

## S 2141

Sunscreen Innovation Act

**Congress:** 113 (2013–2015, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Mar 13, 2014

**Current Status:** Became Public Law No: 113-195.

**Latest Action:** Became Public Law No: 113-195. (Nov 26, 2014)

**Law:** 113-195 (Enacted Nov 26, 2014)

**Official Text:** <https://www.congress.gov/bill/113th-congress/senate-bill/2141>

### Sponsor

**Name:** Sen. Reed, Jack [D-RI]

**Party:** Democratic • **State:** RI • **Chamber:** Senate

### Cosponsors (19 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Isakson, Johnny [R-GA]	R · GA		Mar 13, 2014
Sen. Coons, Christopher A. [D-DE]	D · DE		Apr 7, 2014
Sen. Brown, Sherrod [D-OH]	D · OH		Apr 8, 2014
Sen. Carper, Thomas R. [D-DE]	D · DE		Apr 11, 2014
Sen. Portman, Rob [R-OH]	R · OH		Apr 11, 2014
Sen. Ayotte, Kelly [R-NH]	R · NH		Apr 29, 2014
Sen. Kirk, Mark Steven [R-IL]	R · IL		May 8, 2014
Sen. Roberts, Pat [R-KS]	R · KS		May 8, 2014
Sen. McConnell, Mitch [R-KY]	R · KY		May 21, 2014
Sen. Warren, Elizabeth [D-MA]	D · MA		May 21, 2014
Sen. Landrieu, Mary L. [D-LA]	D · LA		Jun 2, 2014
Sen. Paul, Rand [R-KY]	R · KY		Jun 24, 2014
Sen. Scott, Tim [R-SC]	R · SC		Jul 8, 2014
Sen. Schumer, Charles E. [D-NY]	D · NY		Jul 29, 2014
Sen. Hagan, Kay R. [D-NC]	D · NC		Jul 31, 2014
Sen. Alexander, Lamar [R-TN]	R · TN		Sep 17, 2014
Sen. Booker, Cory A. [D-NJ]	D · NJ		Sep 17, 2014
Sen. Burr, Richard [R-NC]	R · NC		Sep 17, 2014
Sen. Harkin, Tom [D-IA]	D · IA		Sep 17, 2014

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Sep 17, 2014

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
113 HR 4250	Identical bill	Jul 29, 2014: Received in the Senate.

Summary (as of Nov 26, 2014)

(This measure has not been amended since it was reported to the Senate on September 17, 2014. The summary of the Senate passed version is repeated here.)

Sunscreen Innovation Act - (Sec. 2) Amends the Federal Food, Drug, and Cosmetic Act to establish a process for the review and approval of over-the-counter (OTC) sunscreen active ingredients.

Allows any person to request that the Secretary of Health and Human Services (HHS) determine whether an OTC sunscreen active ingredient or combination of ingredients is safe and effective.

Requires the Secretary to review any request regarding a sunscreen active ingredient or combination of ingredients that has been in use and that is not included in the stayed sunscreen monograph published by the Food and Drug Administration (FDA).

Directs the Secretary to invite the sponsor of the request to provide data and other information on the safety and efficacy of the sunscreen active ingredient or combination of ingredients. Requires the Secretary to determine whether the provided information is sufficient to conduct a review, and if so, file the request, and if not, explain to the sponsor why the provided information is insufficient.

Requires the Director of the Center for Drug Evaluation and Research to complete a review of a filed request and determine the safety and efficacy of the sunscreen active ingredient or combination of ingredients within 300 days for new requests or a shorter timeframe for requests pending before enactment of this Act. Directs the Commissioner of Food and Drugs to make the determination if the Director does not make a determination in the allowed timeframe.

Allows sunscreen active ingredients that are determined to be safe and effective to be used in OTC sunscreen products.

Allows the Secretary to amend a determination if additional information becomes available.

(Sec. 3) Allows sponsors of eligible non-sunscreen OTC drug applications to request that the Secretary provide a framework for review of their application. Requires the Secretary to respond with framework options, including options that follow the review process set forth in this Act for sunscreen active ingredients.

(Sec. 4) Directs the Comptroller General (GAO) to report on the progress of the Secretary in establishing this process and the role of the Commissioner of Food and Drugs in issuing determinations on pending requests. Requires the Secretary to report on the decisions made about the safety and efficacy of sunscreen active ingredients, the amount of time between submission and decision for each request, the cost of the review process, and recommended improvements to the review process.

## Actions Timeline

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- **Nov 26, 2014:** Signed by President.
- **Nov 26, 2014:** Became Public Law No: 113-195.
- **Nov 19, 2014:** Presented to President.
- **Nov 13, 2014:** Mr. Latta asked unanimous consent to take from the Speaker's table and consider.
- **Nov 13, 2014:** Considered by unanimous consent. (consideration: CR H7959-7964)
- **Nov 13, 2014:** Passed/agreed to in House: On passage Passed without objection.(text: CR H7959-7964)
- **Nov 13, 2014:** On passage Passed without objection. (text: CR H7959-7964)
- **Nov 13, 2014:** Motion to reconsider laid on the table Agreed to without objection.
- **Sep 18, 2014:** Message on Senate action sent to the House.
- **Sep 18, 2014:** Received in the House.
- **Sep 18, 2014:** Held at the desk.
- **Sep 17, 2014:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Sep 17, 2014:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Harkin with an amendment in the nature of a substitute. Without written report.
- **Sep 17, 2014:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 568.
- **Sep 17, 2014:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.(consideration: CR S5715-5720; text as passed Senate: CR S5715-5720)
- **Sep 17, 2014:** Passed Senate with an amendment by Unanimous Consent. (consideration: CR S5715-5720; text as passed Senate: CR S5715-5720)
- **Mar 13, 2014:** Introduced in Senate
- **Mar 13, 2014:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.