July 15, 2016

U.S. Department of Health and Human Services.
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

Submitted electronically:
http://www.regulations.gov

Re: Definition of Compounding Across All FDA Guidance Documents

To Whom It May Concern:

The Spine Intervention Society (SIS), a multi-specialty association of 3,000 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on the Food and Drug Administration's (FDA) draft Guidances for Industry related to compounding of human drugs. SIS wholeheartedly supports the FDA's efforts to formulate policies to ensure the safety of the human drug supply. While the proposed policies are intended to ensure the safety of compounded drugs, we wish to share concerns about unintended consequences of the current definition employed by the FDA.

The Spine Intervention Society believes that the standard practice of drawing aliquots of two sterile medications from single-dose vials into a single sterile syringe for immediate administration to a specific patient does not constitute compounding, but rather falls under the umbrella of administration of sterile medication.

The FDA draft quidances do not specifically define compounding. The FDA's Web site, under the heading, *Compounding and the FDA: Questions and Answers*, defines compounding as, "a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." Compounding is further defined as, "combining of two or more drugs". According to these definitions of compounding, the practice of a physician mixing local anesthetic with a corticosteroid (both from sterile single-dose vials drawn into a single sterile syringe) immediately prior to injection would be included and subject to the requirements under Section 503A of the Federal Food, Drug, and Cosmetic Act. This has significant implications for physicians performing both intraarticular (joint) and neuraxial (spinal) injection procedures. This has been standard practice for physicians for many years, with millions of these procedures performed in the United States each year without complications. SIS feels that this standard practice does not constitute compounding.

Spine Intervention Society
120 East Ogden Avenue, Suite 202
Hinsdale, IL 60521
415.457.4747 phone
415.457.3495 fax
www.spinalinjection.org

US Pharmacopeial (USP) Convention describes compounding as playing a critical role in treating and preventing disease when commercially available medicine is unsuitable. Traditional compounding involves preparing or mixing a drug to benefit a patient with a unique or specific need. USP Chapter 797 is currently being revised and the proposed revision will include discussion of administration of medications. USP indicates that, "This chapter is not intended to address the administration of sterile medications. Administration of sterile medications should be performed in accordance with the Centers of Disease Control and Prevention's (CDC) Safe Injection Practices and the manufacturer's labeling of the sterile medication." The practice of mixing a local anesthetic or saline with a corticosteroid (sterile single-dose vials drawn into a sterile single syringe) immediately prior to injection is in accordance with the CDC's Safe Injection Practices. The package labeling that includes the manufacturer's recommendations for local anesthetics state that standard textbooks should be consulted to determine the accepted procedures and techniques for administration. The practice of combining local anesthetics and corticosteroids has been described in standard textbooks as well as the medical literature for many decades. For example, the manufacturer's recommendations included in the package insert for the corticosteroid Celestone Soluspan states that if the co-administration of a local anesthetic is desired, Celestone Soluspan Injectable Suspension may be mixed with 1% or 2% lidocaine hydrochloride using formulations that do not contain parabens. Similar local anesthetics may also be used.

Again, the Spine Intervention Society wishes to reiterate that the standard practice of drawing aliquots of two sterile medications from single-dose vials into a single sterile syringe for immediate administration to a specific patient does not constitute compounding, but rather falls under the umbrella of administration of sterile medication. As members of the CDC's One & Only Campaign and as a society that has worked closely with both the CDC and the FDA's Safe Use Initiative to define and promote safe injection practices, we share the FDA's commitment to ensuring the safety of spinal injection procedures.

We ask the FDA to further clarify their definition of compounding to exclude these administration practices. We hope that this information, as well as any dialogue and collaboration between the Food and Drug Administration and the Spine Intervention Society, will lead to the establishment of reasonable guidances that promote safe compounding practices without creating new, unnecessary hurdles for physicians and their patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@spinalinjection.org.

Sincerely,

John MacVicar, MB ChB
President
Spine Intervention Society