SUMMARY OF TESTIMONY OF DAVID GAUGH
SENIOR VICE PRESIDENT FOR SCIENCES AND REGULATORY AFFAIRS, GENERIC PHARMACEUTICAL ASSOCIATION
"REFORMING THE DRUG COMPOUNDING REGULATORY FRAMEWORK"
BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH, U.S. HOUSE OF REPRESENTATIVES
JULY 16, 2013

Patient Safety: GPhA supports the goal of clarifying FDA's authority over compounding in order to protect patient safety and prevent another public health crisis.

Traditional Compounding: Traditional compounding plays a vital role for patients, and any new regulation should maintain that role. Pharmacy compounding should adhere to the standard of "one patient, one prescription, one drug."

Good Manufacturing Practices - Sterile Products: The FDA's regulations for pharmaceutical manufacturers are based on the principle that quality cannot be inspected or tested into a finished product, but quality must be designed into the product and manufacturing processes. cGMP regulations establish the regulatory framework in the U.S. as the blueprint for assuring safety and efficacy. The large-scale manufacture of sterile medicines – no matter who performs this function – must involve similar activities as they have similar potential for risk, and should therefore be regulated in a consistent, risk-based manner. All large-scale manufacturers of sterile injectable medicines should be required to prove that they can manufacture these medicines consistently and safely, through documentation to the FDA and submitting to both preapproval and routine risk-based cGMP inspections. A sterile injectable drug should not be the object of compounding, unless these aforementioned regulations and guidances are enforceable by the FDA or if the products are compounded for a specific individual patient, per a physician prescription.

Bulk Drug Substances: GPhA strongly supports establishing standards for the quality of the bulk substances used in compounding.

Drug Shortage Exemption: To solve a drug shortage by lowering safety and quality standards is not in the best interest of the public health. Any drug shortages exemption should also clarify that sterile products on the drug shortage list cannot be compounded indefinitely.

Notification Prior to Compounding: GPhA strongly supports a requirement for large-scale compounding pharmacies and "compounding manufacturers" who plan to compound a marketed drug on the shortage list to notify FDA prior to the start of compounding.

Pre-marketing Registration, Inspections & Fees: GPhA believes that large-scale compounders and "compounding manufacturers" should be subject to pre-marketing inspections by FDA, and FDA should be provided with the resources needed through fees on these large-scale compounders or "compounding manufacturers."

Labeling: In the interest of providing physicians and patients with complete information, any product compounded outside of the institution in which it will be administered should be labeled as a compounded product.

Adverse Event Reporting: Large-scale compounding pharmacies and "compounding manufacturers" should be required to report adverse events to FDA.

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Good afternoon Chairman Pitts, Ranking Member Pallone, and Members of the House Energy and Commerce Subcommittee on Health. Thank you for inviting me to testify before the Subcommittee on the important topic of drug compounding.

I am David Gaugh, Senior Vice President for Sciences and Regulatory Affairs at the Generic Pharmaceutical Association (GPhA) and a licensed pharmacist. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceuticals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 84 percent of all prescriptions dispensed in the United States but account for only 27 percent of the total spending for prescription medicines. According to an analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs has saved U.S. consumers, patients and the health care system more than $1 trillion over the past decade — which equates to $1 billion in savings every other day. The quality and affordability of generic medicines is vital to public health and the sustainability of the health care system.

Prior to joining GPhA, I was Vice President and General Manager for Bedford Laboratories, the generic injectable division of Ben Venue Laboratories and a wholly owned subsidiary of Boehringer Ingelheim. I have also served as Senior Director, Pharmacy Contracting and Marketing, for VHA/Novation, one of the largest Group Purchasing Organizations in the U.S., and was System Director of Pharmacy for a

regional referral tertiary-care healthcare system in the Midwest, where one of my responsibilities was the oversight of traditional compounding performed by my staff.

Patient Safety

GPhA supports the goal of clarifying the FDA's authority over compounding in order to protect patient safety and prevent another public health crisis like the fungal meningitis outbreak caused by substandard and contaminated compounded drugs from the New England Compounding Center (NECC). I appreciate the opportunity to outline GPhA's principles on appropriate regulation of pharmaceutical compounding in order to prevent substandard products from reaching patients.

Traditional Compounding

Traditional compounding plays a vital role for patients, and any new regulation should maintain that role. GPhA firmly believes that pharmacy compounding should adhere to the standard of "one patient, one prescription, one drug." In other words, a pharmacist or compounding pharmacy should engage in compounding in response to a single prescription, written for a single patient, and the patient should receive the prescribed finished product (drug).

