ISSUE BRIEF:

Compounders can meet shortage drug needs ongoing

Alliance for Pharmacy Compounding
Formerly IACP

Americans needed help in the pandemic. Compounders have stepped up, with FDA's permission. Now the agency should acknowledge how much more compounders can do … and let them do it.

When Covid-19 began to spread, the country was hit with shortages of hand sanitizer and other over-the-counter drugs, and even critical Covid treatment medications for hospital patients.

Thanks to advocacy by APC and other groups, the FDA issued temporary guidance permitting compounders not only to make and distribute alcohol-based hand sanitizer, but, critically, to fill drug shortage gaps by allowing 503A compounders to provide scarce Covid-19 medications to hospitals under tight guardrails overseen by state boards of pharmacy. (FDA also issued temporary guidance to 503B outsourcing facilities relaxing some cGMP standards on a limited list of Covid treatment drugs.)

That FDA guidance, although only in effect during the current emergency, make several points clear:

- Compounders are ready, willing, and able to step up when called upon.
- There are times, especially during a crisis, when an FDA-approved form of a drug may not be available commercially — but can be compounded.
- By virtue of the temporary guidance documents it has issued, the FDA — finally — recognizes these facts.
- We know of no significant adverse events as a result of FDA allowing compounders to meet patient needs for shortage drugs during the pandemic.

ASK: *APC and the entire pharmacy community want FDA to acknowledge compounders' contributions not just during this emergency, but in the agency's other policy-making — specifically on the MOU on interstate shipments of compounded medications and on office-use compounding. We need FDA to revise those policies to recognize the role 503A compounders have played in this national emergency and can play in future shortages … if not constrained by policies and guidance from the agency that go beyond congressional intent to balance patient safety with patient access to critical medications. Now that we have a track record of safety, FDA should consider the range of safe, effective services compounders can provide as it addresses its compounding policies on MOU/office-use. FDA should expand its thinking to allow compounders to meet public health needs for OTC and prescription meds in shortage under tight regulatory guardrails, even for limited office use by physicians when office use medications can't be sourced from 503Bs.*

CONTACT: APC's David Pore – dpore@hslawmail.com; or Scott Brunner – scott@a4pc.org

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