Alliance for Pharmacy Compounding

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August 13, 2024

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2024-N-1809

To Whom it May Concern,

Thank you for the opportunity to provide written comments to the Food and Drug Administration subsequent to our participation in the agency's June 13, 2024, listening session on advisory committees.

APC is the voice for pharmacy compounding, representing more than 500 compounding pharmacies and facilities, including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

We are writing to enunciate our concerns regarding the FDA's use of the Pharmacy Compounding Advisory Committee (PCAC) and its processes, as well as the general perception of PCAC.

PCAC is a select group of experts that advises FDA on issues related to pharmacy compounding. It plays a crucial role in determining which substances can be used as active ingredients in human compounded medications by making recommendations for (or against) inclusion on the FDA's list of bulk drug substances that can be used to compound drug products in accordance with Section 503A of the federal Food, Drug, and Cosmetic Act. While the PCAC makes recommendations, the final decision rests with the FDA.

There is a prevalent perception among pharmacists that FDA does not give adequate consideration to the scientific and clinical merits of compounded therapies. Though the agency continually reminds the public about the risks associated with compounded medications, it rarely reinforces the proper and essential role compounded drugs play in our healthcare system and drug supply chain. Moreover, it seems that the FDA is more interested in dissuading PCAC from adding items to the 503A bulks list than urging it to consider the merits of substances that prescribers believe benefit some patients.

For instance, since the inception of the committee, FDA staff has recommended against adding 45 substances to the compounding list. PCAC has voted against the FDA's recommendation six times, each time supporting the use of a chemical when FDA had advised against it. Tranilast, despite PCAC's narrow-use recommendation, was not approved. The FDA opposed Oxitriptan's addition to the list but later issued a guidance document providing enforcement discretion for its use in BH4 deficiency.

Furthermore, the timeline for FDA to act on recommendations following PCAC votes is unclear, exacerbating these concerns. Since February 2015, there have been 11 PCAC meetings with votes cast for 61 nominated substances. However, final decisions on these substances remain pending for extended periods. The FDA issued a final rule in February 2019 and proposed another rule in September 2019. That rule is still awaiting finalization nearly five years later. This leaves 20 items with no proposed rule.

The agency has repeatedly presented the use of Investigational New Drug (IND) applications as an alternative to patient access via compounding, even though IND is not applicable to the 503A or 503B bulk drug nomination and evaluation process. This approach undermines patient access due to the complexities of the IND process that was evident from a presentation given at a PCAC meeting.

Additionally, the FDA's reluctance to accept and formalize PCAC recommendations, as evidenced by the lack of formal notice and comment rulemaking, leaves the impression that the agency has predetermined certain outcomes, rendering the advisory committee process and recommendations merely a formality. This perception is reinforced when the agency has used taxpayer dollars ineffectively in promulgating rules banning the compounding of dosage forms that are not currently being compounded.

Moreover, the FDA's stakeholder engagement practices raise significant concerns:

1. There is often short notice for meetings, leaving stakeholders insufficient time to prepare.
2. Briefing documents – which can be voluminous – are released with little time for stakeholders to examine them, further hindering meaningful participation.
3. Prior to the pandemic, nominators were denied remote participation, unlike FDA staff and advisory committee members who were allowed this flexibility.
4. Severely restrictive time limits are imposed on nominators who wish to offer comments to the committee, while FDA staff presentations face no such limitations.

The compounding expertise represented on the PCAC is another critical issue. The charter filed in April 2014 states that members should include pharmacists with current experience in compounding, yet many appointees lack direct patient-facing compounding experience – a significant perspective almost always lacking in PCAC meetings. Active compounding pharmacists, when nominated, are seldom selected for membership on the committee. We would expect the PCAC to have diverse expertise – including practicing compounders who not only understand the mechanics of compounding but also have firsthand experience with patients.

Among those of us in the profession, this has led to confusion and frustration about the advisory committee's role and the nonbinding nature of its recommendations. In the most recent PCAC meeting, the committee did not deliberate but merely heard the FDA’s extensive explanation of its recommendations, followed by too-brief comments from nominators, and then it voted without substantive discussion. This reduces the process to little more than a beauty contest, rather than a substantive discussion of the merits of a substance under consideration by the committee.

In conclusion, the current process and stakeholder engagement strategies employed by the FDA regarding the PCAC leave much to be desired and need significant improvement. Greater

transparency, timely communication, and genuine consideration of the nominated substances and the advisory committee's recommendations are essential to restore confidence in the FDA's commitment to patient care through compounding.

Thank you for your time and attention to these critical issues.

Sincerely,

Scott Brunner, CAE
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