



Report of the Task Force on

STATE OVERSIGHT OF DRUG IMPORTATION



Members Present

Andrew Funk (IA), *chair*; Paul Brand (MT); Robert Carpenter (VT); John Colaizzi, Jr (NJ); Brenda McCrady (AR); Shanea McKinney (TN); Rich Palombo (NJ); Jeanne Waggener (TX); Stuart Williams (MN); and Linda Witzal (NJ).

Others Present

Jeffrey J. Mesaros, *Executive Committee liaison*; Cheranne McCracken, New Mexico Board of Pharmacy; Lauren Reveley, Colorado Drug Importation Program; Kelly Swartzendruber, Colorado Drug Importation Program; Caroline D. Juran, NABP president; *Guests*; Lemrey “Al” Carter, Josh Bolin, William “Bill” Cover, Melissa Madigan, Eileen Lewalski, Gregg Jones, Maureen Schanck, Cameron Orr, and Andrea Busch, *NABP staff*.

Introduction

The task force met on September 20-21, 2021, at NABP Headquarters in Mount Prospect, IL. This task force was established pursuant to Caroline D. Juran’s 2021-2022 presidential initiative, which is to increase efforts to support the boards of pharmacy and to educate and protect the public about state drug importation plans.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Evaluate the current regulatory environment related to prescription drug importation and the challenges that states will face with regulating importation.
2. Review NABP programs to determine how they may support states that implement drug importation programs.
3. Develop educational tools to assist states in the oversight of drug importation.

Background and Discussion

The meeting began with guest presentations provided by representatives from Colorado’s Canadian Drug Importation Program and the New Mexico Board of Pharmacy, who detailed their states’ Section 804 Importation Programs (SIPs). As task force members asked numerous questions during their presentations, it became apparent that these particular state SIPs failed to address many of their concerns. It was noted that some state legislatures are passing laws that provide for the development of a SIP without board of pharmacy input or consultation; however, members’ concerns could be alleviated if boards are involved with a SIP’s preliminary planning. A summary of the questions and/or concerns that arose during the meeting, accompanied by the member discussion, is provided below.

Supply Chain Issues

The task force's main concern was basic supply chain issues as it was duly noted that the safest drug supply chain will always be the shortest route from the manufacturer to the patient. Members recognized that the presented SIPs failed to consider the intricacies in supply chain logistics but rather seemed focused on acquiring foreign-sourced drugs, and not what happens as medications continue through the supply chain and ultimately to patients. Members voiced concern that the supply chain is already a global issue as foreign countries, such as China and India, provide most of the active pharmaceutical ingredients with questionable oversight. This concern, in conjunction with other state and federal authority oversight, increases the complexity of the boards' responsibility to oversee public health and patient safety. It was noted that 10 states are actively considering legislation to implement a SIP due to the fact that these plans have bipartisan support and will likely be considered in many more states as an opportunity to save patients' money. The task force agreed that boards of pharmacy should be consulted during SIP development to provide insight into supply chain security to ensure public protection, and NABP should assist boards of pharmacy in monitoring bills for legislation on prescription drug importation and proactively communicating these to the boards. Additionally, NABP should assist boards in developing talking points based on the 2020 NABP comments to the United States Department of Health and Human Services (HHS) regarding the federal importation proposal and other resources that include NABP's guiding principles and concerns that can be used to educate legislatures on importation issues.

Enforcement Responsibility

Task force members also voiced concerns over which entities would have enforcement responsibility, particularly when multiple agencies in different countries are involved. Questions arose regarding which agency would oversee the Canadian drug source so that there would be confidence that the drugs were safe and not counterfeit. The New Mexico SIP provides for the US Food and Drug Administration (FDA) to approve the foreign drug seller that ships to the US-based importer(s). Members discussed how these importers would be licensed as it appears there will be a very limited number, thus the issue of nonresident licensure will need to be addressed if they are not required to be domiciled in the state in which they are selling the imported drugs. This could pose significant interjurisdictional enforcement issues if an importer is domiciled in a state that has not authorized importation. One member shared that a known wholesale distributor domiciled in Florida will likely be one of the few, thereby states such as New Mexico and Colorado will have to determine if a special nonresident license category will need to be promulgated. Accordingly, it was noted that everything is dependent on what might ultimately happen with the entire federal importation of prescription drugs rule based on policy decisions made by the current and future administrations. Ultimately, the task force agreed that NABP should communicate with National Association of Pharmacy Regulatory Authorities (NAPRA), Health Canada, as well as pharmacy regulators in the individual Canadian provinces and foreign jurisdictions, to discuss importation issues, particularly the regulation of their wholesale distributors that will be selling prescription medications to the approved US importers. Additionally, NABP should discuss with the aforementioned Canadian regulators, state and federal agencies, as well as other foreign countries if and as they are approved, information

about NABP programs, such as the Supply Chain Inspection program, that could assist with regulatory oversight by possibly being utilized for nonresident importers within the US. However, it will be challenging for NABP to ensure the safety of imported prescription drugs.

Related SIP Issues

While discussing the broader topic of drug importation during the SIP presentations, the task force touched upon several miscellaneous but important issues that need to be considered. Members were concerned with the availability of Canadian drugs and whether drug shortages would result if and when larger states passed SIP legislation and entered the importation arena. It was noted that the Colorado SIP only provides for therapeutic categories that currently include respiratory, oncology, and HIV drugs. The expectation is that the states can partner with Canadian manufacturers to ensure that SIPs will be able to provide less expensive prescription medications to US patients, while not negatively impacting the drug supply for Canadian patients. Another concern expressed by several task force members was how negligible the actual savings to US patients would be, particularly in light of the additional costs associated with a SIP. Colorado's SIP mandates for authenticity testing and relabeling of the imported medications to include new National Drug Codes, and while the representatives informed the members that these costs were taken into consideration, it is still unknown what the actual savings to patients will be. Along the lines of medication costs arose the concern of reimbursement issues and whether the medications would be considered FDA-approved and subsequently billed to federally funded programs. Another issue members discussed was whether nonresident patients would be able to obtain medications from a state that is obtaining prescription drugs from Canada. The Colorado representatives informed the members that their SIP stated that imported medications were only allowed to be dispensed to Colorado residents, and their medications will be labeled accordingly. While the task force was extremely interested in these various miscellaneous issues and voiced that they should be monitored, members decided not to make any specific recommendations for NABP upon which to act.

Patient Safety

Additionally, the task force discussed the overarching issue of patient safety as the public's general knowledge about drug importation may cause confusion. Members were especially concerned that patients' perceptions regarding importation plans may lead to the erroneous belief that all prescription drugs obtained from foreign sources are safe. Also members discussed the various ways in which NABP can educate the public regarding patient safety and agreed that NABP should collaborate with other stakeholders, such as the Tri-Regulator Collaborative, pharmacy organizations, industry organizations, FDA, Drug Enforcement Administration (DEA), US Pharmacopeial Convention (USP), International Pharmaceutical Federation (FIP), and consumer groups, to develop nationwide consumer education programs that inform patients about legal state importation programs versus illegal importation with a focus on the dangers associated with the latter. The task force also agreed that NABP should continue to drive consumers to *safe.pharmacy* and encourage the use of the Buy Safely and Drug Disposal Locator Tool.

Drug Supply Chain Security Act

Lastly, members discussed the importance that the Drug Supply Chain Security Act (DSCSA) plays in ensuring the integrity of the US prescription drug supply and how to bridge the gap in educating health care providers, including pharmacists about this Act. It was noted that in 2023 the DSCSA will require the collecting and sharing of transaction data and the requirement that it must be interoperable throughout the supply chain. Thus, the task force agreed that NABP should collaborate with other stakeholders to develop DSCSA educational programs and tools for health care providers and regulators to ensure compliance for domestic and, in the event that any SIPs are approved, imported drugs.

After careful review and deliberation, the task force recommended that NABP do the following:

1. Assist boards of pharmacy by monitoring bills for legislation on prescription drug importation and proactively communicating these to the boards. Develop resources for boards to use in educating their legislators when an importation bill is being considered that are based on the 2020 NABP comments to HHS regarding federal importation proposals and that include NABP's guiding principles and concerns that encompass the boards of pharmacy. Such resources may include:
 - a. Developing a one-pager with talking points that include NABP's guiding principles and concerns over proposed legislation, the current federal landscape, and the fact that HHS has yet to approve a SIP;
 - b. Assisting boards of pharmacy, when requested, to provide educational and technical assistance to policymakers; and
 - c. Providing information about dangers of procuring drugs from rogue online foreign sellers.
2. Communicate with NAPRA, Health Canada, as well as pharmacy regulators in the individual Canadian provinces and foreign jurisdictions, about importation issues, particularly the regulation of wholesale distributors that sell prescription medications to approved state agents.
3. Discuss with the aforementioned Canadian regulators, state and federal agencies, as well as other foreign countries if and as they are approved, NABP programs, such as Supply Chain Inspection, that could assist with regulatory oversight and can possibly be utilized for nonresident importers within the US.
4. Collaborate with other stakeholders (ie, Tri-Regulator Collaborative, pharmacy organizations, industry organizations, FDA, DEA, USP, FIP, and consumer groups) to develop nationwide consumer education programs that inform patients about legal state importation programs versus illegal importation, focusing on the dangers associated with the latter. Continue to drive consumers to *safe.pharmacy* to use the Buy Safely and the Drug Disposal Locator Tools.
5. Collaborate with other stakeholders to develop DSCSA educational programs and tools for health care providers and regulators to ensure compliance for domestic and imported drugs.