to revise requirements for electronic prescriptions. The rule defines electronic image transmission and electronic prescription and allows prescribers or their authorized agents to transmit prescriptions or medication orders to pharmacies by such means. The rule also establishes requirements for the contents and formatting of electronic image transmissions and electronic prescriptions. In addition, the rule allows pharmacists to accept paper prescriptions or medication orders with electronic signatures if provided on paper that utilizes specified security features. The rule is effective June 30, 2018. Contact: DIFIPR, State Board of Pharmacy; 573-751-0091; pharmacy@pr.mo.gov

Virginia - Final rule of the Department of Health Professions, Board of Pharmacy, amends regulations under 18 VAC 110-20 to add seven compounds to Schedule I of the Drug Control Act. The placement of the compounds will remain in effect until Dec. 13, 2019, or until the compounds are placed in Schedule I by legislative action. The compounds include three synthetic opioids and four research chemicals. The rule is effective June 13, 2018. Contact: Caroline Juran; DHP, Board of Pharmacy; 804-367-4456; caroline.juran@dhp.virginia.gov

House Committees Advance Opioid Legislation in Markups

The House Energy and Commerce and Ways and Means Committees held markups recently on opioid legislation with numerous provisions.

On May 17, the House Energy and Commerce Committee advanced more than 30 mostly bipartisan bills addressing the opioid crisis. Among the bills included:

- H.R. 5795, the Overdose Prevention and Patient Safety Act, that amends the Public Health Service Act to protect the confidentiality of substance abuse disorder (SUD) patient records.
light of the Ninth Circuit's decision. The Ninth Circuit enjoined enforcement of what is now 21 C.F.R. Â§ 1308.11(d)(31) (drug code 7370) with respect to products that are excluded from the definition of marijuana in the Controlled Substances Act (CSA). DEA thus does not enforce that provision as to such products.

Consistent with the Ninth Circuit's decision, DEA does not enforce 21 C.F.R. Â§ 1308.35.

Products and materials that are made from the cannabis plant and which fall outside the CSA definition of marijuana (such as sterilized seeds, oil or cake made from the seeds, and mature stalks) are not controlled under the CSA. Such products may accordingly be sold and otherwise distributed throughout the United States without restriction under the CSA or its implementing regulations. The mere presence of cannabinoids is not itself dispositive as to whether a substance is within the scope of the CSA; the dispositive question is whether the substance

- H.R. 5590, the Opioid Addiction Action Plan, requiring the Secretary of HHS to provide for an action plan on recommendations for changes under Medicare and Medicaid to prevent opioid addiction.

In addition, on May 16, the House Ways and Means Committee held a markup on seven opioid-related bills.

2018 BJA Comprehensive Opioid Abuse Program (COAP) National Meeting Scheduled

The PDMP Training and Technical Assistance Center (TTAC) at Brandeis University, in partnership with the Bureau of Justice Assistance, is pleased to announce the dates for the 2018 BJA COAP National Meeting - From Crisis to Collaboration: Innovations to Address the National Opioid Epidemic. The event will convene on September 5th at 8:30 a.m., ET, and run through September 7th, adjourning by 12:00 Noon, and will be held in Washington, DC at the Marriott Wardman Park Hotel.

The meeting will consist of several ‘educational tracks’ covering topics pertaining to the six (6) categories of BJA’s COAP grants:

- Category 1 - Overdose Outreach Projects
- Category 2 - Technology-Assisted Treatment Projects
- Category 3 - System-Level Diversion and Alternatives to Incarceration Projects
- Category 4 - Statewide Planning, Coordination, and Implementation Projects
- Category 5 - Harold Rogers PDMP Implementation and Enhancement Projects
- Category 6 - Data-Driven Responses to Opioid Misuse Projects

Additional information will be made available as the event draws near. This event is open to anyone who would like to attend and there is no registration fee.
falls within the CSA definition of marijuana.

The Controlled Substances Import and Export Act incorporates the schedules of the CSA. See generally 21 U.S.C. §§ 951-971. Accordingly, any product that the U.S. Customs and Border Protection determines to be made from the cannabis plant but which falls outside the CSA definition of marijuana may be imported into the United States without restriction under the Controlled Substances Import and Export Act. The same considerations apply to exports of such products from the United States, provided further that it is lawful to import such products under the laws of the country of destination. This directive does not address or alter DEA's previous statements regarding the drug code for marijuana extract and regarding resin. See Establishment of a New Drug Code for Marihuana Extract, 81 Fed. Reg. 90194 (Dec. 14, 2016); Clarification of the New Drug Code (7350) for Marijuana Extract. As DEA has previously explained, the drug code for

**GAO Recommends US Agencies Develop Performance Metrics to Gauge Effectiveness of Efforts to Combat Synthetic Opioid Threat**

A new report by the US Government Accountability Office (GAO) indicates that many United States agencies documented that opioid response strategies lack specific outcome-oriented performance measures. Without specific federal agencies will not be able to truly assess whether their respective investments and efforts are helping them to limit the availability of and better respond to the synthetic opioid threat, states the GAO report "Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts."

