Asthma and Allergy Foundation of America

July 24, 2025

The Honorable Bill Cassidy, M.D.
Chair, Committee on Health, Education, Labor, and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bernie Sanders
Ranking Member, Committee on Health, Education, Labor, and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

Re: *Amend S. 2292 to Reaffirm the GRAS/E Standard for Clarity and Trust*

Dear Chairman Cassidy and Ranking Member Sanders:

On behalf of the Asthma and Allergy Foundation of America (AAFA), we are writing to express our support for S. 2292 which reauthorizes the Over-the-Counter (OTC) Monograph User Fee Program (OMUFA). AAFA is the leading patient organization for nearly 100 million Americans with asthma and allergies. AAFA is also the oldest asthma and allergy patient organization in the world, committed to saving lives and reducing the burden of disease for people with asthma and allergies through support, advocacy, education and research.

As you consider this important legislation, we urge you to include an amendment to reaffirm the foundational standard that ensures over-the counter (OTC) medicines are Generally Recognized as Safe and Effective (GRAS/E), a principle that is essential to preserving consumer trust, regulatory clarity, and innovations that the people we serve want and need.

Why do we care about this specific policy?
Millions of Americans rely on safe and effective OTC medicines every day as their first line of defense from common self-treatable conditions including pain relief, allergies, digestive health, oral care, and more. OTC medicines save the U.S. healthcare system $167 billion annually by reducing the need for

prescription drugs and minimizing unnecessary visits to the doctor. Public trust in OTC products is rooted in confidence that they meet published, science-based standards – with the GRAS/E framework as the foundation of the OTC monograph system.

Why is this important to consumers?
OTC medicines are intended to be used without a healthcare provider's supervision. The GRAS/E standard ensures OTC products are evaluated under a public process with a science-based model that is uniquely designed for OTC ingredients, purposely different than the prescription drug evaluation model. Unlike the New Drug Application (NDA) process required for prescription drugs, the monograph pathway anchored by GRAS/E gives consumers faster access to new, innovative product formulations of existing, well-known, proven ingredients to help meet their evolving needs without the added costs and delays of the NDA process.

What's the problem?
Since OMUFA was enacted in 2020, there has been growing misalignment between Congress's intent and the U.S. Food and Drug Administration's (FDA) implementation of the law. FDA has indicated it may want NDA-type requirements to finalize standards for unfinished OTC monographs, rather than relying on the established GRAS/E framework based on published studies. As a result, monograph innovation has stalled, which is bad news for patients and consumers. In fact, in the last five years, there has only been one manufacturer-initiated request for a monograph innovation, and it hasn't been issued yet, due in part to the perceived FDA shift away from established GRAS/E principles. This threatens to limit access to affordable self-care and makes everyday health solutions harder to reach – especially for vulnerable populations and underserved communities with limited healthcare options.

Reaffirming GRAS/E is good for public health.
A clear confirmation of the GRAS/E standard would remove uncertainty and ensure FDA, Congress, and industry are aligned. An amendment confirming GRAS/E isn't a rewrite, it's a affirmation that will keep the OTC monograph system operating as Congress always intended. This would strengthen public trust, encourage manufacturers to develop innovative new OTC products on behalf of consumers in your districts, and preserve consistent, science-based

standards that enable additional safe, effective, and affordable self-care options for the communities we all serve.

We support S. 2292 and urge you to add an amendment reaffirming the GRAS/E standard to ensure that patients and consumers continue to have access to – and confidence in – the variety of safe and effective OTC medicines they want, need, and trust.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America