Submitted electronically to: www.regulations.gov

August 12, 2024

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Listening Session: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees; Public Meeting; Request for Comments [Docket No. FDA–2024–N–1809]

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA to its docket: *Listening Session: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees; Public Meeting; Request for Comments*.

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 $94 billion healthcare marketplace, employ 230,000 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.

Given that the purpose of the listening session is for FDA to solicit feedback on the Agency's use of and processes for its advisory committee system, NCPA submits these comments regarding FDA's Pharmacy Compounding Advisory Committee (PCAC).

Concerns with June 2022 PCAC Meeting

Timeline to prepare

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

For the June 8, 2022 PCAC meeting, the Federal Register notice of the meeting pre-published on May 5, 2022, and FDA sent an official invitation on May 6, 2022. On May 18, 2022, NCPA sent an e-mail to FDA requesting the briefing packet with meeting analysis, and FDA published this

document at 5:37 PM EST on that day. This meant that stakeholders lost 12 calendar days (from May 6, 2022 through May 18, 2022) in which they could have commented. As nominator slides were due on June 1, 2022, those seeking to comment had only nine business days (from May 18, 2022 through June 1, 2022) to review all material, notify stakeholders and experts in the field, coordinate with all nominators, and generate and submit slides.

Condensed time to speak at meeting

During the June 8, 2022 PCAC meeting, nominators were granted only 10 minutes to speak, which was time shared among all seven nominators. On the other hand, there was no time limit for FDA presentations. When NCPA member A.J. Day exceeded the time limit, the next agenda item (AC questions for nominator) was skipped.

Concerns with November 2017 PCAC Meeting

Timeline to prepare

NCPA also had concerns with the accelerated timeline for submitting materials ahead of the 2017 PCAC meeting. In 2017, PCAC met on November 20-21. The meeting was first announced on October 25, 2017, giving only 3.5 calendar weeks' notice to comment. The meeting had also been scheduled for Monday and Tuesday of Thanksgiving week, with travel required for those participating on Sunday and Wednesday. FDA then released its briefing document on October 30, 2017. As the public comments were due on November 3 to be shared with the Committee, this gave approximately four business days after the materials were available to be able to comment. Slides were due on November 7, only approximately six business days after materials were made available.

Condensed time to speak at meeting

During the November 20-21, 2017 PCAC meeting, a psychiatrist wanted to participate but could not cancel patient appointments during the holiday week. The psychiatrist requested to participate via phone, but FDA denied that request, stating that all participants must be physically at the meeting. The psychiatrist then recorded his video that was incorporated into NCPA member A.J. Day's presentation, but due to the in-person only rule, the psychiatrist was not available to answer questions from the PCAC. Meanwhile, two voting members of PCAC (including the Committee Chair) and 2 FDA staff participated via phone for this meeting, creating a double standard where PCAC and FDA could attend remotely, while others could not.

Conclusion and Recommendations

The process of sending PCAC materials, and the brief review time, impedes compounder and other stakeholder participation in the process and makes it more difficult for nominators to address the breadth of issues raised in FDA's evaluation. For example, the advisory committees are set up such that they don't have to provide these materials very far in advance, and only need to announce the meeting at least 15 calendar days in advance.[1] The accelerated timeline

[1] https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings

employed by FDA is inappropriate to create a robust discussion on the future of the availability of the compounding agents at issue for patient care. While nominators can speak to these agents, it has often been years since the original nominations were submitted. Nominators would therefore appreciate more time to gather the most recent and relevant research. The nominators also need more time to review FDA's lengthy analyses.

In sum, participation in FDA's PCAC process consists of many challenges created by FDA, including: 1) short notification timelines; 2) short timelines to submit nominator slides; 3) denial of remote participation for nominators; and 4) restrictive time for nominators to respond to FDA concerns in formal presentation.

To remedy our concerns, NCPA recommends that:

- **Nominators have at least three calendar weeks from the release of the FDA packet to the due date for nominating speakers.**
- **Nominators have at least two calendar weeks from the due date for nominating speakers to the due date for submitting slides.**
    - NCPA does not understand why slides need to be turned in a calendar week before the meeting, when FDA is already giving nominators a short timeline.
- **Nominators may participate in the PCAC meetings either remotely or in person.**

NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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