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The Honorable Jerry Moran 521 Dirksen Senate Office Building Washington, DC 20510

The Honorable Tim Scott 104 Hart Senate Office Building Washington DC 20510 The Honorable Chris Murphy 136 Hart Senate Office Building Washington, DC 20510

The Honorable Sherrod Brown 503 Hart Senate Office Building Washington, DC 20510

Re: Concerns regarding S. 701, Allergy Testing Access Act of 2021

Dear Senators Moran, Murphy, Scott, and Brown:

Established in 1943, the American Academy of Allergy, Asthma & Immunology (Academy) is a professional association with over 7,000 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

If S. 701 is enacted, we are concerned that allergy blood testing will be ordered as a *screening test* for allergic disease in the absence of a careful medical history, and that this will lead to untoward patient care outcomes. It is paramount that any allergy testing, whether skin or blood based, is used as a *confirmatory test*, to be interpreted in the context of the patient's complete medical history. More specifically, when allergy blood (allergen specific IgE) tests are used as a screening test, this commonly leads to "overdiagnosis" -- assigning a diagnosis of food and/or inhalant allergy to patients not truly allergic who undergo this testing. Such "false positive" diagnoses will be harmful to these patients, resulting in unnecessary care and lifestyle restrictions. This inappropriate testing will also result in increased healthcare spending.

We do not question the medical equivalence of blood testing and skin testing as confirmatory tests for food and inhalant allergies, and acknowledge that many allergists use blood testing as a confirmatory test for allergies. The key word in this statement is "confirmatory" test. Standalone testing is not the appropriate standard of care for the accurate diagnosis and subsequent treatment of food and inhalant allergies. This is true whether the test is a skin test or a blood test.

Unfortunately, due to the nature of blood testing, we are concerned that health professionals will simply add allergy testing to a panel of other screening tests that were already planned. For some clinicians and patients, the attitude when drawing blood for testing appears to be that it is most efficient to test for a broad range of potential conditions. This approach to ordering laboratory blood tests as a screening tool may make sense with regard to some medical conditions, but this is not the case for the diagnosis of allergic disease.

There are two key steps in clinical practice to establish a diagnosis of allergic disease: it starts with a careful medical history which then sets the stage for choosing appropriate allergy testing. This paradigm is based on an individual's medical history being absolutely essential in directing the tests that are appropriate to perform, as well as in interpreting the test results. Thus, the medical history that takes into account symptoms, environmental and occupational exposures, food history, and age is the critical connection between allergy test results and establishing a diagnosis of allergic disease.

The AAAAI is committed to educating patients about the necessity of making sure food allergy testing is done appropriately. Since 2012, the AAAAI has participated in the Choosing Wisely program of the American Board of Internal Medicine Foundation, identifying patient interventions that may be performed unnecessarily, and providing recommendations to avoid inappropriate use of healthcare resources and the patient harm that might follow. One of these items identified by the AAAAI includes the specific recommendation, Don't perform food IgE testing without a history consistent with potential IgE-mediated food allergy. This recommendation was made to emphasize that the patient's symptom history, as well as time between ingestion and symptom onset, is an important tool for the determining what foods a patient should be tested for, and whether skin or blood testing is appropriate. The recommendation highlights the importance not just of proper education on which foods to avoid, but also to keep patients from avoiding foods unnecessarily. We are concerned that widespread availability of blood testing for allergy without restriction, would lead to overuse and frequent misinterpretation. The diagnosis of allergy is not made with blood or skin tests, but those tests are used to confirm an allergy that is suspected based on careful evaluation by someone specialty trained.

Your consideration of these concerns is appreciated as you consider this legislation. We would be happy to discuss this further if you need additional information or have questions about the use and relative effectiveness of skin testing and blood-based allergy testing.

Sincerely,

Giselle S. Mosnaim, MD, MS, FAAAAI

President, American Academy of Allergy, Asthma & Immunology

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cc: The Honorable Shelley Moore Capito