A national, uniform set of requirements for compounding is needed to ensure that all patients receive safe compounded drugs. We support clarifying that compounded drugs are subject to the Federal Food, Drug, and Cosmetic Act.

GPhA supports a federal requirement for compounding pharmacies to comply with USP standards for sterile pharmaceutical compounding. More specifically, GPhA supports USP 797, a longstanding practice in sterile pharmaceutical preparation, as a minimum Federal and/or State standard. We believe that all compounding pharmacies and other practitioners who compound sterile preparations, and the sterile products they compound, should fall under this standard.

Additionally, there are certain complex, high-risk products for which patient safety concerns preclude compounding under any circumstances.

Good Manufacturing Practices – Sterile Products

Patient safety is the highest priority for approved pharmaceutical manufacturers. These companies comply with quality and sterile manufacturing processes and procedures as defined by the FDA's current Good Manufacturing Practice (cGMP) regulations and associated guidance documents. These regulations and guidance documents apply to all prescription drugs approved by the FDA for sale in the United States, no matter what country they are manufactured in, and extend to all ingredients (active and inactive) and components of a finished drug product. The FDA's regulations and guidances are based on the fundamental principle that quality cannot be inspected or tested into a finished product, but quality must be designed into the product and manufacturing processes. These regulations and guidances also drive manufacturers to establish a quality systems approach to assuring consistent quality.

In pharmaceutical manufacturing, quality systems and cGMP requirements begin at the product development stage. The FDA requires that a drug application – a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) – describe the quality safeguards for the proposed manufacturer of the product in the application. Part of the evidence required by the 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 manufacturing, processing, and packaging of a drug. As such, ALL manufacturers must be held to these same standards.

The importance of the cGMP regulations is that they establish the regulatory framework in the U.S. as the blueprint for assuring safety and efficacy. Whether you are a small start-up manufacturer or a large multinational manufacturer, the regulations and guidance documents provide the single template for success. From the construction of facilities, to selection of equipment, to training of employees, to designing quality into a manufacturing process, to the selection of materials and suppliers, to the final approval to distribute product, the regulations and guidelines provided by the FDA are the foundation for a consistent risk-based approach to assure quality.

The large-scale manufacture of sterile medicines – no matter who performs this function – must involve similar activities as they have similar potential for risk. These large-scale sterile manufacturing functions involve the mixing of active and inactive ingredients, the finish fill of the product and the packaging of the product. Therefore, in order to assure the safety of the American public, the large-scale manufacture of these sterile

medicines, whether by pharmaceutical manufacturers or compounding pharmacies, should be regulated in a consistent, risk-based manner. As such, consideration for large-scale commercial manufacturing of prescription medicines, whether the producer is designated as a “compounding manufacturer” or as a pharmaceutical manufacturer, must be governed by the same high standards as pharmaceutical manufacturing are held to today. Thereby, all must be held to the same inspection and enforcement actions by the FDA. As such, all large-scale manufacturers of sterile injectable medicines should be required to prove that they can manufacture these medicines consistently and safely by submitting documentation to the FDA and submitting to both preapproval and routine risk-based cGMP inspections.

Based on the framework I have just provided, any large-scale manufacturer of sterile injectable medicines should comply with these same regulations and guidances. A large-scale manufacturer, which is in full compliance, will have a high degree of assurance that the medicines they produce will be of consistently high quality and sterility. A large-scale company making thousands of doses of medicines, whether labeled a “compounding manufacturer” or a pharmaceutical manufacturer should be regulated in a similar manner when it performs similar manufacturing steps and presents similar risks to patients. Therefore, a sterile injectable drug should not be the object of compounding, unless these aforementioned regulations and guidances are enforceable by the FDA or if the products are compounded for a specific individual patient, per a physician prescription, and adhering to the standard of “one patient, one prescription, one drug.”

Bulk Drug Substances

GPhA strongly supports provisions establishing standards for the quality of the bulk substances used in traditional or large-scale compounding. We believe that these standards should also include a requirement that the bulk substances used in compounding be from FDA-inspected, cGMP compliant facilities.

The FDA should inspect and approve bulk substances manufacturing facilities *prior to* the initiation of any compounding activities. A requirement for compounding pharmacies or "compounding manufacturers" to only use bulk substances manufactured by facilities registered with the FDA is an important step in ensuring the quality of the bulk substances used in compounding. The registration requirement itself, however, does not necessarily guarantee a facility has been inspected by the FDA – the inspection requirement for a bulk substances facility is triggered by the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), not by the filing of a Drug Master File (DMF) for the bulk substances facility. Because compounded drugs do not have an NDA or ANDA, a bulk substances facility could be registered with the FDA but not have been inspected. It is important to note that over 80% of bulk materials come from facilities outside the U.S., and the average inspection cycle of the FDA for these facilities is greater than seven years. Therefore, we believe that an additional requirement for the FDA review and approval of bulk substances facilities *prior to* compounding is critical to ensure patient safety.

Drug Shortage Exemption

GPhA recognizes that many in Congress believe that there should be an exception to these requirements for certain medically necessary, sterile products that are in drug shortage.

The generic pharmaceutical industry is committed to working with the FDA and all stakeholders to minimize current shortages and mitigate factors that could contribute to future shortages. While drug shortages represent a complex, multi-faceted issue, we are acutely aware of the distress caused to patients, families and clinicians by the shortage of critical drugs, and our industry has and will continue to work tirelessly to be part of the solution. Nothing is more important to our industry than ensuring patients have access to their lifesaving generic medications.

We believe that the requirements for any new category of large-scale compounding ("compounding manufacturers") should be the same FDA standards that apply to pharmaceutical manufacturers. To solve a drug shortage by lowering safety and quality standards is not in the best interest of the public health. Allowing large-scale compounding of sterile injectable marketed drugs, because they are in drug shortage, with less oversight and regulation than applies to pharmaceutical manufacturers, would undermine the level of safety and quality the FDA requires of current pharmaceutical manufacturers in order to protect the American public.

Applying the same quality and safety requirements that apply to FDA-approved drug manufacturers to large-scale compounders who are currently manufacturing or planning to manufacture the drugs on the drug shortage list would strengthen FDA's ability to protect patient safety. We believe that these quality and safety requirements would prevent bad actors from abusing a new category of "compounding manufacturer" to the detriment of patient safety.

GPhA believes any drug shortages exemption should include explicit language clarifying that a large-scale compounding pharmacy or "compounding manufacturer", which is compounding marketed products due to the product's inclusion on the FDA drug shortage list, cannot compound these products indefinitely. The compounder must immediately stop *both* the compounding and the distribution of these products when the shortage has ended. The FDA should also establish a process to notify the large-scale compounding pharmacies or "compounding manufacturers" of the end of the drug shortage.

We also believe that any drug shortage exemption included in legislation should be restricted to the FDA drug shortage list established under Sec. 506E of FFDCA and posted on the FDA website (www.fda.gov). We do not believe that it should also include regional shortages or private drug shortage lists.

Notification Prior to Compounding

GPhA strongly supports a requirement for large-scale compounding pharmacies or "compounding manufacturers" that plan to compound a marketed drug on the shortage list notify the FDA prior to the start of compounding. We do not believe it is appropriate for large-scale compounders to notify the FDA only after initiating large-scale compounding. Additionally, the FDA should be given the authority to deny the request of a large-scale compounding pharmacy or "compounding manufacturer" to compound a marketed drug on the shortage list, if the FDA believes it is not in the best interest of the public based on prior risk or other risk factors as identified by the Agency.

Pre-marketing Registration, Inspections & Fees

GPhA believes the registration process should also include a requirement for a large-scale compounder or "compounding manufacturer" to notify, and regularly update, the FDA of any sterile products on the shortage list it plans to compound from bulk materials.

We strongly support providing the FDA with the additional resources needed to conduct inspections through fees on large-scale compounders or "compounding manufacturers." These fees should be sufficient for the FDA to conduct effective oversight and to ensure that resources are not diverted from other areas within the Agency.

Labeling

In the interest of providing physicians and patients with complete information, any product compounded outside of the institution in which it will be administered should be appropriately labeled as determined by the FDA and should specifically be identified as a compounded product. Additionally, any admixture/parenteral nutrition product, made with compounded sterile products, should be labeled to the patient level that compounded drugs were used in the formulation of the admixture.

Adverse Event Reporting

GPhA believes a requirement for large-scale compounding pharmacies or "compounding manufacturers" to report adverse events related to compounded products would enhance the FDA's ability to earlier identify and prevent future health crises. Large-scale compounding pharmacies or "compounding manufacturers" should be held to the same adverse event reporting requirements as pharmaceutical manufacturers.

Conclusion

In conclusion, Mr. Chairman, GPhA and our member companies are committed to ensuring both the role of traditional compounding for patients and that the products used by patients are safe. We look forward to continuing to work with this Committee and others as they develop this important legislation. Thank you, and I would be happy to answer any questions you may have.