Summary of Proceedings
October 27-28, 2020, Inter-governmental Working Meeting on Compounding

The U.S. Food and Drug Administration convened its ninth inter-governmental working meeting on drug compounding with state government officials on October 27 and 28, 2020. 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, and was conducted virtually for the first time.

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

Officials from 44 states and the District of Columbia attended the 2020 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 and September 2018 and October 2019. 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.

Compounding and Oversight During COVID-19

FDA and states shared perspectives on compounding oversight during the pandemic. FDA's Office of Regulatory Affairs (ORA) reported it postponed conducting routine foreign and domestic inspections in March of 2020 and resumed mission-critical inspections in July 2020, which have continued. FDA also described an initiative to conduct remote regulatory assessments of outsourcing facilities to help inform the agency's oversight during the pandemic, which includes review of certain records. Finally, FDA provided an overview of temporary policies issued related to compounding during COVID 19, including:

- Compounding of certain alcohol-based hand sanitizer products
- Compounding of certain drugs for hospitalized patients by outsourcing facilities
- Compounding of certain drugs for hospitalized patients by pharmacy compounders not registered as outsourcing facilities
- Non-standard PPE for sterile compounding by pharmacy compounders not registered as outsourcing facilities
- Repackaging or combining propofol drug products

Three state boards of pharmacy described how the pandemic affected their compounding oversight programs. All three states reported moving to a form of virtual oversight due to concerns about the risk of travel and conducting inspections in-person, including use of "desk audits" or document review, as well as using video in some cases, to inform the board's understanding of the compounder's compliance status. Even as states have begun to resume in-person inspections more recently, they reported maintaining certain adjusted approaches, including conducting scheduled versus unannounced inspections, and continued use of document review in advance to help minimize time in the field. Overall, states did not see significant changes in their licensure counts. One state that requires non-

resident compounders to provide evidence of inspection said they accepted inspection reports from other parties such as NABP and, for outsourcing facilities, a third-party quality manufacturing auditor.

Finally, FDA and the states engaged in group discussion about the impacts of the pandemic. States spoke favorably about increases in FDA outreach to states regarding COVID-19-related issues and other compounding policy topics. States expressed interest in continued opportunities for dialogue and timely updates from the agency, such as through FDA participation in NABP executive calls. FDA and states discussed entering into an information sharing agreement (as described under 21 CFR 20.88) and becoming a commissioned official as two good mechanisms for being able to have FDA share information with state officials.

Compounding Quality Center of Excellence

The first day of the intergovernmental meeting concluded with a discussion of FDA's Compounding Quality Center of Excellence (COE), an initiative begun in the fall of 2019 to help improve the quality of compounded drugs, with a focus on outsourcing facilities. FDA provided an update on activities under the center and future plans, including training, outreach and research. In its first year, the center delivered 11 multi-day instructor-led courses for outsourcing facilities on topics related to current good manufacturing practice (CGMP) as well as six self-guided web-based trainings. So far, hundreds of compounding staff and other stakeholders have participated in the trainings. In September 2020, FDA held the Compounding Quality Center of Excellence Virtual Conference: Working Together for Patient Safety with more than 350 participants, to engage outsourcing facilities and other stakeholders on key topics and best practices.

FDA also commissioned a study under the center to better understand barriers and opportunities encountered by outsourcing facilities. The study helped support FDA's understanding of the sector – which is still relatively small and diverse, in terms of business models and product portfolios. The study underscored that CGMP adoption and compliance continue to present challenges for outsourcing facilities, although this is slowly improving. Outsourcing facilities reported desiring more interaction with FDA.

The center will continue to offer its initial set of trainings as well as new courses, conduct additional follow-on research, hold another annual cross-sector conference, explore new lab-based research activities, and expand on engagement activities.

State Legislative and Regulatory Updates

Following an in-depth pre-conference training on cleanrooms and cleanroom behaviors, which is available here at FDA.gov, the second day of the intergovernmental meeting began with a report from three states on legislative and regulatory changes. One state shared its plans for the upcoming 2021 legislative session, including mirroring federal requirements described in section 503A of the Federal Food, Drug and Cosmetic Act and requiring an inspection report for outsourcing facilities that is no older than two years. Another state reported they are considering revising compounding regulations due to updates in U.S. Pharmacopeia chapters on compounding and may incorporate the USP chapters by direct reference. Similarly, a third state is advancing pharmacy compounding rule changes to align with USP chapters, 795, 797, 800 and 825.

