

119th NABP Annual Meeting May 10-12, 2023

Report of the Executive Committee

Presented by:

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Good morning, and welcome to the First Business Session of the 119th NABP Annual Meeting. It's a pleasure to be here in the beautiful

city of Nashville, standing before you as the chairperson of the Executive Committee. For more than a decade now, it seems that every year has been an eventful year for boards of pharmacy, and the last 12 months are no exception.

The pharmacy profession has been subject to frequent changes, but there can be no doubt that the global pandemic and the related demands on health care providers have put an unprecedented pressure on pharmacy professionals to provide expanded services to patients. After my address, Reggie will be speaking to you about how NABP has responded to some of those changes, particularly regarding expanded scope of practice and his initiative to support a new practice model.

This morning, I plan to talk to you about the work the Association has put forward over the last year in several other key initiatives. These include activities related to drug importation safety, the DSCSA state regulator network and pilot project, how NABP is promoting the safe purchase of

medications online, and an update on the Medication Safety Academy and the Leadership Academy.

As many of you know, prescription drug importation and its potential impact on the proliferation of roque online drug outlets is an important issue to me. During the early months of the COVID-19 pandemic, we all witnessed the increased number of disreputable websites trying to take advantage of an unprecedented public health emergency to sell fake cures or treatments for the virus. While highly visible in recent years, this sort of predatory behavior by illicit online drug sellers has been something NABP has been combatting for decades.

In that time, NABP's Rogue Rx Investigations Team has identified over 40,000 illegal online pharmacies. Most of these websites claim to be legitimate Canadian pharmacies, hoping to entice American patients to purchase cheaper, unapproved prescriptiononly drugs without requiring a prescription. NABP has long expressed concern that encouraging prescription drug importation at any level may lead patients to these rogue online websites purporting to be legitimate pharmacies.

This is perhaps made more complicated by the final rule published by FDA in 2020, which allows states to establish a wholesale prescription drug importation program for products distributed from Canada. The rule

pushes most of the requirements to the states for implementation. This includes securing the supply chain and establishing product testing procedures, as well as demonstrating a significant cost reduction for American consumers.

During my term as president from 2021 to 2022, I established an initiative to support the states on this issue. As part of this initiative, we convened a task force, the report of which is available on the NABP website, and members issued multiple recommendations. Pursuant to these recommendations. we assisted boards by monitoring proposed state legislation on prescription drug importation and developed resources to help boards educate policymakers on importation issues and the dangers patients can face when looking to purchase medications from roque online foreign sellers.

Not surprisingly, over the last year, at least 13 states have considered legislation related to wholesale importation of prescription drugs. While most of this legislation failed to pass, some are still being considered. These include acts that would authorize Canadian importation programs in states such as Illinois, Nebraska, and New Jersey. Florida was one of the first states to authorize a Canadian **Prescription Drug Importation** Program after guidance from FDA in 2020, though FDA has not yet approved it. Should it eventually be approved and implemented, Florida has authorized pharmacists and wholesalers working with forensic facilities managed by their Agency for Persons with Disabilities to import prescription drugs for dispensing to clients in these facilities.

The bottom line is, with the ease and ubiquitous nature of internet advertising and the high cost of prescription drugs, these issues are not going away. It's vital that we continue to work not only with patients, but with other health care providers and policymakers on this issue to ensure patient safety.

While NABP completely understands the need for affordable medications, we encourage state legislators and regulators who are grappling with this issue to exercise caution and to take a deliberate and thoughtful approach to any such programs they implement. When the possibility of drug importation is discussed in your state, please remember that NABP has developed resources for you on this subject that I hope will be helpful to you as your state considers or implements such a program.

Because supply chain security is such an essential part of this importation issue, it seems natural that we also discuss developments related to NABP's project that supports the implementation of DSCSA, which facilitates interoperability for NABP member boards of pharmacy and provides accessible tools for trading partners to meet DSCSA obligations. We have gathered a team of experts from across the pharmacy industry to create a platform that will facilitate communication between states and trading partners in anticipation of FDA's November 2023 deadline.

To review, our first informational webinar was held in January 2022. At that time, NABP conducted a survey to solicit pilot participants. Based on that response, a pilot was conducted that simulated multiple scenarios where regulators would communicate with trading partners as they conduct investigations into suspect products. The pilots ran into March 2022, at

which point the participants met with other key stakeholders to discuss the pilot outcomes and what the ideal system looked like to them. The Executive Committee and I carefully reviewed the proposed plan drafted from the comprehensive pilot.

