

S 2740

Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019

Congress: 116 (2019–2021, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Oct 30, 2019

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Dec 14, 2019)

Official Text: <https://www.congress.gov/bill/116th-congress/senate-bill/2740>

Sponsor

Name: Sen. Isakson, Johnny [R-GA]

Party: Republican • **State:** GA • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		Oct 30, 2019
Sen. Braun, Mike [R-IN]	R · IN		Oct 31, 2019
Sen. Alexander, Lamar [R-TN]	R · TN		Nov 7, 2019
Sen. Murray, Patty [D-WA]	D · WA		Nov 7, 2019
Sen. Sinema, Kyrsten [D-AZ]	D · AZ		Dec 10, 2019

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 14, 2019
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Nov 5, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 HR 748	Related bill	Jul 23, 2020: Committee on Small Business and Entrepreneurship. Hearings held. Hearings printed: S.Hrg. 116-517.
116 HR 19	Related bill	Dec 19, 2019: Referred to the Subcommittee on Antitrust, Commercial, and Administrative Law.
116 HR 3443	Related bill	Jul 24, 2019: Sponsor introductory remarks on measure. (CR E971)
116 HR 269	Related bill	Jan 10, 2019: Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 10.

Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019

This bill makes significant changes to the regulation by the Food and Drug Administration (FDA) of nonprescription (i.e., over-the-counter or OTC) drugs.

The bill establishes a new approval process for OTC medications. Specifically, it creates an FDA administrative order process for the evaluation of OTC products, replacing the present notice and comment rulemaking approach. Under the new process, the FDA may issue an administrative order determining that a specific OTC drug, class of drugs, or combination is generally regarded as safe and effective and not subject to the new drug application process. The FDA may also use the administrative order process to (1) determine that a drug, class of drugs, or combination poses an imminent hazard to the public health; or (2) require labeling changes to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug.

The bill provides for market exclusivity under certain circumstances. For drugs determined to be generally regarded as safe and effective pursuant to an administrative order requested by a sponsor (rather than initiated by the FDA), the requestor is granted 18 months of market exclusivity. This market exclusivity applies to an OTC drug with a new active ingredient or if the requestor conducted new human studies to get approval.

The bill allows a sponsor of a nonprescription sunscreen active ingredient or a combination of such ingredients that was subject to a proposed sunscreen order to transition to the administrative order process. Market exclusivity provisions also apply to new sunscreen active ingredients.

The FDA must establish a user fee program for OTC drugs.

Actions Timeline

- **Dec 14, 2019:** Referred to the Subcommittee on Health.
- **Dec 11, 2019:** Message on Senate action sent to the House.
- **Dec 11, 2019:** Received in the House.
- **Dec 11, 2019:** Referred to the House Committee on Energy and Commerce.
- **Dec 10, 2019:** Passed/agreed to in Senate: Passed Senate without amendment by Yea-Nay Vote. 91 - 2. Record Vote Number: 389.(consideration: CR S6921-6930; text: CR S6921-6930)
- **Dec 10, 2019:** Passed Senate without amendment by Yea-Nay Vote. 91 - 2. Record Vote Number: 389. (consideration: CR S6921-6930; text: CR S6921-6930)
- **Nov 5, 2019:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander without amendment. Without written report.
- **Nov 5, 2019:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 290.
- **Oct 31, 2019:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported without amendment favorably.
- **Oct 30, 2019:** Introduced in Senate
- **Oct 30, 2019:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

LegiList

CONGRESS, MADE CLEAR.

Search Every Federal Bill, Law, and Vote

LegiList is the fastest way to research Congress. Track any bill from introduction to enactment, see how every legislator voted, follow committee activity, and read the full text of every bill — all in one place, always up to date.

legilist.com

Free Course: Learn How Congress Actually Works

LegiList Learn is a free, self-paced course that walks through the entire legislative process — from drafting a bill to a presidential signature. Seven modules, plain language, no politics. Earn a certificate when you finish.

legilist.com/learn

Developer API: Build Apps on Legislative Data

The LegiList API gives developers direct access to bills, votes, legislators, committees, and more. Start free with 1,000 requests per day — no credit card required. Upgrade to Pro when you need to scale.

legilist.com/api

Public data belongs to the public. — legilist.com