CHPA | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

OVER-THE-COUNTER MEDICINES

Modern Regulation

After **more than four decades,** we now have a modern over-the-counter (OTC) Monograph system, the regulatory framework for OTC medicines, to unlock gridlock, spur innovation, and better serve consumers.

OTC Monograph reform **benefits the healthcare system as a whole.**

8 IN 10 ADULTS USE THEM AS A FIRST RESPONSE TO MINOR AILMENTS

OTC medicines provide millions of Americans with **safe, effective, and affordable** therapies to treat, manage, and prevent many common ailments and conditions.

60%

OTC medicines make up **60% of medicines** – an estimated 100,000 products sold in the U.S.

The concept of the OTC Monograph system remains sound **but the way it operated broke down.**

Developed in 1972, the system relied on an **outdated, multi-layered rulemaking process** that led to gridlock.

The FDA **lacked the necessary funding** and staff to keep up with OTC-related work.

OTC MONOGRAPHS WERE BACK-LOGGED AND PRODUCT LABELS COULD **TAKE YEARS TO UPDATE.**

FDA, public health stakeholders, and industry came together with bi-partisan support **to fix what was broken and create a modern regulatory system.**

OVER THE NEXT **5 Years**

WITH INCREASED FUNDING, FDA'S CAPABILITY TO WORK ON OTC MONOGRAPH INGREDIENTS WILL MORE THAN TRIPLE.

ENHANCE FDA EFFICIENCY AND CAPACITY

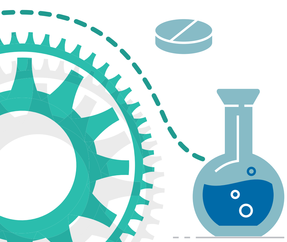
- Provide FDA with significantly **more funding and staff** to support OTC-related work
- Build a critical IT infrastructure to speed reviews and **access to information**

IMPROVE RESPONSIVENESS

- Enable FDA to **quickly address** labeling and safety issues
- Accelerate decisions considerably, while **maintaining high standards**

BOOST INNOVATION

- Create a pathway for **innovation**
- **Support marketplace innovations**, such as new uses for ingredients, dosage forms, and common-sense ingredient combinations



Improving the mechanics of this critical regulatory structure will **increase the efficiency and responsiveness necessary** to protect the public health and ultimately provide Americans with more self-care choices.

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Taking healthcare personally.