



Sound Policy. Quality Care.

February 5, 2018

Scott Gottlieb, MD
Commissioner
Food and Drug Administration (FDA)
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements

Dear Dr. Gottlieb,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

The undersigned members of the Alliance appreciate the opportunity to provide feedback to the agency as it works to identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing FDA to achieve its public health mission and fulfill statutory obligations. Specifically, we have concerns about draft and final guidance documents issued by the agency, as well as delayed final rules related to "intended uses," which we discuss in detail below.

Guidances Related to Drug Compounding

Insanitary Conditions at Compounding Facilities

A wide array of specialty physicians, including dermatologic surgeons, Mohs surgeons, plastic surgeons, spine specialists, urologists, and rheumatologists, prepare medicines (e.g., buffered lidocaine, bicarbonate and steroids, and interstitial cystitis instillation mixtures) for use in their offices and for their own patients. However, an August 2016 draft guidance -- "*Insanitary Conditions at Compounding Facilities*" -- sets forth new standards that would require physicians that prepare such medicines in their offices to, among other things, have engineering control devices capable of maintaining an ISO Class 5 environment, to avoid being deemed "insanitary." We appreciate that FDA's recent announced its 2018 Compounding Policy Priorities Plan, which outlines how the agency will implement certain key aspects of the Drug Quality and Security Act (DQSA) and other provisions of the law relevant to compounders, and explained its intent to

issue revised draft guidance describing examples of conditions that the FDA considers to be insanitary and in violation of the Federal Food, Drug and Cosmetic Act (FD&C Act). Specifically, FDA stated that

“This guidance will address concerns raised by some providers who compound small quantities of drugs in their offices for patient use, and as part of their routine clinical practice. This came up in the setting of certain dermatological procedures, for example. The FDA plans to better define the circumstances under which we believe drugs are being mixed and applied in a manner that creates negligible patient risk, and therefore wouldn’t be subject to the same compliance policy under the agency’s risk-based approach to implementing these requirements.”

Specialty physicians have been safely preparing medicines in their offices using the aseptic technique consistent with current medical literature and without adverse event. The FDA and Centers for Disease Control and Prevention (CDC) have yet to produce any scientific evidence to suggest there has been a problem to warrant this level of precaution with respect to physician office preparation of compounded medications. The expense and impracticality of complying with the August 2016 draft guidance, if finalized as written, would prohibit most specialty physician practices from complying.

We believe the FDA can help prevent future problems, such as those associated with the New England Compounding Center (NECC), without imposing a one-size-fits-all approach. ***We look forward to providing input on a revised draft guidance that maintains patient access to important, medically necessary medicines prepared in the physician-office setting.***

Prescription Requirement under Section 503A of the Food, Drug, and Cosmetic Act

Some specialists, including dermatologic surgeons and ophthalmologists, work with compounding pharmacies to develop important therapies for in-office use in quantities appropriate for small physician practices. However, under FDA’s December 2016 guidance -- *“Prescription Requirement under Section 503A of the Food, Drug, and Cosmetic Act”* -- physicians must write individual prescriptions for compounded medications before they can be filled by compounding pharmacies. This creates a significant access to care issue, particularly in emergency situations. While these medications may be filled without a prescription from an outsourcing facility, they do not come in quantities appropriate for small physician practices or in formulas necessary for certain uses (i.e., in ophthalmic solutions or “eye drops” or creams). ***We urge FDA to rescind the final guidance and work with the specialty physician community on a solution that preserves patient access to these important and cost-effective therapies.***

Guidance on Physician-Directed Applications (“Off-Label Use”)

Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices

A February 2014 revised draft guidance -- *“Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices”* -- attempts to clarify existing guidance with respect to FDA’s recommended practices, offering recommendations for manufacturers on best

practices for disseminating scientific and medical journal articles as well as scientific and medical reference texts. The Alliance is concerned that the revision inappropriately restricts specialty physicians' access to scientific information provided by manufacturers on the safe and effective use of medical products (including drugs, devices and biologics).

FDA has long recognized that physicians may use products "off-label," even if manufacturers cannot promote those same uses. However, disseminating truthful, non-misleading scientific information on the medically accepted alternative uses of approved medical products is not viewed as promotional by our organizations, as discussed in our Position Statement on Physician-Directed Applications (also attached).

"To enhance patient care, physicians must have unrestricted access to truthful, non-misleading information about the benefits and risks of all therapies available for treatment, including medically accepted alternative uses of approved prescription drugs, biologics, and/or devices. Manufacturers must be able to provide adequate directions for use of both approved and medically accepted alternative indications of approved medicines and treatments, along with adequate disclosures regarding risks and the limitations of scientific understanding.

Provided there is prominent disclosure that FDA does not approve such use, limitations on communications should only be related to patient risk based on factors including the approval status of the medicine, general medical acceptance of the treatment, and the level of scientific sophistication of the audience."

Following the ruling from *Amarin Pharma, Inc. v. FDA*, where US District Court Judge Engelmayer held that speech promoting the off-label use of Amarin's Vascepa may not form the basis of a prosecution for misbranding, we anticipate FDA will be revising its policies and guidance on off-label promotion. Toward that end, ***we urge the FDA to ensure that access to scientific information from manufacturers on the safe and effective approved and unapproved use of medical products is not disrupted. FDA should reissue a revised draft guidance for comment, to allow for the appropriate distribution of truthful, non-misleading information.***

We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Society of Cataract and Refractive Surgery

American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions