

S. 2315, the Over-the-Counter (OTC) Drug Safety, Innovation, and Reform Act

OTC Monographs: A Broken System

Americans routinely use over-the-counter (OTC) drugs to treat a wide variety of ailments ranging from headaches to bad breath. Once these products are found safe for use without the supervision of a physician by the Food and Drug Administration (FDA), they are readily available to consumers in their local drugstores or supermarkets. However, the system by which OTC drugs are regulated is outdated, putting consumer health at risk and hindering innovation that can benefit consumers. The Over-the-Counter Drug Safety, Innovation, and Reform Act of 2017 seeks to modernize the system to better serve the American public.

There are two ways a drug can be marketed as a nonprescription product:

1. A prescription drug approved through the New Drug Application (NDA) process can be “switched” to nonprescription status if it is shown safe and effective for use without the guidance of a licensed practitioner.
2. More commonly, a manufacturer can follow the appropriate **OTC drug monograph**. A monograph is a published “recipe” for a category of drugs that lists the active ingredients, dosage form and amount, and mandatory labeling that a manufacturer must follow to legally market a drug without FDA approval.

The OTC monograph system was created to streamline the approval process in 1972 without user fees or review timelines, and it has not been updated since. If a monograph needs to be updated or added, the FDA must go through a formal notice-and-comment rulemaking process, which may take years or even decades to resolve. This delay means that consumers can still access OTC products with unsafe or ineffective ingredients. For example, the monograph for cough and cold products was published in 1976,ⁱ permitting usage in children at least 2 years of age, but used a crude formula to determine dosage for this young population: a quarter of the adult dose. In 2007, after an internal review linked the deaths of 54 children younger than 6 to decongestants between 1969 and 2006, an FDA advisory committee recommended updating the monograph.ⁱⁱ While the manufacturers who are members of the Consumer Healthcare Products Association voluntarily changed their labeling and made other safety changes, the monograph remains unchanged and there is nothing preventing a manufacturer from introducing a product without the updated label – and it would be perfectly legal.

Additionally, the current system is cumbersome for manufacturers who wish to develop innovative products, for example, by adding new ingredients or creating new dosage forms of existing OTC drugs. Consumers want these additional choices and options, and they want to know that those products are safe and effective. Reforming the OTC monograph system will benefit consumers and give FDA the resources it needs to provide effective oversight of these products.

The Over-the-Counter Drug Safety, Innovation, and Reform Act

The FDA, industry and public health stakeholders are in clear consensus that OTC drug regulation reform is long overdue. The **Over-the-Counter Drug Safety, Innovation, and Reform Act**, introduced by Senators Johnny Isakson and Bob Casey, would streamline and modernize the monograph system to protect public health and encourage innovation.

The **Over-the-Counter Drug Safety, Innovation, and Reform Act**:

- Reforms the cumbersome rulemaking monograph process to an administrative order process (the same legal authority used for other medical product approvals).
- Allows the Secretary to take rapid action to protect the public health in the event of safety issues.
- Establishes processes for manufacturers to request administrative orders, or for the Secretary to initiate administrative orders at the recommendation of the FDA or in response to citizens' petitions.
- Establishes a process by which drug developers can request meetings with FDA, similar to existing processes for prescription drug development.
- Creates a new incentive to bring innovative OTC products to consumers, by providing a two-year period of product differentiation to reward innovation.
 - Unlike marketing exclusivity (which is provided to a new chemical entity approved through the NDA process and prohibits marketing of that drug by any other manufacturer for a set period of time), a period of OTC monograph product differentiation applies only to the specific formulation. For example in the case of a new gummi dosage form, only the gummi formulation would have product differentiation; other existing dosage forms (pills, tablets, capsules) would remain options for consumers.
 - New OTC monograph ingredients would receive a period of product differentiation.
 - NDA-to-nonprescription switches do not qualify for product differentiation.
- Conforms to sunscreen regulations to make sure Americans have access to latest protective technology.
- Requires an annual update to Congress on FDA's evaluation of the cold and cough monograph with respect to children under the age of 6.
- Authorizes FDA to collect user fees so that the agency has the necessary resources to evaluate and monitor the OTC market.

This legislation has been endorsed by:

ⁱ Joshua M. Sharfstein, Marisa North, Janet Serwint. *Over the Counter but No Longer Under the Radar – Pediatric Cough and Cold Medicine*. The New England Journal of Medicine. December 6, 2007.

<http://www.nejm.org/doi/full/10.1056/NEJMp0707400>

ⁱⁱ Food and Drug Administration, Division of Drug Risk Evaluation. *Nonprescription Drug Advisory Committee meeting: cold, cough, allergy, bronchodilator, antiasthmatic drug products for over-the-counter human use*. 2007:29. memorandum. <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4323b1-02-FDA.pdf>