OTC Monograph Reform is an essential update to an outdated system. Every day without reform limits the ability of manufacturers and the FDA to deliver affordable, innovative medicines to millions of Americans.

Better for Consumers
$1 Spent = $7 Saved
60% of medicines in the U.S. are sold “over the counter.”
Each dollar spent on these medicines saves more than $7 for the US healthcare system.

Better for Regulators
$130M USG Revenue
FDA stands to gain more than $130 million under proposed reforms to update the OTC regulation, allowing the agency to hire over 100 new staff.

Better for Industry
1972 – 2020
The current OTC system was created in 1972, and lags way behind industry innovations to deliver low-cost health care to Americans who need it.

“When it was first created over 40 years ago, the [OTC] monograph system was relatively efficient, permitting timely monograph development to address safety and effectiveness issues.
As product innovation unfolded, however, the monograph system has not kept up, leaving a system that does not well-serve consumers or industry.”
— Janet Woodcock, M.D.,
Director, Center For Drug Evaluation and Research, Food and Drug Administration
The Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system more than $7, contributing a total of $146 billion in savings each year. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. www.chpa.org

Support for S.2740 ("OTC Monograph Reform")

## Consumer Advocates

### 63 OTC Medicine Manufacturers

Including:

- The Pew Charitable Trusts
- American Academy of Pediatrics
- National Association of City Health Officials
- American Academy of Allergy Asthma & Immunology
- March of Dimes
- NACCHO
- American Public Health Association

## History of Reform

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1972</td>
<td>FDA adopts OTC Monograph System to more efficiently govern over-the-counter drugs.</td>
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<td>2015</td>
<td>Coalition of FDA, industry, and consumer advocates forms to update and modernize Monograph System.</td>
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<td>2018</td>
<td>OTC Drug Monograph Reform (H.R. 5333) passes in the House by voice vote.</td>
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<tr>
<td>2020</td>
<td>Monograph reform signed into law as part of the CARES Act.</td>
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## Mechanics of Reform

- **Streamlined Approval Process**
  - Replaces onerous rulemaking process with administrative orders.
- **Funding For FDA**
  - Requires manufacturers to fund critical staff and infrastructure updates at FDA.
- **Safer and More Transparent**
  - Updates and centralizes labeling requirements.
- **Pro-Innovation**
  - Encourages companies to develop new uses for approved ingredients and easier-to-take medicines.