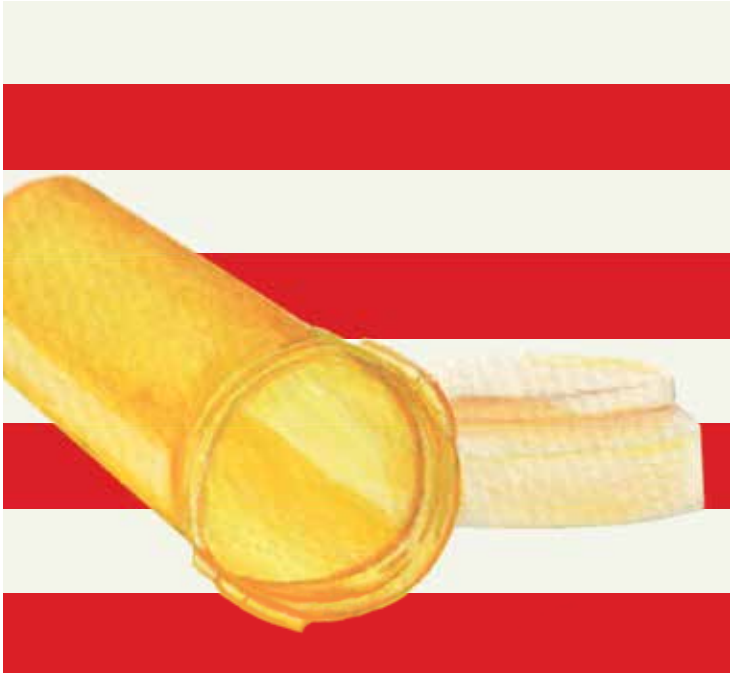

A PERMANENT PATH FOR URGENT-USE COMPOUNDING?

APC-supported Legislation Would Allow 503As to Fill Gaps in Coverage When 503Bs Cannot

Scott Brunner, CAE

If we learned just one thing from the past 18 months, it's that America's healthcare system isn't structured to accommodate the demands put upon it by a global pandemic. In particular, the drug supply chain failed to function in a way that assured that hospitals and clinics had the drugs they needed to treat the most seriously ill COVID-19 patients. During the worst of the pandemic, hospitals found themselves pleading with manufacturers, suppliers, other health systems, the FDA, 503B outsourcing facilities, and compounding pharmacies for medications to keep those COVID patients alive.

In the midst of that crisis, in consultation with the Alliance for Pharmacy Compounding and other industry groups, the FDA promulgated temporary guidance allowing 503A pharmacies to compound COVID medications that were in severe shortage, when those drugs could not be acquired from manufacturers or 503B outsourcing facilities. That temporary guidance includes a number of essential conditions under which 503As can source any of 13 listed COVID drugs to hospitals, including the requirement that the state board of pharmacy explicitly permit them to do so. APC supported it fully and expressed gratitude to the FDA for its flexibility under the circumstances.

Though at this writing that FDA temporary guidance remains in effect, we expect it to be withdrawn soon, as the pandemic subsides. But the problem of drug shortages will surely persist – and it extends well beyond the 13 COVID drugs authorized under that temporary guidance document.

That's why APC has worked with members of Congress to have legislation introduced that will create a permanent path, similar to that in the FDA's 2020 temporary guidance document, for 503A pharmacies to provide urgent-use and shortage drugs to hospitals and physicians.

That bill is HR 3662, the *Patient Access to Urgent-Use Pharmacy Compounding Act of 2021,* sponsored by Rep. Henry Cuellar of Texas and Rep. Morgan Griffith of Virginia. The legislation was introduced in early June and is seeking additional co-sponsors.

Background

By publishing its Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency, the FDA has acknowledged:

1. That urgent patient need should outweigh prescription requirements for 503A compounding, provided that other safeguards are in place.
2. The value of 503A compounding in addressing shortages of critical drug products.

The introduced legislation codifies a policy, largely based on the temporary guidance document, to address both urgent need and drug shortages.

