Committee on Energy and Commerce

Opening Statement
of
Subcommittee on Health Ranking Member Gene Green
January 30, 2018

Examining the Implementation of the Compounding Quality Act

Thank you Mr. Chairman.

In 2012, the interstate distribution of contaminated compounded drug products led to an outbreak of fungal meningitis in 20 states, which tragically resulted in 64 deaths and left more than 750 people with infections that were often severe and caused long term damage.

The New England Compounding Center (NECC), the entity responsible for compounding and shipping the contaminated drugs, had been the subject of prior complaints and had been investigated by both FDA and the Massachusetts state board of pharmacy.

However, in part because of uncertainty over the validity of Section 503A of the Federal Food Drug and Cosmetic Act, it was not clear which "cop" – the FDA or the State – was on the beat and the NECC continued to operate.

Unfortunately, while it was the most fatal incident to date, the NECC outbreak was not a one-off event.

It certainly wasn't the first tragedy and hasn't proven to be the last.

Just late last year, we learned that at least 43 patients were left with diminished vision from a steroid antibiotic injection compounded by a Texas pharmacy.

FDA studies have found quality problems with drugs compounded by other pharmacies, including sub- and super-potent drugs and contamination.

According to one report, from 1990 to 2005, FDA became aware of almost 240 serious illnesses and deaths associated with improperly compounded products, with the actual number likely being greater since pharmacies are not required to report adverse events to the FDA.

Pew Charitable Trusts published a report in 2014 that identified more than 25 reported compounding errors or potential errors linked to more than 1,000 adverse events between 2001 and 2013.

Following the NECC outbreak, Congress finally took action and the Compounding Quality Act (CQA) of the Drug Quality and Security Act (DQSA) was signed into law in 2013.

It sought to protect patients and provide industry with clarity by drawing a distinct line of authority between state boards of pharmacy and the FDA.

CQA made two key changes: re-establishing FDA's role regarding traditional compounding under section 503A and creating a new category of drug compounders deemed "outsourcing facilities" under section 503B.

The NECC outbreak and other adverse events underscored the need to establish a strong legal framework to provide for safe compounded medications that meet patients' needs while clarifying and strengthening oversight of such drugs to protect public health.

There was an obvious need to address the growing number of enterprises that had cropped up during the time of legal uncertainty between the states and FDA.

Many of these enterprises had come to act like drug manufacturers operating outside FDA's standard oversight, often failing to meet current good manufacturing practices and skirting oversight by inappropriately operating under the guise of a 503A pharmacy.

DQSA was not perfect, and like all compromises, not every problem was solved to everyone's satisfaction and not everyone got exactly what they wanted.

During bipartisan, bicameral negotiations, we tried to address as many discrepancies as we could and satisfy the needs of patients, providers, pharmacists and manufacturers.

What was ultimately important is that DQSA fix the problems that led to the deadly fungal meningitis outbreak and require the FDA to succeed where in the past, it had not.

Compounded medications fill an important role in our health care system and offer patients an option when an approved product does not fit their needs.

Patients' ability to timely access safe compounded drugs is vital, and pursuit of this goal is something I believe we all share.

I understand questions remain about office stock, bulks lists, the Memorandum of Understanding and interstate distribution, copies of FDA-approved products, and other issues.

More needs to be done to foster a robust 503B sector, support traditional pharmacists, ensure patient access to needed medications, and inform providers on how they can get the drugs they need when they need them so they can successfully treat their patients.

As the FDA and stakeholders continue to work to implement DQSA, and the Agency, patients, providers and industry continue to learn and adjust, I hope we can work together to refine the rules of the road so patient access isn't unduly diminished and patient safety is upheld.

Thank you and I yield back.