

2016 – 2017 Board of Directors

President

Thomas A. Fleisher, MD, FAAAAI
Bethesda, MD

President-Elect

David B. Peden, MD, MS, FAAAAI
University of North Carolina at Chapel Hill
Chapel Hill, NC

Secretary-Treasurer

Robert A. Wood, MD, FAAAAI
Johns Hopkins University School of
Medicine
Baltimore, MD

Immediate Past-President

Robert F. Lemanske, Jr., MD, FAAAAI
University of Wisconsin School of
Medicine and Public Health
Madison, WI

At-Large Executive Committee Member

Aidan A. Long, MD, FAAAAI
Massachusetts General Hospital
Boston, MA

At-Large Members

Melody C. Carter, MD, FAAAAI
Bethesda, MD

Mariana C. Castells, MD, PhD, FAAAAI
Brigham and Women's Hospital
Boston, MA

Jeffrey G. Demain, MD, FAAAAI
Allergy, Asthma and Immunology Center
of Alaska
Anchorage, AK

James E. Gern, MD, FAAAAI
University of Wisconsin
Madison, WI

Mitchell H. Grayson, MD, FAAAAI
Medical College of Wisconsin
Milwaukee, WI

John M. Kelso, MD, FAAAAI
Scripps Clinic
San Diego, CA

David A. Khan, MD, FAAAAI
University of Texas Southwestern
Medical Center
Dallas, TX

Giselle Mosnaim, MD, MS, FAAAAI
Rush University Medical Center
Chicago, IL

Andrew W. Murphy, MD, FAAAAI
Asthma, Allergy & Sinus Center
West Chester, PA

Kelly D. Stone, MD, PhD, FAAAAI
Bethesda, MD

Kathleen E. Sullivan, MD, PhD, FAAAAI
Children's Hospital of Philadelphia
Philadelphia, PA

Executive Vice President

Thomas B. Casale, MD, FAAAAI

Executive Director

Kay Whalen, MBA, CAE

Associate Executive Director

Bert Slivensky, CAE

November 23, 2016

Vice President-elect Mike Pence
Trump Transition Team
1800 F Street, NW
Washington, DC 20405

Dear Mr. President-Elect Trump and Mr. Vice President-Elect Pence:

We offer our congratulations and express our willingness to provide assistance and feedback as you and your team prepare and launch your term as President of the United States.

The American Academy of Allergy, Asthma & Immunology represents 7,500 physicians and professionals engaged in the provision of evidence-based medicine to patients with allergies, asthma and immunologic disease. We are writing to you out of concern for what we feel may be an imminent regulatory threat to that provision of care, which in some cases is a life-saving treatment.

In 2012, 64 people were killed and more than 750 people were made seriously ill after being given steroid injections that had been manufactured under unsafe conditions by a compounding pharmacy in Framingham, Massachusetts. In light of this tragedy, multiple individuals have faced criminal and civil prosecution, and the US Food and Drug Administration and others have sought to crack down on insufficient compliance with standards to protect patient safety. We applaud these efforts and share an utmost concern for patient safety. The standards that apply have been developed and are currently being rewritten by an independent safety and standards setting organization called the United States Pharmacopeia, a process that will take some time yet to complete.

However, the Food and Drug Administration (FDA) issued a draft guidance in August that provides parameters for safety standards that all compounding facilities would have to meet. Unfortunately, in a serious case of gross overreach of regulatory authority, the FDA is extending its authority over drugs and pharmaceuticals, to the extent that their proposal would limit our member physicians' ability to practice medicine. As alluded to above, the New England Compounding debacle was the result of the failure of the FDA to enforce its own regulations, not from the lack of appropriate regulation. If the FDA's draft guidance is finalized in the next couple of months, as we fear might happen, our allergist/immunologists' offices could be subject to the same clean room

(more)

requirements necessary for commercial compounding pharmaceutical enterprises. Allergist/immunologists could be ordered by state authorities to immediately stop providing allergen immunotherapy to the patients they currently have on active treatment plans with this highly effective therapy. Allergist/immunologists could face the decision to discontinue providing allergen immunotherapy until they develop the capacity to meet commercial pharmacy compounding standards that would require thousands of dollars to comply, or to discontinue this important therapeutic approach permanently.

Allergist/immunologists have been providing allergen immunotherapy, also known as “allergy shots,” for over 100 years, improving the quality of life for millions and saving the lives of those with potentially deadly anaphylactic reactions, such as to stinging insects. We provide this treatment under safety standards established by the United States Pharmacopeia (USP) in 2007, and there is no data to show that this practice, as used to treat millions of patients over many years, has resulted in any serious infections. This bears repeating: there is no data that allergen extract compounding following current USP <797> guidelines has resulted in infectious complications. In fact patients on allergen immunotherapy are at much greater risk of a serious allergic reaction to their immunotherapy than they are to any other medical complication. Each of our patients is tested to identify which specific allergies should be treated, and the patient’s treatment set based on their own individual needs is prepared in an allergist/immunologist’s office. Patients then come to the office to receive immunotherapy at regular intervals based on their own customized treatment schedule, and are carefully followed in regard to their symptoms, overall condition and progress towards disease resolution over the course of treatment.

We recognize and support the importance of patient safety and are committed to treating our patients according to appropriate clinical safety standards. However, the FDA draft guidance treats all settings for compounding as equally and inherently dangerous, whether they are mixing thousands of doses for interstate delivery, or in an allergist/immunologist’s office: for one allergy patient at a time, with the subcutaneous injections administered by nurses, according to existing safety standards.

Should the ill-advised FDA draft guidance be approved, patients currently receiving immunotherapy in allergist/immunologist’s offices may not be able to continue their treatment, and patients newly diagnosed may not be able to start therapy as quickly as necessary for relief of symptoms. Further, if allergist/immunologists have to acquire allergen extracts mixed by commercial compounding pharmacies, it would interfere with the ability to carefully monitor the concentration and safety of the allergens to which we know our patients are allergic, thus putting them at significantly increased risk of an adverse reaction to this treatment – the exact opposite of the intent of the FDA’s draft guidance. Therefore, this vast overreach of regulatory authority not only presents an immediate threat to patient access to care, but also creates a new threat to their safety.

We have made the FDA aware of our concerns, but we fear that this document could be finalized despite this. At its recent meeting, the American Medical Association House of Delegates voted in

(more)

support of our request that the FDA definition of a compounding facility NOT include physician offices. We are certainly not the only specialty potentially impacted if this draft guidance is finalized. The American Medical Association is better able to speak broadly on behalf of the many medical specialties involved.

We are sharing this information to make you aware of this potential threat to patient safety, patient access to care, and physicians' ability to provide the life improving healthcare services we are committed to provide. In regards to the physician's practice of medicine in their own office, as opposed to regulatory oversight of commercial compounding activities, this draft guidance is a serious regulatory overreach by the FDA that has the real potential of negatively impacting patient care. We sincerely hope that the FDA will not finalize the draft guidance, or at least does so with its applicability narrowed appropriately to commercial enterprises rather than invading the practice of medicine.

We thank you for your attention to our patient related concern and request to be allowed to conduct our business without FDA interference in the practice of evidence-based medicine.

Sincerely,

AAAAI Board of Directors