Oral Statement of Gerry Migliaccio
Quality Systems Consultant
Retired Senior Vice President of Global Quality
Pfizer Inc

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Examining Pharmacy Compounding

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I would like to thank Chairman Pitts and Ranking Member Pallone for inviting me to speak today. My name is Gerry Migliaccio. I am a consultant in the area of pharmaceutical quality systems. In 2012, I retired after a 33-year career in pharmaceutical manufacturing and quality operations at Pfizer. For eleven years I served as the head of Pfizer's Global Quality Operations. This experience has provided me with an intimate knowledge of the quality requirements and regulatory framework applicable to manufacturing medicines for the United States public.

Patient safety is the highest priority for pharmaceutical manufacturers. Companies comply with the "gold standard" of quality manufacturing as defined by FDA's current Good Manufacturing Practice (cGMP) regulations

and associated guidance documents. These regulations apply to all prescription drugs approved for sale in the United States, wherever they are made, and extend to all components of a finished drug product including active pharmaceutical ingredients. FDA's regulations are based on the fundamental principle that quality cannot be inspected or tested into a finished product. Quality must be designed into the manufacturing process and product. The regulations also drive manufactures to establish a quality systems approach to assuring consistent quality.

In pharmaceutical manufacturing, quality systems and cGMP requirements begin at the investigational stage. FDA requires that a new drug application (NDA) describe the quality safeguards for the proposed manufacture of a new medicine in the Chemistry, Manufacturing, and Controls (CMC) section of the application. Part of the evidence required by FDA to demonstrate safety and effectiveness is the requirement that a manufacturer provide "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of [a new] drug…."[1]

[1] See 21 U.S.C. 355(b)(1).

The manufacture of medicines – whether by NDA holders or large-scale compounders – involves similar activities and the potential for risk. Large-scale compounding can involve mixing of active and inactive ingredients as well as other chemical and even biological manufacturing steps. Therefore, in order to assure the safety of the American public, the manufacture of medicines, whether by manufactures or pharmacies, should be regulated in a consistent, risk-based manner. Large-scale commercial manufacturing of prescription medicines, whether the producer is designated as a "pharmacy" or as a "manufacturer" should be governed by the same high standards as biopharmaceutical manufacturing, and subject to the same inspection and enforcement actions by FDA.

Moreover, large-scale compounders should be required to prove that they can manufacture medicines consistently and safely by submitting an application to FDA containing a CMC section and submitting to both pre-approval and routine cGMP inspections.

Let me give you a personal perspective on the importance of the cGMP regulations. During my career, I considered the regulatory framework in the US as the blueprint for assuring safety and efficacy. Whether you are a

small start-up company or a large multinational manufacturer, the regulations and guidance documents provide the template for success. From designing quality into a manufacturing process, to the selection of material suppliers, the construction of facilities, selection of equipment, training of employees and final approval to distribute product, the regulations and guidelines provide for a consistent risk-based approach to assure quality. The regulations have also evolved to encourage innovation and continuous improvement and to help support the justification of new technology to further enhance quality assurance.

It is logical to me that any large-scale manufacturer of medicines, including compounders, should comply with these same regulations. A manufacturer in full compliance will have a high degree of assurance that the medicines they product will be of consistent high quality. A large-scale company making thousands of doses of medicines with the name “pharmacy” on its building and another with the name “pharmaceutical company” should be regulated in a similar manner when they perform similar manufacturing steps and present similar risks to patients.

Thank you for your attention.