



**Virtual FDA Listening Session on Drug Compounding
for Pharmacy, Consumer, and Industry Organizations
June 22, 2020
2:00PM – 4:00PM**

Statement by the American Pharmacists Association

APhA thanks FDA for holding its annual listening session virtually this year to continue agency efforts to gather stakeholder input on meeting the demand for safe, effective compounded drugs, which is of paramount importance to our members. We commend FDA staff for your tireless efforts to publish timely guidance and information that ensures continued patient access to drug products and mitigates and prevents drug supply disruptions during the pandemic. In particular, we appreciate the increased communication with the Center for Drug Evaluation and Research (CDER) which has allowed APhA to share information about how drug shortages affect pharmacy practice and patient care during the COVID-19 pandemic—particularly drugs at risk of being in short supply in the near future or currently in short supply in the community and hospital settings. Thanks to FDA’s guidances aimed at easing drug shortages, hospital and community compounding pharmacists have more flexibility than ever before in meeting both providers’ and patients’ needs during this public health emergency (PHE). We are also grateful for FDA’s recent use of enforcement discretion for pharmacy compounders who prepare alcohol-based hand sanitizers for consumer use during the COVID-19 PHE.

APhA, founded in 1852, represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. Our Academy of Pharmacy Practice and Management (“APhA-APPM”) Compounding Pharmacy Special Interest Group or “SIG,” consists of more than 5,000 members committed to meeting the individual needs of the patients they serve. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

To assist FDA’s efforts to meet providers’ and patients’ needs for compounded drugs, APhA offers the following comments:

Maintain Compounding Flexibilities Under the PHE to Address Current and Future Drug Shortages

On April 20, 2020 FDA issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under 503A and 503B for hospitalized patients without patient-specific prescriptions to address COVID-19. On May 21, 2020 FDA added morphine

sulfate and epinephrine to the list of drugs¹ covered by the earlier guidance documents² to address shortages and access concerns affecting drugs urgently needed for hospitalized COVID-19 patients. In addition, FDA clarified that medications on the agency's drug shortage list are effectively considered to be "not commercially available," freeing 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. While there has been notable progress against COVID-19, new outbreaks have recently occurred in across the country. Many of our members have told us FDA's compounding flexibility is the only reason hospitals were able to keep up with patient demand. Accordingly, the recent flexibility to compound medications under both sections 503A and 503B are likely to be necessary for the foreseeable future. As this health crisis continues, pharmacies, wholesalers and manufacturers are experiencing or are likely to experience shortages of critical over-the-counter (OTC) products and FDA-approved prescription drugs, including those distributed to hospitals, clinics and doctors to administer to patients in a clinical setting. Compounding pharmacists stand ready to provide needed medications for COVID-19 treatment and drugs in shortage in the U.S. because of this global crisis. As FDA understands, compounding pharmacies can help meet the increased demands for these products to prevent and mitigate shortages. Accordingly, we urge FDA to continue to leverage the flexibility the agency has granted for pharmacists to compound medications in shortage under 503A and 503B for hospitalized patients without patient-specific prescriptions to continue to address COVID-19. FDA should also expand this flexibility to any additional drugs in shortage for all medically necessary conditions. Permitting pharmacists to compound drugs for "office stock," for all drugs in shortage during the pandemic will help ensure our nation's hospitals and other providers have the medications they need without disruption and be able to focus their efforts on patient care.

Conduct an Evaluation that Will Produce Accurate Data for the States, Pharmacy Stakeholders, Patients and the General Public About the True Impact of the Final Memorandum of Understanding (MOU)

On June 5, 2020 APhA submitted joint comments with other pharmacy compounding organizations in response to the FDA's proposed information collection for the Office of Management and Budget (OMB) review on the final MOU.³ FDA assumed that 45 states will sign the final MOU, however, we are not aware that FDA surveyed the individual state boards of pharmacy and other state regulatory agencies that will be impacted by the MOU. Our organizations confirmed that the National Association of Boards of Pharmacy (NABP) is currently in the process of surveying member Boards on the MOU with initial results expected in late-June. At a minimum, our organizations urged OMB to recommend FDA wait to include this data in any reformulated final MOU. The final MOU makes minor changes to the previous draft, increasing to five days from the previously proposed three days states have for reporting adverse events to the FDA. However, if finalized, this requirement would likely result in state boards of

¹ FDA. List of Drugs Used for Hospitalized Patients with COVID-19. Updated May 21, 2020, available at: <https://www.fda.gov/media/138279/download>

² FDA. Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised). Updated May 21, 2020, available at: <https://www.fda.gov/media/137125/download>

³ APhA. Joint Letter to OMB on FDA Information Collection on Final MOU. June 5, 2020, available at: https://www.pharmacist.com/sites/default/files/OMB_JointComment_MOU_June2020.pdf

pharmacy reporting to FDA a number of minor customer service events, rather than actual “adverse events.” For example, when the flavoring of a compounded medication was rejected or a pharmacy compounded 28 ml of a product instead of 30 ml, etc.

