House Committee on Energy and Commerce, Subcommittee on Health
Prepared Testimony of Scott Melville, President and CEO Consumer Healthcare Products Association
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Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

Thank you for the opportunity to provide testimony today on the over-the-counter (OTC) Monograph system and the importance of modernizing regulation to enhance the public health.

My name is Scott Melville and I am the President and CEO of the Consumer Healthcare Products Association (CHPA).

Since 1881, CHPA has served as the industry association representing leading manufacturers and marketers of over-the-counter (OTC) medicines in the United States. CHPA member companies produce the vast majority of OTC medicines in our country and provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and conditions. The availability of self-care treatment options saves money, reduces burdens on the healthcare system, and keeps consumers active and productive. CHPA also shares educational tools and information with partners across the globe to ensure the safe and responsible use of OTC medicines.

Value of OTC Medicines

More and more consumers are taking their health into their own hands, and they are doing this with the help of OTC medicines. For the more than 240 million Americans who use OTC medicines every year, these remedies are a trusted and affordable way to get well, stay well, and feel well.

The availability of OTC medicine provides significant value to the U.S. healthcare system—$102 billion in annual savings relative to alternatives and an important increase in access to medicine. This means that, on average, every dollar spent on OTC medicines results in $6-7 in value for the U.S. healthcare system.

In addition to cost savings relative to alternatives, OTC medicines provide value through significantly expanded access to treatment for the most frequent and common illnesses. The availability of OTC medicines, off-the-shelf, without a prescription, provides symptomatic relief for an estimated 240 million people, 60 million of whom would not seek treatment if OTC medicines were not available. OTC medicines also contribute to increased economic productivity due to less time out of work for physician visits or to care for a sick child.

Commitment to Education and Safety

With more than 100,000 OTC products widely available, the CHPA Educational Foundation is dedicated to helping consumers lead happier, healthier lives through responsible self-care. Through public/private partnerships, national educational campaigns, and media efforts, the foundation educates consumers on how to safely use, store, and dispose of OTC medicines and dietary supplements. Information and materials represent the latest medical and scientific thinking and research and address specific areas where we know consumers need guidance and support.

Up and Away and Out of Sight is an educational program to remind families of the importance of safe medicine storage to prevent young children from getting into medicine. It is led by the Centers for Disease Control and Prevention (CDC) in partnership with the CHPA Educational Foundation, under the umbrella of the PROTECT Initiative.

Know Your Dose educates patients and consumers about safe and effective use of acetaminophen, the most commonly used drug ingredient in the United States. The campaign is organized by the Acetaminophen Awareness Coalition—a group of consumer organizations, health organizations, and healthcare provider organizations, including the CHPA Educational Foundation. The U.S. Food and Drug Administration's Safe Use Initiative and the CDC both serve as coalition advisors. The coalition provides information to consumers as they are making healthcare decisions in pharmacies, health clinics, physician offices, and online.

The foundation's Treat with Care program provides parents and caregivers the information they need to safely treat their children's cough and cold symptoms with pediatric OTC cough and cold medicines. Timed around cold and flu season, "Treat with Care" efforts have included print and radio public service announcements; ads and content in popular parenting media; and posters and brochures for doctors' offices, clinics and pharmacies.

Modernizing the Monograph System

Given the importance of OTC medicines to consumers and our nation's healthcare system, it's essential that the regulatory structure that oversees these medicines is one that is efficient, transparent, and accommodating to innovation. While some OTC medicines are regulated under new drug applications or abbreviated new drug applications, the vast majority of OTC medicines in our homes today are regulated under the OTC Monograph system, which our members strongly support. This system oversees over 300 active ingredients and more than 100,000 products, ranging from antacids to diaper rash creams, from pain relievers to cough and cold products.

The Monograph system has saved time and other resources for the FDA since there is no need to re-review each individual product with established ingredients, already proven safe and effective. For makers of these medicines, it also saves time, resources, and provides for more efficient market access – stimulating competition, thus providing Americans with a wide array of affordable choices and access.

While the OTC Monograph system was created more than 40 years ago, the process is still not complete. Movement on unfinished items has ground to a halt, largely because the system is based on notice and comment rulemaking – a thorough, but time consuming and expensive process, that has slowed across all government agencies and departments in recent years. Change is needed to have a regulatory system that accounts for advances in science, accommodates innovation, permits timely updates to safety information, and creates a workable process for completing unfinished monographs.

CHPA has therefore worked with FDA and Members of Congress to provide recommendations for a modernized Monograph process by which FDA could make scientific determinations for these ingredients through an administrative order process, rather than notice and comment rulemaking, with

necessary due process protections for dispute resolution and issue escalation. This would empower FDA to act quickly when needed to address safety issues or monograph changes, while preserving the existing monograph structure – a structure which does not require unnecessary pre-market review when manufacturers utilize ingredients that have been found to be generally recognized as safe and effective by the FDA.

We want to thank Chairman Burgess, Congressman Latta, Ranking Member Green, Congressman Guthrie, Congresswoman DeGette, Congresswoman Dingell and the entire Committee and its staff for working over many months to craft a discussion draft to bring the OTC Monograph system into the 21st Century.

Striking the Right Balance with User Fees

We understand that this new system, if enacted by Congress, will require more effort on FDA's part, which is why our industry is willing to supplement government resources with a modest user fee program. We believe the fee agreement strikes the right balance and will help to achieve a more nimble regulatory structure for monograph drugs that would be a win win win for consumers, manufacturers, and regulators.

In summary, the draft legislation we are discussing today is incredibly important and will, if enacted, impact the health of nearly every American for decades to come. It is the product of months – and even years -- of consideration and compromise between many stakeholders, including CHPA's manufacturer members. CHPA has some important technical comments on the discussion draft, we look forward to continuing work with members of this committee to finalize the text and support its introduction and consideration by the Congress in the very near future.

Thank you. I look forward to addressing any questions you might have.