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Compounding Pharmacies Are an Unchecked Threat to Americans' Health

BY **LISA DWYER**
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Earlier this month, audiences tuned in to watch HBO's John Oliver call attention to a national health care crisis that has gotten little coverage in the popular press.

Oliver's audience was rightly shocked to learn that compounding pharmacies, companies that purportedly create customized prescription medications, face an extreme lack of regulatory oversight, which puts patients at risk. One such compounder kept a patient's medication on a refrigerator shelf alongside a worker's salad, while another stored an open bin of pills in a bathroom next to the toilet. "I've never been to pharmacy school," Oliver deadpanned, "but I'm pretty sure lesson one is don't put the pills where you poop."

Such bits would be hilarious if they weren't so serious. Compounding pharmacies have already spawned health disasters, and they are likely to spawn more if they remain largely unchecked.

For years, the industry has sought to exploit loopholes in the federal law to mass manufacture and market drugs that have not gone through the Food and Drug Administration's drug approval process — such that the FDA has no idea whether they are safe and effective. This lack of oversight led to a meningitis outbreak in 2012, which killed 64 people and sickened 793 others. The drug that caused the outbreak was compounded by the New England Compounding Center.

In 2013, Congress enacted the Drug Quality and Security Act to provide additional oversight, but this has not been enough. It does not require physicians to inform patients when they are getting a compounded drug, and many patients have no clue that the drug they're taking has not been shown to be safe and effective — or that there may be an FDA-approved alternative. Furthermore, the FDA has outright refused to enforce certain provisions of the DQSA, which has enabled compounding pharmacies to get away with practices that violate the law.

The inadequacy of the DQSA and its implementation is already apparent. In 2018, nearly 68 people were allegedly blinded or visually impaired after a drug containing formaldehyde, which was compounded by Guardian Pharmacy Services, was injected into their eyes. It took months for the federal government to alert the public, and even when it finally did, the pharmacy was not shut down.

In September, the FDA announced that another entity marketing compounded drugs had failed to report over 4,000 adverse events related to testosterone pellets to the agency. Again, it took the FDA months to make that announcement, and even after it did, the entity was not shut down. In Oliver's words, "When oversight is this weak, compounding pharmacies can hurt large numbers of people for a long time."

When done responsibly, compounding can provide necessary therapies to patients whose medical needs cannot be met by commercially available drug products: for example, a lower dose or liquid form of a drug for a child. But Congress and the FDA should do more to ensure that compounding is in fact done responsibly.

At a minimum, the FDA must fully enforce federal compounding laws already in effect. Currently, the agency is not enforcing the so-called "5 percent rule," which prohibits traditional pharmacies from shipping more than 5 percent of their total prescription orders across state lines.

This rule exists because certain states do not have adequate infrastructure to protect Americans from unsafe compounded drugs crossing state lines. The importance of that requirement is underscored by the NECC tragedy, where patients in 20 different states were killed or injured.

In addition, the FDA must also enforce the clinical need rule, which was enacted as part of DQSA in 2013. That rule prohibits outsourcing facilities (special compounders registered with the FDA) from using bulk active ingredients (rather than finished drug products) to compound drugs unless the drugs are necessary to meet a "clinical need," or unless there is a drug shortage.

This rule is intended to significantly limit the type of drugs that outsourcing facilities can compound to drugs that are necessary for patients. That makes sense because drugs compounded by outsourcing facilities are risky: They have not been shown to be safe or effective, and they have not been approved by the FDA.

Rather than enforcing the clinical need rule, the FDA is allowing outsourcing facilities to compound from approximately 250 bulk ingredients that have been nominated for FDA review for "clinical need" — but that have not actually been reviewed. Under the FDA's lax policy, outsourcing facilities can mass manufacture and market drugs containing any combination of those ingredients to the public without any assurance that the drugs are safe or effective. The FDA's refusal to enforce this rule as well as the 5 percent rule will expose a lot of patients to unnecessary risk for a long time.

Congress should do more, as well. Lawmakers should hold an oversight hearing to ensure that patients are adequately protected from unsafe compounded drugs crossing state lines. Lawmakers also should amend the compounding law to ensure that patients receive notice and have an opportunity to give informed consent before they are prescribed riskier compounded drugs, rather than drugs that have been FDA-approved.

The FDA and Congress need to do more to prevent future compounding tragedies. Thank you, John Oliver, for reminding us of that urgency.

Lisa Dwyer was a senior FDA official during the Obama administration, and she is now a partner at King & Spalding LLP and serves as counsel to the Campaign for Responsible Compounding.

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