FDA also cites the yet-to-be-developed “information sharing network” as an additional improvement to the previous draft, however, without more information about this network, it is unclear if this will have an impact on whether states sign the MOU.

For the reasons mentioned in our joint comments, APhA urged OMB to consider the NABP data to ensure accuracy in estimating the potential impact of a final MOU.

Redraft a Workable Final MOU All States Will Sign

APhA appreciates that the final MOU includes a few recommendations that we made in earlier comments, specifically in relation to the requirements on states (e.g., increasing the reporting threshold from 30% to 50%). However, pharmacies in states that are unable or unwilling to sign the MOU are statutorily prohibited from “distributing” more than five percent of their compounded products interstate. Because FDA has redefined the key term “distribution” to include “dispensing” of compounded drugs, patients who rely on out-of-state pharmacies in states that do not sign the MOU will see their access to compounded medications greatly restricted. Therefore, it’s critical that that FDA accurately assess the true burden of the MOU on each individual state to increase the likelihood that each individual state will sign.

Coordinate with the Centers for Medicare and Medicaid Services (CMS)

APhA understands FDA does not have authority or jurisdiction over reimbursement policy regarding compounded medications. However, FDA regulation and guidance does impact access to compounded medications and increased costs and lack of CMS reimbursement can have significant implications on patients’ access to these necessary medications. To this point, former FDA Commissioner Gottlieb stated “FDA shares the goal of ensuring that American patients have access to quality and affordable care that meets their needs.”⁴ Accordingly, APhA urges FDA to coordinate its regulatory efforts with CMS to ensure compounded products made from bulk substances can be reimbursed by CMS to ensure access and affordability of these necessary medications during the PHE and moving forward.

Address the Omission of Pharmacist and Pharmacy Organizations in the NASEM FDA-commissioned Study “Compounded Topical Pain Creams Review of Select Ingredients for Safety, Effectiveness, and Use”

We appreciate the National Academies of Science, Engineering, and Medicine’s (NASEM) recognition of APhA’s submission of data, resources, context, and perspective that we provided in the recent FDA-commissioned study “Compounded Topical Pain Creams Review of Select

⁴ FDA. Statement from FDA Commissioner Scott Gottlieb, M.D., on the Trump Administration’s plan to lower drug prices. May 11, 2018, available at: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-trump-administrations-plan-lower-drug-prices>

Ingredients for Safety, Effectiveness, and Use.”⁵ We also appreciate the NASEM Committee’s significant efforts in the research and writing that generously contributed to this body of work. However, we want to highlight NASEMS’s noticeable omission of including any pharmacist and/or pharmacy organization in the Recommendations in follow up on this topic, as this directly pertains to the practice of pharmacy. Specifically, “Recommendation 3,” as an “[i]nter-professional organizations that could drive these efforts,” to “[r]evise current educational requirements for compounding pharmacists.”

Compounding is a central activity to the practice of pharmacy, along with the clinical knowledge and skills related to drug therapy management. Pharmacists are taught in pharmacy school how to properly compound medications, along with the extensive clinical training related to the selection and management of drug therapy to optimize therapy outcomes. Pharmacists’ education and practice licensure requirements test pharmacists’ compounding knowledge and skills. For clarification, any revision of the educational requirements for compounding pharmacists will be led from the pharmacy profession, including APhA, the American Association of Colleges of Pharmacy (ACCP), and affiliated organizations.

APhA agrees with the need for additional double-blind, placebo-controlled clinical studies, which can better inform FDA’s position and pharmacy compounding practice on the subject of compounded topical pain creams. We also emphasize that FDA should consider the relative risks of compounded topical pain creams, particularly for patients afflicted with chronic pain, compared to other treatment options, such as narcotics.

APhA thanks FDA for its work with stakeholders to construct a framework to ensure patients have access to safe and effective compounded medications. We look forward to being part of ongoing discussions on this topic and serving as a resource for FDA. If you have any questions or require additional information, please contact Michael Baxter, Senior Director, Regulatory Policy, at mbaxter@aphanet.org.

⁵ National Academies of Sciences, Engineering, and Medicine. 2020. Compounded Topical Pain Creams: Review of Select Ingredients for Safety, Effectiveness, and Use. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25689>