Alliance for Pharmacy Compounding
Compounding the Joy of Living®

ISSUE BRIEF SEPTEMBER, 2024

FDA's Proposed "Demonstrably Difficult to Compound" rule exceeds its authority and puts essential therapies at risk.

Proposal may set-up framework for future restriction of compounded hormones and other therapies that are used by millions of patients.

Background

The Food, Drug & Cosmetic Act provides authority to FDA to restrict compounding of drugs that are deemed to be "Demonstrably Difficult to Compound (DDC)." DDC drugs are those that may exceed the current capabilities of 503A pharmacies and/or 503B outsourcing facilities.

- **503A pharmacies** are traditional pharmacies that prepare and dispense compounded medications to individual patients based on a valid prescription. They're regulated and inspected by state boards of pharmacy.

- **503B outsourcing** are regulated by the FDA directly. 503Bs must adhere to current good manufacturing practices and are authorized to distribute compounded medications in bulk directly to hospitals or clinics, and in some states to 503A pharmacies, without a prescription.

Federal law requires FDA to have a list of specific DDC *drug products* for 503A pharmacies *and a separate list* of DDC drugs *and categories of drugs* for 503B Outsourcing Facilities.

APC's Concerns

1. ***The FDA has proposed a rule that would allow it to add entire categories of drugs to both the 503A and 503B DDC lists***. The FD&C Act states that the agency is allowed to add drug categories to the 503B DDC list. Only specific drug *products* can be added to the 503A DDC list. By adding categories of drugs to both lists, FDA exceeds its authority and sets up a pathway for restricting entire therapies — say, all compounded hormones or compounded GLP1 drugs — instead of an individual drug product itself. It's a distinction that matters both in law and to millions of patients who benefit from certain categories of compounded medications. FDA has long had its sights on compounded hormones, for instance – drugs that are widely prescribed to millions of patients and which have been safely compounded for a half century or more.

2. ***FDA's proposed rule uses the undefined terms "complex" and "complexity" without linking them***. Federal law requires that a DDC drug have a "reasonable likelihood that such difficulty will lead to an adverse event." Yet FDA does not establish the link between their use of complex/complexity and the potential for an adverse event.

3. ***The FDA is trying to do two things at once***. The proposed rule creates both the criteria for the DDC lists and looks to add three categories of drugs. These should be handled in two separate proposed rules. Notably, the 3 categories of drugs FDA is attempting to add are not being compounded at all to our knowledge.

4. ***FDA has not proposed any mechanism to make changes to the DDC list.*** Technology in compounding continues to evolve and what may be difficult today is not guaranteed to be difficult in the future.

What we're asking

The proposed rule's comment period ended June 18, 2024. APC and many other stakeholders have written to FDA to raise concerns about the agency's proposal and the overreach it represents. As FDA considers how to proceed, we urge members of Congress to reach out to the FDA to express concern and urge the agency to address these issues before releasing a final rule. For convenience, a sample letter accompanies this brief.

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