Summary of Proceedings
October 26-27, 2021, Intergovernmental Working Meeting on Compounding

The U.S. Food and Drug Administration convened its tenth intergovernmental working meeting on drug compounding with state government officials on October 26 and 27, 2021. Attendees included officials from state boards of pharmacy and state health departments, representatives from the National Association of Boards of Pharmacy (NABP), and representatives from FDA. The meeting was held virtually.

The purpose of this meeting was to continue discussions about compounding oversight, efforts to support implementing the Compounding Quality Act (CQA), and opportunities to protect the public health through federal-state collaboration and policy and regulatory discussions.

Officials from 37 states and the District of Columbia attended the 2021 intergovernmental working meeting on compounding.

FDA previously held intergovernmental working meetings on compounding with state officials and their designated representatives in December 2012, March 2014, March 2015, November 2015, September 2016, September 2017, September 2018, October 2019, and October 2020. FDA initiated these meetings after the 2012 fungal meningitis outbreak associated with contaminated compounded drugs, which led to deaths and serious illnesses across the country.

Adverse Events and Emerging Issues

FDA, NABP, and states shared perspectives on adverse events, information sharing, and emerging trends in drug compounding. FDA's Compounding Incidents Team described FDA's case process from receipt of complaint to action. The Compounding Incidents Team also provided case examples and described emerging issues surrounding compounding in medical offices and intravenous (IV) hydration clinics. Finally, FDA reviewed Section 20.88 agreements (adopted in accordance with 21 CFR 20.88) and the process for commissioning officials to allow for the sharing of non-public information between FDA and state boards of pharmacy.

NABP presented on trends in drug compounding. They highlighted their observations of pharmacies shipping compounded drugs into states where they are not licensed, pharmacies not registered as outsourcing facilities selling non-patient-specific compounded drugs and purchasing compounded drugs from outsourcing facilities, the increasing sale of compounding kits, and the use of food ingredients as components for nonsterile compounded preparations.

These presentations were followed by a panel discussion that included FDA staff, NABP staff, and representatives from three state boards of pharmacy. The states described adverse event reporting requirements and processes for handling complaints, including when compounded drugs are made in or shipped to another state. They expressed concern over increasing sales from outsourcing facilities to pharmacies, as well as concerns about oversight of physician compounding, including new business models such as IV hydration clinics. State participants on the panel and in the audience said that state boards of pharmacy generally lack oversight of physician compounding and that state medical boards may not have the same resources and tools as the pharmacy boards to oversee compounding practices. States asked for FDA's help in engaging with medical boards regarding appropriate regulation. Several states also noted that their state laws and regulations do not require pharmacies to report adverse

events to the pharmacy board, and also do not clearly define "adverse events." States expressed interest in information-sharing efforts with respect to adverse event reporting.

State & FDA Policy Updates

The first day of the intergovernmental meeting concluded with a discussion of FDA's recent policy and rulemaking updates, including:

- FDA's revised draft guidance *Hospital and Health System Compounding Under Section 503A of the FD&C Act*
- FDA's final guidance *Insanitary Conditions at Compounding Facilities*
- Advancement of FDA's effort to develop the list of bulk drug substances that may be used in compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

FDA described in detail the proposed policies in the revised draft guidance on pharmacies compounding in the hospital and health-system setting, including the circumstances under which FDA generally does not intend to take action against a hospital or health system pharmacy that is distributing non-patient-specific compounded drugs or compounding a drug regularly or in inordinate amounts that is essentially a copy of a commercially available drug product. FDA also provided an overview of the June 2021 Pharmacy Compounding Advisory Committee meeting and presented on topics of interest to state pharmacy regulators, including the prohibition on wholesaling under section 503B and the transition of biological products that were approved under the FD&C Act to being licensed under the Public Health Service (PHS) Act and implications for drug compounding.

In a separate session, three states presented updates on their recent legislative and regulatory actions related to drug compounding. Two of the states discussed chapters of the United States Pharmacopeia (USP) that are incorporated into their compounding regulations. These states are considering adopting USP's revised chapters once they are finalized. All agreed that FDA's pause in in-person inspections has not significantly affected the licensing of pharmacies in or by their state. Only one of the presenting states has rules to regulate physician compounding.

Compounding and Oversight during the Public Health Emergency

Following an in-depth pre-conference session on investigations and root cause analysis, the second day of the intergovernmental meeting began with presentations from FDA and NABP on compounding oversight during the ongoing public health emergency. FDA described tools it used during the public health emergency, including remote regulatory assessments, and reiterated FDA's July 10, 2020, announcement of preparations to resume domestic inspections guided by a new COVID-19 Advisory Rating system. FDA also shared information about the May 2021, "Resiliency Roadmap for FDA Inspectional Oversight" (the Roadmap), which describes effects that the pandemic has had on FDA's inspectional activities and plans for returning to standard operations for domestic inspections using a Best-Case Scenario. NABP discussed their resumption of on-site visits, subject to a 10-point checklist based on federal public health emergency guidance. They have also incorporated additional inspection approaches, including increased off-site document reviews, pre-inspection calls, and both announced and unannounced inspections.

Two state boards of pharmacy joined FDA and NABP for a panel discussing how the public health emergency affected their oversight programs, and whether and how they are now resuming normal practices. Both states reported using virtual oversight approaches due to concerns about the risk of travel and conducting inspections in-person, including the use of remote regulatory assessments or document review, as well as using video in some cases. As in-person inspections resume, they reported maintaining certain adjusted approaches such as the continued use of document review in advance to help minimize time in the field. However, states emphasized that remote oversight cannot fully replace live, in-person inspections to best understand a firm's compliance status.

Open Forum Discussion

FDA provided a forum for open discussion between the Agency and the states. During the discussion, we learned that some states have resumed their normal oversight activities, some are beginning to conduct modified inspections, and some are continuing to use virtual/hybrid tools to catch up on simpler inspections and preserve time for more complex inspections.

During the open forum states also raised ongoing desire for training on compounding quality and current good manufacturing practice topics. Only some states were aware of the trainings sponsored by the Compounding Quality Center of Excellence, though the states that have attended trainings found them to be helpful.

States also shared additional views on oversight of physician compounding, the prohibition on wholesaling under section 503B, and proposed revisions to compounding standards published by USP. States also expressed the desire for increased interaction with FDA.

DSCSA Update

FDA also provided an update on the implementation of the Drug Supply Chain Security Act (DSCSA) during 2021 and information about the following draft and final guidances:

- Final Guidance: Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers
- Final Guidance: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification
- Revised Draft Guidance: Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act
- New Draft Guidance: Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act

October 26-27, 2021, Intergovernmental Working Meeting Action Items

- FDA will work with NABP to raise state awareness of available trainings sponsored by FDA's Compounding Quality Center of Excellence. FDA will also explore hosting additional training opportunities specifically targeted to state regulators.

- FDA will continue to work with states and NABP to identify, understand, and enhance pathways for information sharing about adverse events, complaints, and product quality issues related to compounded drugs.

- FDA will explore pathways to facilitate additional dialogue between state regulators of pharmacy and medicine regarding oversight of physician compounding practices.