Joint Statement for the Record

Hearing of the Energy and Commerce Committee,
Subcommittee on Health
on
Examining Implementation of the Compounding Quality Act

January 30, 2018

The undersigned stakeholders from the public health, manufacturing, and outsourcing facility communities, appreciate this opportunity to submit a statement for the record outlining our recommendations on the full implementation and enforcement of the Drug Quality and Security Act (DQSA).

We applaud the Energy and Commerce Committee's (Committee) bipartisan efforts to defend the DQSA and ensure its proper implementation[1], including by holding this hearing. We also commend the Committee's continued work with the Food and Drug Administration (FDA or Agency) as part of those efforts. We too look forward to continuing to work with the agency as it implements the DQSA, including the recently released Compounding Policy Plan and guidances.[2]

As the Committee members know, millions of Americans rely on prescription medicines on a daily basis, and they expect and trust that those drug products will be safe and effective. Some of those Americans rely on receiving compounded medicines, whether it is because they are allergic to a dye in the original drug, because they are unable to swallow pills and need a liquid form, or for any other of the number of reasons that an FDA-approved drug might not meet a patient's medical need. Due to the leadership of this Committee, Congress enacted the DQSA in 2013, in response to a public health crisis associated with compounded drugs, where approximately 76 people died and 778 individuals in 20 states were stricken with meningitis or other infections.[3] The DQSA was intended to ensure that compounded drugs meet appropriate standards to ensure drug quality, and to protect patients. It is imperative that all members of the health care

[1] Such as the House vote against the Carter Amendment, which failed by recorded vote: 141-279.
[2] FDA, "2018 Compounding Policy Priorities Plan" (January 2018); FDA, "Compounded Drugs That Are Essentially Copies of Approved Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (January 2018).; "Compounded Drugs That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (January 2018).; and "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application" (January 2018).
[3] Tennessean. "Meningitis Outbreak Trial: Potentially Deadly Bacteria Found in NECC Drugs" (October 2017). https://www.tennessean.com/story/news/2017/10/12/meningitis-trial-new-england-compounding-center/759459001/

system work together to ensure that patients are protected, and that compounded drugs are made under appropriate quality standards. As Congress provides oversight over the implementation of the law, we recommend that the oversight follow these principles:

Ensure compounding is performed under appropriate standards wherever it occurs[4]

The foundation of the DQSA is a risk-based approach, ensuring that compounding takes place under quality standards appropriate to the level of risk of the drugs being produced. Current federal law, as amended by DQSA, will help prevent another tragedy – but only if compounding is performed in a way that is consistent with the law, and if FDA prioritizes the law's implementation and enforcement.

Regulators should ensure that physicians can acquire compounded drugs produced under the appropriate standards, unless physicians are able to produce drugs under those standards themselves. Similarly, if current Good Manufacturing Practices (cGMPs) are tailored to the needs of smaller-scale producers, any such revision must preserve outsourcing facilities as a reliably safe supply of sterile office stock product.

Ensure that patients who have a clinical need for a compounded drug have access to the highest-quality product

Compounded drugs benefit patients who have a medical need for a particular drug formulation that is not commercially available. It is important that these drugs are produced in full compliance with applicable standards and under conditions that guarantee potency, stability and freedom from contamination.

Encourage the implementation of an effective, robust "Section 503B" program

The DQSA established the outsourcing facility category to ensure hospitals, other health care facilities, physicians, and patients have access to a safe supply of high-quality, sterile drugs. This category provides for the compounding of drugs under rigorous standards different than those that apply to traditional compounders, including adherence to cGMPs. 503B outsourcing facilities can compound without patient-specific prescriptions, strongly differentiating 503B facilities from traditional compounders. This distinction is integral to the DQSA because it incentivizes compounding facilities to register with FDA and ultimately make the investments necessary to bring their facilities into compliance with the standards under Section 503B. DQSA also clearly restricts the use of bulk ingredients for 503B compounding except when truly clinically necessary. This restriction must be enforced by FDA.

Preserve the traditional role of pharmacy practice consistent with the DQSA prescription requirement

A key distinction between Section 503A and Section 503B in the DQSA is the prescription requirement. While Section 503B allows for outsourcing facilities following cGMP standards to provide stock supplies of medications, Section 503A dictates that traditional compounders must obtain individual patient prescriptions to compound and dispense or distribute medications. Although limited quantities can be produced in advance of the receipt of a prescription in the case that a history for such prescriptions exists, a prescription

[4] Such as the enforcement of the MOU provision of Section 503A(b)(3)(B)(i), which establishes an agreement between a State and the FDA regulating the distribution of inordinate amounts of compounded drug products. The MOU provision ensures that there are adequate protections and regulations in place, which makes states responsible for investigating complaints about compounded drugs made in the state and distributed outside of the state. This ensures that compounders shipping compounded drugs interstate are held to robust quality and safety standards. In their recently released "2018 Compounding Policy Priorities Plan", FDA stated that they intend to release a revised version of the current MOU, with language that would increase the amount considered to be "inordinate" from 30 to 50 percent of total drugs distributed interstate, as well as putting a mechanism in place that would require reporting obligations on compounders that distribute more than 50 percent across state lines.

must be received prior to distribution. The foundational aspect of a prescription requirement ensures the traditional practice of pharmacy is maintained, including the accountability of a patient care triad between a patient, a prescriber, and a pharmacist.

Protect the FDA approval process (innovator and generic pathways) by ensuring that commercially available drug products cannot be copied

Another key to protecting patients is safeguarding the FDA approval process for new drugs. Unlike compounded drugs, FDA approved drugs are supported by substantial evidence demonstrating safety and efficacy. To uphold patient safety, Congress sought to ensure that FDA-approved drugs would be used whenever possible, including in the preparation of compounded formulations. Compounders should not use an active pharmaceutical ingredient (API) from a bulk substance that is available through an FDA-approved medication unless doing so would produce a clinical difference for an identified patient. In addition, federal law prohibits the compounding of drugs that are essentially a copy of an FDA-approved medicine, unless FDA has placed that drug on the drug shortage list. It is critical that these provisions be fully implemented and enforced to avoid a disincentive for a drug maker to invest in new drug approvals and in the production of approved versions of drugs. While compounded drugs are an important option when approved drugs cannot meet a patient's clinical needs, only products that have been evaluated and proved through FDA's approval process meet the gold standard for safety and efficacy.

In conclusion, the undersigned organizations[5] believe that enabling FDA to further implement and enforce the DQSA will create a clearer framework for compounded medicines and protect the patients who rely on them. We again thank the Committee's leadership and would like to offer our help in ensuring this bipartisan law is successfully implemented so that the nation's patients are protected.

Association for Accessible Medicines

Biotechnology Innovation Organization

National Association of County & City Health Officials

Pew Charitable Trusts

Pharmaceutical Research and Manufacturers of America

PharMEDium

Trust for America's Health

[5] Some of these organizations have joined together to form the Compounding Quality Coalition.