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Patrizia Cavazzoni, M.D.
Director for Center for Drug Evaluation and Research
Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Draft Guidance - Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act [Docket No. FDA–2023–D–0939]

Director Cavazzoni,

The National Community Pharmacists Association (NCPA) writes today to provide feedback on FDA's draft guidance: *Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

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 $78.5 billion healthcare marketplace, employ 240,000 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.

According to FDA's draft guidance:

> Section 503B(a)(8) of the FD&C Act provides that the prohibition on wholesaling "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)."
>
> FDA interprets this provision to mean that a drug compounded by an outsourcing facility may be eligible for the exemptions in section 503B of the FD&C Act where the drug is distributed directly from an outsourcing facility to a health care facility, such as a hospital or clinic, where the drug is administered to a patient, **or to a State-licensed pharmacy** or Federal facility where the drug is dispensed pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act. [NCPA emphasis]

Access concerns

FDA's policy is likely to create patient access challenges for low volume compounded medications. If outsourcing facilities are selling manufactured-scale compounded products to state-licensed pharmacies, 503A compounders will likely reduce or cease compounding activities. Patients who rely on compounded therapies which may not be suitable for scale production will suffer because without larger volume prescriptions, 503A pharmacies can no longer invest in the quality systems and laboratory to provide the personalized medications for the smaller demand patient populations. This may create unintended consequences where 503As will compound less or may close entirely. This in turn will negatively impact patient access, as more 503As will not be able to provide such compounds to their patients.

There is currently a shortage of 503As doing sterile compounding, particularly in rural and underserved areas. A further decrease in 503A pharmacies performing sterile compounding will further harm patient access. We have a member in Bismarck, North Dakota that is the only 503A left in the state that performs sterile compounding, and his pharmacy also conducts a lot of business for Montana and Minnesota residents. A NCPA member in Jamestown, NY stated that the nearest pharmacy to him that performs sterile compounding is another one of his pharmacies in Erie, PA (60 miles away), followed by one in Buffalo, NY (80 miles away), while there are no sterile compounding pharmacies for hundreds of miles to the east and south.

Safety concerns

NCPA is further concerned about unintended effects to patient safety. In a traditional relationship the pharmacist who oversees the preparation and dispensing of the customized medication will know about the needs of the patient and prescriber. In this new scenario that FDA is creating, the pharmacy is likely ignorant of compounding details, ingredients, and appropriateness.

Pertaining to our safety concerns, NCPA requests that FDA clarify the following under this guidance:

- Does the dispensing label show the pharmacy's information like a traditional commercial product, with the 503B listed as the manufacturer?
    - If a 503B product is sold to a state-licensed pharmacy for further dispensing, the pharmacy would have to treat it as a manufactured product and put the pharmacy's label on it and provide patient counseling. How are pharmacies expected to counsel patients on 503B products?
    - In a traditional compounding environment, the dispensing pharmacy is also the facility that prepared the compound so they have all ingredient information available. Without that direct knowledge, if a state-licensed pharmacy procures products from an outsourcing facility how will the pharmacy know the ingredients and other detailed information about the product to evaluate for patient safety?
- Can a pharmacy repackage a 503B product?
- Can a pharmacy further manipulate a 503B product? Specifically, can that pharmacy:

- Dilute the product?
- Mix the product with other raw ingredients?
- Mix the product with commercial products?

NCPA has long advocated for the ability of 503A pharmacies to be able to compound drugs within the full scope of their license, and supports patient access to those compounded drugs. **NCPA advises FDA to consider our concerns stated above when it chooses to finalize this guidance.**

Conclusion

NCPA is committed to working with 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