Urgent Need

With respect to urgent need, physician organizations have noted that the requirement to have a patient-specific prescription for an urgent patient need may delay and hamper care. For instance, ophthalmologists require an inventory of anti-bacterial, anti-fungal, and anti-viral compounded medications to treat eye-infections in immediate if not emergent circumstances. Any delay in providing the medication can result in patient harm. Thus, in limited circumstances, it would be appropriate for 503A entities to compound the medications without having a patient-specific prescription, but then later to ensure that the patient information is married with the particular compounded product.

Related to urgent use, HR 3662:

- Waives the patient prescription requirement.
- Requires the prescriber to certify that the prescriber is unable to obtain the drug as an FDA-approved product or from a 503B entity.
- Only allows for compounding of limited quantities of the drug.
- Only allows the compounded drug to go to the prescriber (not directly to the patient).
- Only allows the administration of the drug by a licensed prescriber in a clinical setting.
- Ensures that patient information is later married with the compounded drug information by requiring:
  - The compounder to label the drug to request the patient information (within 7 days of administration or 7 days of patient discharge of each patient involved).
  - That the compounder couple the compounded drug information with the patient information, once received.
  - That the compounded product be labeled with a beyond-use date (BUD) (per the *United States Pharmacopeia*).
- Requires that the compounder and prescriber report adverse events to the FDA.

HOW YOU CAN HELP PUSH HR 3662

HR 3662 was introduced in June by lead sponsors Henry Cuellar (TX) and Morgan Griffith (VA). They're seeking additional cosponsors now. The more cosponsors, the greater the chance the bill will get a hearing in the House Energy & Commerce Committee. Here's how you can help in that process:

1. **Write to your U.S. Representative – email is best. Tell them about the legislation and why it's important to you, and urge them to sign-on as a co-sponsor.**
2. **Invite your member of Congress for a visit to your pharmacy, and discuss HR 3662 with them – as well as other issues impacting your business and patients. APC can help with scheduling and talking points.**
3. **Share this article with the prescribers you work with, and urge them to reach out to their member of Congress to voice support for the bill (and urge the member of Congress to sign on as a sponsor).**

CAMPAIGN TO SAVE COMPOUNDED HORMONES IS UNDERWAY

APC has launched its media campaign to confront the FDA's threat to restrict cBHT. The aim is to collect the stories of patients who have benefited from compounded hormone therapy and share those stories with members of Congress – so that when the FDA moves to restrict cBHT, members of Congress will already be briefed on the benefits of the therapy and poised to push back against the FDA.

To learn more about the campaign, go to compounding.com – that's the central landing page and the place to direct your patients and prescribers, too. It's also where you can make a contribution to support the campaign!

And if you're an APC member, we've provided a full suite of communication and briefing resources you can use in your pharmacy or facility to educate patients about the campaign. You'll find those resources at a4pc.org/cBHTtools.

MORE ONLINE

Read and download HR 3662 at a4pc.org/urgentuse. You'll find talking points there as well.

MORE ONLINE

To learn more about the campaign, go to compounding.com – that's the central landing page and the place to direct your patients and prescribers, too. It's also where you can make a contribution to support the campaign!

Drug Shortages

With respect to drug shortages, the FDA has noted that it was using its enforcement discretion with respect to the "essentially a copy" requirements, provided that certain conditions are met (i.e., those contained in the temporary guidance document). The proposed legislation would codify that flexibility, while also expanding the definition of drug shortage to include not only the FDA's definition of drug shortage but also the American Society of Health-System Pharmacist's (ASHP's) drug shortage list. The ASHP list encompasses local and regional (not just national) shortages. As with urgent need, under certain circumstances the patient-specific requirement would need to be waived, while putting into place additional safeguards.

Related to drug shortages, HR 3662:

- Waives the patient prescription requirement (when necessary).
- Ensures, when the patient prescription requirement is waived, that the patient information is later married with the compounded drug information by requiring:
  - That the compounder label the drug to request the patient information (within 7 days of administration or 7 days of patient discharge of each patient involved).
  - That the compounder couple the compounded drug information with the patient information, once received.
- Requires that the compounded product be labeled with a BUD (per the *USP*).
- Expands the definition of shortage to include drugs listed on the FDA or ASHP lists.
- Requires that the compounder and prescriber report adverse events to the FDA.

You can read and download HR 3662 at a4pc.org/urgentuse. You'll find talking points there as well.

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