SAFE ▪ EFFECTIVE ▪ SOLUTIONS
OFA
OUTSOURCING FACILITIES ASSOCIATION
Lee H. Rosebush
Chairman | OFA

Statement for the Record of the Outsourcing Facilities Association
Energy and Commerce Health Subcommittee Hearing
"Examining Implementation of the Compounding Quality Act"
January 30, 2018

The Outsourcing Facility Association (OFA) appreciates the opportunity to provide written testimony for the Energy and Commerce Health Subcommittee hearing titled "Examining Implementation of the Compounding Quality Act." OFA's members are strong supporters of the Compounding Quality Act. With that said, OFA members have concerns related to the Food and Drug Administration's recently released 2018 Compounding Policy Priorities Plan, as well as with current FDA guidance documents related to Outsourcing Facilities and compounding.

About OFA and 503B Outsourcing Facilities

OFA is the trade association representing FDA-registered 503B Outsourcing Facilities whose goal is to provide patients and healthcare providers with high quality and safe compounded medications. OFA members continuously work with patients, healthcare providers, and hospitals on a daily basis to ensure the specific needs and access, of both providers and patients, for compounded medications are satisfied.

FDA oversight of Outsourcing Facilities was authorized by Congress in the wake of the 2012 New England Compounding Center (NECC) scandal, in which 64 people died and hundreds more were harmed by NECC's fungal-contaminated sterile-injectable drugs. Patient advocacy groups, healthcare providers, and the pharmaceutical industry worked with Congress for a year to enact legislation that balanced the safety risks posed by batch compounding with the clear need for these products.

Outsourcing Facilities exist in the space between small pharmacies that compound drug products for individuals (subject to section 503A of the FD&C Act) and large pharmaceutical manufacturers. There are currently more than 70 FDA-Registered Outsourcing Facilities, located in 24 states, and the number is rapidly growing. These businesses must be registered with FDA as Outsourcing Facilities and must comply with all of the requirements of section 503B of the FD&C Act.

OFA's Specific Concerns

OFA supports the FDA's overall implementation and enforcement of the Compounding Quality Act as written and intended by the Congress. However, OFA has four areas of specific concern: 1) the impact FDA's risk-based current good manufacturing practices (cGMP) standards will have on product quality and safety; 2) patient access to 503B compounded medications; 3) FDA's consideration of cost; and 4) the use of bulk drug substance for compounding. These topics are discussed in greater detail below.

SAFE ▪ EFFECTIVE ▪ SOLUTIONS

OFA

OUTSOURCING FACILITIES ASSOCIATION

Lee H. Rosebush
Chairman | OFA

FDA's risk-based cGMP Standards will adversely impact product quality and safety

FDA announced in its 2018 Compounding Policy Priorities Plan that a risk-based approach will be utilized for the applicability of compounding standards, which will essentially allow FDA to permit a new, more flexible cGMP standard for smaller compounders. This policy will result in detrimental effects to current 503B Outsourcing Facilities and would allow a lesser standard of cGMP that would have a negative effect on the quality standards for compounded medications.

Specifically, the 2018 Plan notes that FDA plans to draft proposed regulations on cGMP requirements for Outsourcing Facilities. While OFA applauds FDA for moving forward with regulations, FDA's proposal, in the interim, is to revise the current 503B Outsourcing Facility cGMP draft guidance to describe a new flexible, risk-based approach to cGMP requirements for Outsourcing Facilities based on the size and scope of an Outsourcing Facility's operations. For the FDA to allow a "less rigid" cGMP standard simply because a compounding facility is smaller or produces limited volumes unnecessarily exposes patients to higher-risk compounded medications that could lead to patient injury or illness, the exact area that Congress and FDA sought to prevent after the NECC scandal. For example, "less rigid" cGMP standards might allow an entity to compound without requiring certain testing or meeting other standards, which would put patients at unknown risk for harm, as those drugs may not have undergone testing to ensure they are sterile, potent, and/or stable or be made in proper conditions. This is exactly why and how NECC occurred.

In addition, FDA has stated many times, both in administrative actions such as 483s and Warning Letters and in various public statements and testimony, that the current cGMP Standards are necessary to ensure patient access to quality compounded medications. By allowing a lesser cGMP standard, FDA would be reversing this position that Congress established in the DQSA to address NECC just a few years ago. Accordingly, OFA believes that one consistent cGMP standard should be utilized for 503B Outsourcing Facilities regardless of the volume of drug products compounded by the facility in order to ensure consistent quality of compounded drugs for patients and ultimately assuring patient access.

Patient Access to Compounded Medications

OFA and its members are committed to patient care and ensuring access to compounded drugs. In striving to meet this goal, OFA members work closely with prescribing practitioners and patients to compound drugs that serve the needs of patients and providers. At this time, OFA is not aware of issues limiting access to compounded drugs that are typically produced by Outsourcing Facilities. OFA is committed to an open dialog with FDA and patient advocacy groups about any known patient access issues with specific compounded medications that could otherwise be safely compounded.

FDA's Consideration of Cost

In its 2018 Plan, and recently released draft guidance documents, FDA stated that cost will not be taken into consideration in FDA's determinations relating to whether a compounded drug is an essential copy of an approved drug product. FDA has communicated various reasons for this, including that it seeks to preserve the new drug application and abbreviated new drug application process. Yet, FDA proposes to utilize cost as a consideration as to whether 503B Outsourcing Facilities are meeting patient access concerns. For example, FDA states that cost is one reason why FDA wants to offer flexible cGMP standards to pharmacies that are compounding in limited batches, to encourage them to register as 503B Outsourcing Facilities. Therefore, the question must be asked, why is cost being eliminated as a consideration when 503B Outsourcing Facilities are compared to drug manufacturers, but used as a consideration when comparing 503B Outsourcing Facilities and compounding pharmacies?

Bulk Drug List - Clinical Need Requirement

According to the Compounding Quality Act, 503B Outsourcing Facilities cannot compound with a bulk drug substance unless: 1) the bulk drug substance appears on a list developed by the FDA for which a determination of a clinical need has been made; or, 2) the drug compounded from the bulk drug substance is on the drug shortage list. According to FDA's 2018 Priorities Plan, FDA is still in the process of developing a Clinical Need list applicable to 503B Outsourcing Facilities. OFA, in reviewing the criteria that would possibly permit the FDA to make a determination of a clinical need, believes that the criteria utilized by FDA should actually define a clinical need. In the new drug approval process, FDA already reviews whether there is a clinical need for a drug substance. Specifically, during the new drug approval process FDA reviews the efficacy of a drug substance. Accordingly, FDA would not approve a drug if there was no "clinical need" for the drug. Therefore, OFA advocates that all drug substances used to make products listed in the FDA's Orange Book should be eligible for nomination on the clinical need list, as the FDA has already determined that there is a clinical need for those products. FDA has already determined that these products are both safe and efficacious for a patient to use for a specific disease. Accordingly, every component of a product that is listed in the Orange Book has a clinical need and, therefore, should be included on the clinical need and bulk drug substance list. To the legitimate concern of FDA to protect the new drug application process, the essential copy protection still exists. But the use of a bulk substance to compound, and the essential copy protection, should not be conflated. These are separate areas that must be reviewed accordingly.