FDA-State MOU and NABP Information Sharing System

FDA and NABP provided a joint session on the Standard Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) and NABPs information-sharing system that is being developed to support state reporting under the MOU. FDA began by presenting on the final MOU, which was published in the *Federal Register* on October 27, 2020 and is available for states to consider and sign. FDA reviewed the changes made from prior drafts of the MOU, including refining the definition of "inordinate amount," a threshold for certain information identification and sharing which does not place a limit on the distribution of compounded human drug products interstate by a pharmacy located in a state that has entered into the MOU. The final MOU provides flexibility to states in how they identify pharmacies that may be distributing inordinate amounts and report related information to FDA. FDA announced a one-year period during which the agency does not intend to enforce the 5% statutory limit on distribution out of state for compounders located in states that have not signed the MOU, to allow states additional time to consider signature.

NABP provided an update on development of an information-sharing network, supported by an FDA grant, to improve information available to states and FDA about interstate movement of compounded drugs. The information-sharing network is also intended to assist state boards of pharmacy in their efforts to complete the information collections associated with the MOU, recognizing that many states are faced with resource constraints. The network will allow pharmacies and state boards to enter data and will allow boards to review and annotate data before submission to FDA. Implementation of the network is expected to begin in early 2021. At the end of the three-year grant period, NABP will evaluate the usability of the network and the accuracy of the information collected during the pilot and present a final analysis to FDA.

Following presentations, FDA and states engaged in group discussions where states emphasized the importance of ongoing opportunities for dialogue with FDA as they consider the MOU. States valued the information presented at the intergovernmental meeting and expressed desire for additional information about how data to support reporting under the MOU can best be obtained, including ways in which states can work with NABP and the information sharing system to collect this information. States also asked questions about states that elect to not sign the MOU and potential patient access implications.

Additional FDA Policy Updates

In addition to the MOU discussion, FDA provided an overview of other recent policy updates. The agency first presented on the draft guidance on compounding animal drugs from bulk drug substances, which was published in November of 2019. FDA then presented on the insanitary conditions at compounding facilities draft guidance, FDA policies on the use of bulk drug substances under section 503B of the FD&C Act and FDA evaluation of substances for the 503B bulks list, and compounding hand sanitizers in the wake of methanol contamination incidents.

Perspectives on FDA Form 483s

The inter-governmental meeting closed with a presentation on FDA Form 483s, including information and examples to help facilitate state interpretation of FDA Form 483 observations and insights for states on what FDA looks for in a facility's response to a FDA Form 483. FDA explained the importance of a

facility documenting information regarding the agency's observations, taking immediate steps to correct issues and describing planned actions to further resolve the issues and prevent reoccurrence.

COVID-19 and Fraud

The 2020 intergovernmental meeting began with several sessions related to the COVID-19 public health emergency. During the first session, representatives from FDA and NABP shared an update on activities to address entities marketing fraudulent cures for COVID-19. The Center for Drug Evaluation and Research/Office of Compliance's Fraud Drug Branch described warning letters issued to companies marketing products with fraudulent claim to diagnose, treat, cure or prevent COVID-19. The team described the work of an agency-wide task force to address such products, and ongoing collaboration with other federal partners, such as the Federal Trade Commission, Department of Justice, Customs and Border Patrol and others. NABP described adding 10,000 websites to the NABP Not Recommended list in the past 12 months, noting that numerous types of COVID-19 therapies illegally marketed and sold online, and more than 200,000 COVID-19-related domain names have been created.

Supply Chain Security during COVID-19

FDA also provided an update on a new guidance on exemption and exclusion from certain requirements of the Drug Supply Chain Security Act (DSCSA) during the public health emergency. The guidance clarifies the scope of the existing public health emergency exemption and exclusion under the DSCSA during the public health emergency and describes discretion in the enforcement of authorized trading partner requirements under section 582 of the FD&C Act.

October 27-28, 2020 Inter-governmental Working Meeting Action Items:

1. FDA will seek to provide states more opportunities to interact with the agency on drug compounding matters. As part of this effort, FDA will:
    a. Continue to join monthly executive calls held by the NABP, as possible and appropriate
    b. Explore additional virtual meeting opportunities with state boards of pharmacy to discuss and answer questions on current topics such as the MOU and compounding during the public health emergency
2. FDA will establish methods to share additional information about the MOU with states as they consider signature, including answers to frequently asked questions.
3. FDA will explore providing more training that is useful to state pharmacy regulators, including expert-led trainings on compounding quality and pertinent FDA policies. FDA will also continue to make Compounding Quality Center of Excellence trainings available.