May 29, 2014

Jane Axelrad, J.D.
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Ms. Axelrad:

We are writing concerning implementation of the Drug Quality and Security Act ("DQSA", P.L. 113-54) and to request a meeting with you on this issue. As organizations representing physicians who treat patients with a wide array of conditions requiring a wide spectrum of treatments, we have been closely monitoring the development of the pharmacy compounding portion of the legislation. We remain concerned about the law's impact on physician and patient access to critical compounded drug products

Many of our physician members rely on various types of repackaged and compounded medications to treat their patients. Because of this, we are concerned about the ongoing availability of these medications. Over the past year, many of our members have experienced increasing difficulties in accessing both repackaged and compounded drug products, particularly those they order without a patient-specific prescription, or for "office use." Some examples include:

- Cantharidin to treat warts in office by dermatologists
- Buffered lidocaine for use in dermatology procedures
- Antibiotics for urgent and emergent use in treating ophthalmology patients
- Vasoendothelial growth factor inhibitors used in treating age-related macular degeneration by ophthalmologists
- Injection therapies used to treat erectile dysfunction in urology patients

As the Food and Drug Administration (FDA) moves forward with implementation activities, we strongly urge that you consider the compounded drug needs of patients and their providers. In many cases, the use of a compounded drug product is the only option for treatment for the patient. In other cases, a compounded drug product may be the best treatment option for patient. In several situations, a provider must be able to have a compounded drug on hand in order to offer treatment to patients presenting with urgent or emergent conditions for whom treatment delays may be extremely detrimental. In others, not having drugs on hand to treat patients necessitates a second follow-up appointment, which is in many cases very difficult and costly for

both patients (particularly seniors) and providers and not an appropriate way in which to offer treatment.

We are also concerned about the FDA's plans with respect to repackaged drugs. Many physicians across many specialties use drugs that are simply repackaged, and not necessarily altered in any meaningful way outside of altering the dosage size or method of delivery. As the DQSA did not explicitly provide for repackaging by either traditional compounding facilities (section 503A facilities) or the newly created outsourcing facilities (section 503B facilities), physicians and patients must rely on the FDA for issuance of further guidance on this issue. We strongly urge the FDA to allow the new FDA-regulated 503B outsourcing facilities to repackage drug products so that they are available to physicians and patients for office use. As the outsourcing facilities will be required to meet stringent standards for safety and quality and will be subject to FDA inspection and registration requirements, we see no compelling reason to not allow outsourcing facilities to repackage drug products for office use by physicians.

Maintaining access to essential compounded drug products for office use is not only vital for physicians and patients, but also follows the legislative intent of the DQSA, as evidenced by numerous statements made by members of both the U.S. House of Representatives and United States Senate during consideration of the DQSA. The numerous statements made clear that there was no intent on the part of Congress to limit any physician or patient access to compounded drug products. However, early implementation activities by the FDA have physicians and patients extremely concerned about the continued availability of many drugs, in particular those for office use. Several of our groups have received reports from member physicians that access to certain drugs for office use has become limited or impossible. We believe that any implementation action taken to limit or completely impede access to critical compounded treatments goes against the intent of Congress and we urge the FDA to implement the law in such a way that honors the intent in passing the law.

We applaud the FDA for its actions to improve the safety and ensure the quality of compounded drugs products and look forward to assisting in efforts that further these goals. However, we remain concerned about actions that limit access to compounded drug products without increasing the safety profiles of the medications. We look forward to working with you as you continue to implement the legislation and hope to meet with you regarding these issues soon. To schedule a meeting or to further discuss these issues, please contact Shannon Curtis (scurtis@aaodc.org, 202-737-6662).

Sincerely,

Ambulatory Surgery Center Association
American Academy of Dermatology
American Academy of Ophthalmology

American College of Surgeons
American Medical Association
American Society of Retina Specialists
American Society of Cataract and Refractive Surgeons
American Society of Anesthesiologists