Opening Statement of Chairman Walden
Subcommittee on Health
"Examining Implementation of the Compounding Quality Act."
January 30, 2018

It has been nearly five years since enactment of the Compounding Quality Act as a part of the Drug Quality and Security Act. The signing of that law was set in motion by an unprecedented public health tragedy caused by the egregious actions of a compounding pharmacy in Massachusetts. The New England Compounding Center distributed contaminated drugs across America to be injected into the spines and joints of unsuspecting patients. Over 750 individuals were infected with fungal meningitis, more than 60 lost their lives, and those who were spared continue to suffer the devastating impact to this day. In fact, one of the witnesses we will hear from, Nancy Dargan, has bravely shared the heart wrenching details of her near-death experience and the consequences she and her loved ones continue to bear. While this devastating event was historic in its magnitude, it was not the first time patients had been harmed by improperly compounded products and it wasn't the last.

Following the New England Compounding Center tragedy, this Committee worked to get to the bottom of what went wrong—clearly the system for oversight of compounding had failed to protect public health. The Subcommittee on Oversight and Investigations conducted a thorough examination, and published a report that served as the basis for the policies of the Compounding Quality Act.

While products approved by the FDA as being safe and effective should be relied on in the majority of circumstances, there is an appropriate role for compounded medical products in our health care system. Certain patients have unique medical needs and cannot be treated with available FDA-approved products. Furthermore, as we'll hear from our physician witnesses today, certain medical specialties require the availability of compounded medicines in their offices to provide timely and efficient treatment. In drafting the Compounding Quality Act, this Committee sought to strike the right balance.

Where medications are compounded in advance of a patient specific prescription to be stored for future use, it is vital that they be prepared under heightened standards for safety and

that FDA play a larger role. While it is important to maintain patient access to medications that can be tailored to meet their unique needs, it is just as important that sufficient safeguards are in place to ensure these medications are safe, work as intended, and prepared under sanitary conditions. Pharmaceutical compounding has traditionally been regulated at a state level, but when compounding begins to look more like manufacturing we have learned that patients are at the greatest risk. Over time, even before the 2012 meningitis outbreak, Congress has sought to increase the FDA's oversight where compounding goes beyond patient-specific activity. A prescription written for a patient is what clearly delineates between traditional compounding for an individual's needs, and manufacturing.

While outsourcing facilities are intended to meet health care providers' needs for office-stock compounded products, it is also critical that implementation of the law does not undermine our nation's drug approval framework. The regulatory system for both innovative therapies and generic drug products, reflects an intricate balance, keeping us on the cutting edge of medicine while making more affordable medications available to millions of Americans. It now falls on FDA to uphold the integrity of that system, by making sure that outsourcing facilities do not evade the requirements of the Hatch-Waxman Amendments, and do not undermine the protections in place that drive pharmaceutical research and development.

For FDA to achieve the goals of Congress, FDA must ensure that outsourcing facilities do not compound products that are essentially copies of approved drugs. That includes compounding that consists solely of preparing an approved product for administration as indicated in that product's labeling, or that involves no more than trivial modifications to approved therapies. FDA must also guarantee that bulk drug substances are not used in compounding by outsourcing facilities, until there has been a final determination that there exists a clear clinical need to do so.

I'd like to thank all of our witnesses for being here today, particularly Commissioner Gottlieb, to share your expertise on this important topic. The Energy and Commerce Committee is committed to making sure that patients have access to safe and effective medicines that meet their needs, and this Compounding Quality Act is an important aspect of that goal.