Since then, NABP has released a detailed report that includes a summary of those findings and makes key recommendations for FDA to consider.

Over the last year and a half, many of you have heard this project referred to as the DSCSA State Regulator Network or, more simply, the DSCSA Interoperability Network. But as we worked with stakeholders from across the supply chain, we quickly realized that the platform we were building would be a tool that connected the supply chain in ways beyond DSCSA. And because of that, the platform debuted under its new name - Pulse by NABP - at the Healthcare Distribution Alliance conference in March. Since that time, we have been pushing out educational information about the upcoming DSCSA requirements to stakeholders across the supply chain. And in July, we will release version 1 of Pulse, at which time regulators, distributors, dispensers, and manufacturers can begin creating their accounts and profiles, and they will have the ability to verify authorized trading partner status. In the fall, in time for FDA's deadline, the tracing and verification tools for DSCSA will be implemented for the supply chain. These tools will help ensure that regulators have an efficient means to assist in inspections and investigations.

It has been exhilarating to see how much can be achieved in the name of patient safety when representatives from across the supply chain work together. NABP staff is committed to continuing this inclusive approach to developing the Pulse platform. And the Executive Committee and I look forward to seeing the culmination of all the stakeholders' efforts in the fall.

This year also saw some significant changes in how NABP operates

the .pharmacy top-level domain. NABP has split this program into two distinct offerings: accreditation and .pharmacy domain name registration. The portion of the program responsible for application review has been rebranded the Healthcare Merchant Accreditation. Over the year, the Association's expertise has been recognized by many industries, including payment processors and digital advertising, and the name change better reflects the variety of businesses eligible to apply for the program. The .pharmacy domain remains restricted, and domain names are only granted to entities once they have completed the accreditation process. And, of course, boards of pharmacy may obtain a .pharmacy domain name upon request and at no cost.

Because .pharmacy is a restricted top-level domain, websites must meet program standards to qualify, including appropriate licensure or registration where customers reside. Consumers can continue to confidently identify safe, legitimate pharmacies that have a .pharmacy web address for purchasing drugs online. Accredited organizations also benefit through automatic eligibility to advertise on major platforms, including Google, Yahoo!, and Bing, and automatic compliance with Visa and Mastercard's card-not-present policies.

To further our goal of patient safety when buying medication online, NABP has also been working to educate consumers. I'm particularly proud of the joint campaign between NABP and several other stakeholders and law enforcement organizations, including the Los Angeles County Sheriff's Department and the LA Police Department, the Alliance for Safe Online Pharmacies, and the National Intellectual Property Rights Coordination Center.

Released in December 2022, the campaign is built around the slogan "Bad meds kill real people," and addresses the dangers of fake medications being sold online. The campaign also highlights how counterfeit drugs often contain

dangerous ingredients, including potentially lethal doses of illicitly manufactured fentanyl. A public safety video, featuring actor Danny Trejo, directs viewers to "verify their meds with safe.pharmacy." The video was launched in December 2022.

Another way NABP is working to support its members is through its new Leadership and Medication Safety Academies.

Last September, the first Leadership Academy for executive directors was held the day before the NABP Executive Officer Forum. The meeting included sessions on:

 building high-performing teams with a focus on teamwork,

- overcoming challenges to board authority and leadership, and
- legislative and regulatory research and drafting.

There were also a number of breakout sessions, and many opportunities for discussion and networking.

Then, in March, NABP set another milestone in promoting medication safety by hosting the Medication Safety Academy. This two-day event included in-depth presentations and discussion of important safety topics including medication errors, "just culture," CQI programs, and more.

As you can see, NABP continues each year to work tirelessly to support its member boards.

During my seven years on the Executive Committee, I have witnessed firsthand the dedication and commitment from my fellow colleagues and NABP staff, and I am grateful to all of you. While new challenges will always present themselves and some are harder to address than others, we are fortunate to belong to an association wherein we can collaborate, share best practices, and identify solutions.

In closing, I thank you for this opportunity to serve on the Executive Committee. It has truly been an honor and privilege. I am excited to see what the future holds for NABP, and I look forward to continuing to work with you in the coming years.