In response to a request from members of Congress to review US agency efforts to combat illicit synthetic opioids, GAO reviewed documents that described agencies' international coordination efforts, domestic opioid reduction strategies and prevention and treatment approaches, and interviewed international and federal agency officials engaged in drug control policy. GAO also interviewed state and local law enforcement and public health officials in seven states that were selected in part for their high rates of overdose deaths.

According to the report, establishing goals and outcome-oriented performance measures for some of the existing strategies will help agencies assess whether the resources they have invested in their efforts are yielding their intended results. GAO makes six recommendations, including: one to the Department of Homeland Security (DHS): US Customs and Border Protection; two to the Executive Office of the President: Office of National Drug Control Policy (ONDCP); one to the Department of Justice (DOJ): Organized Crime Drug Enforcement Task Forces; one to the DOJ; and one to the DOJ: Drug Enforcement Administration.
marijuana extract extends no further than the CSA does, and it thus does not apply to materials outside the CSA definition of marijuana.

Illegal Veterinary Medicines Affect Health and Safety for Both Animals and the Public, Reports Global Animal Medicines Association

Counterfeit, falsified, and unregistered illegal veterinary medicinal products, including bulk supplies, are a growing problem for companion animals in the United States, Canada, and in other developed countries, indicates a new report. Such products are distributed via internet pharmacies, other e-commerce sites (e.g. eBay and Amazon), and more recently, via social media (Facebook and Twitter), according to the report: "Illegal Veterinary Medicines: Impact and Effective Control." "Illegal internet sites distributing authorized veterinary medicines is also a growing problem across all regions.

As noted in the report, the risks of illegal veterinary medicines include: lack of efficacy and safety for animals; risks to human safety through food from animals treated with illegal veterinary medicines; and less effective control of zoonotic infections and increasing antimicrobial and antiparasitic resistance. The report makes several recommendations and offers strategies for animal health companies, enforcement agencies, customers, and other stakeholders to take against illegal veterinary medicines.

FDA warns companies selling illegal, unapproved kratom products marketed for opioid cessation, pain treatment, and other medical uses

The U.S. Food and Drug Administration recently has issued warning letters to three marketers and distributors of kratom products - Front Range Kratom of Aurora, Colorado; Kratom Spot of Irvine, California and Revibe, Inc., of Kansas City, Missouri - for illegally selling unapproved kratom-containing drug products with unproven claims about their ability to help in the treatment of opioid addiction and withdrawal. The companies also make claims about treating pain, as well as other medical conditions like lowering blood pressure, treating cancer and reducing neuron damage caused by strokes.
The FDA continues to warn consumers not to use Mitragyna speciosa, commonly known as kratom, a plant which grows naturally in Thailand, Malaysia, Indonesia and Papua New Guinea. The FDA is concerned that kratom, which affects the same opioid brain receptors as morphine, appears to have properties that expose users to the risks of addiction, abuse and dependence. There are no FDA-approved uses for kratom, and the agency has received concerning reports about the safety of kratom.

The FDA is actively evaluating all available scientific information on this issue and continues to warn consumers not to use any products labeled as containing the botanical substance kratom or its psychoactive compounds, mitragynine and 7-hydroxymitragynine. The FDA encourages more research to better understand kratom’s safety profile, including the use of kratom combined with other drugs.

The companies receiving warning letters use websites where they take orders for kratom products or they use social media to make unproven claims about the ability of their kratom drug products to cure, treat, or prevent a disease, which is against the law. Examples of claims being made by these companies include:

- "Along with helping drug addiction, the health benefits of kratom leaves include their ability to lower blood pressure, relieve pain, boost metabolism, increase sexual energy, improve the immune system, prevent diabetes, ease anxiety, eliminate stress, and induce healthy sleep."
- "The mood elevation qualities of kratom reduces opiate withdrawal effects."
- Kratom, like any other pain killer, relieves temporary or even chronic pain."
- "This plant can relieve headaches, vascular pain, arthritic pain, muscle pain among others."
- "Kratom can be used as a remedy for stroke-related ailments and condition as it is a powerful antioxidant that works to reduce neuron damage."
- "It can . . . help in lowering blood pressure."
- "Kratom is also said to have elements that control blood sugar level in the body for diabetic patients."
"It is said, that kratom is very effective against cancer."

Health fraud scams like these can pose serious health risks. These products have not been demonstrated to be safe or effective and may keep some patients from seeking appropriate, FDA-approved therapies. Selling these unapproved products with claims that they can treat opioid addiction and withdrawal and treat other serious medical conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

For more information, please visit: Kratom Warning Letters.