NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPA.ORG

June 7, 2022

Food and Drug Administration
10903 New Hampshire Ave
WO 51, Room 2231
Silver Spring, MD 20993

Submitted via e-mail: navdeep.bhandari@fda.hhs.gov; jacquin.jones@fda.hhs.gov; Compounding@fda.hhs.gov

Re: Statement of Cheri Garvin for FDA Drug Compounding Annual Listening Session on June 17, 2022

Dear Sir or Madam:

Below please find the prepared statement for Cheri Garvin, RPh, Owner and CEO of The Compounding Center in Leesburg, VA, and representing the National Community Pharmacists Association (NCPA) at the FDA Drug Compounding Annual Listening Session on June 17.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA appreciates the opportunity to share our views on various topics during the listening session. NCPA is committed to working with the FDA and other stakeholders on these important matters. If the agency requires further information or has questions, please contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

Statement of Cheri Garvin, RPh
Owner and CEO of The Compounding Center in Leesburg, VA
Representing the National Community Pharmacists Association (NCPA)

Good morning. My name is Cheri Garvin, and I am the owner and CEO of The Compounding Center in Leesburg, VA, representing the National Community Pharmacists Association, or NCPA. NCPA appreciates the opportunity to share our comments and perspectives as we continue to work with FDA on issues in drug compounding.

I will discuss several of our concerns, taken from NCPA's longer statement for the record submitted ahead of this session.

1. Timeline of FDA's PCAC meeting

First, NCPA expresses concern regarding the unreasonably condensed timeline and review process surrounding its June 8, 2022, PCAC meeting. For the PCAC meeting, it is extremely onerous to review the 876-page PCAC packet one week before the list of speakers is due to FDA, and two weeks before nominator slides are due. And NCPA finds it unreasonable that FDA published the PCAC packet only after NCPA sent a letter requesting the release of this information.

NCPA believes that nominators should have at least three weeks from the release of the FDA packet to the due date for speakers, and five weeks from the release of the FDA packet until the due date for slides.

2. Insanitary conditions overreach

Second, NCPA takes issue with FDA's insanitary conditions guidance. In November 2020, FDA issued its final guidance Insanitary Conditions at Compounding Facilities: Guidance for Industry. Unfortunately, FDA failed to respond to most of the comments NCPA provided on November 26, 2018, when the original draft guidance was released. There are still unresolved questions regarding the difference between the guidance and the requirements of USP <797>. Specifically, the encouragement of recalls of possibly contaminated product, adequate coverage of hair and skin when compounding drugs in sterile environments, and terms used by the FDA in the guidance left undefined and vague which makes compliance difficult and burdensome for compounders.

3. Any future MOU

Third, NCPA welcomes FDA's delay of the MOU to October 27, 2022, the suspension of the October 2020 MOU, its plans to establish a new MOU through rulemaking, and its "plans to further extend the period during which FDA does not intend to enforce the statutory 5 percent limit during the rulemaking process."

NCPA hopes that any future MOU will address our previously stated concerns. We hope that states are given sufficient time to assess any conflicts of law, and if they choose to sign, modify existing laws to comply with the MOU. Already, several state boards of pharmacy have raised issues about

the potential conflicts between the old MOU and existing state laws regarding confidentiality of information – which conflicts with the reporting requirements of the old MOU. Some of these states have significant patient populations who use compounded drugs.

We also remain concerned about the consequences of not signing the MOU on patient access to essential compounded medications. In states that choose not to sign, a five percent cap on interstate shipments would be imposed on pharmacies. NCPA is also concerned that patients who rely on compounded medications from pharmacies in states that cannot or do not sign the final MOU deadline will be penalized by disruption of care and inability to receive therapy from their pharmacy of choice.

4. Addressing drug shortages

Fourth, NCPA also urges FDA to continue to dialogue with stakeholders on addressing drug shortages. NCPA recommends that FDA adopt a policy to permit 503A compounding pharmacies to be a tertiary supplier of office stock compounded medications when others are unable to provide medications, as shown by the issues with supply during the Public Health Emergency and recognized by the Agency's 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 Guidance for Industry.

NCPA supports the Patient Access to Urgent-Use Pharmacy Compounding Act (HR 3662), which creates a narrow path for 503A to source shortage drugs (on the FDA or ASHP shortage list) to hospitals and clinics when they cannot be acquired from a manufacturer or 503B.

5. Adverse event reporting

Lastly, NCPA requests that FDA engage stakeholders in addressing the proper role, responsibilities, and repercussions for adverse event reporting.

6. Conclusion

In conclusion, NCPA feels there is a path forward on these issues which can meet the needs of patients and compounding pharmacists while ensuring the safety goals of the FDA. Thank you again for the opportunity to discuss these issues.