HR 4976

Opioid Review Modernization Act of 2016

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 18, 2016
Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and
Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (May 12, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/4976

Sponsor

Name: Rep. Maloney, Sean Patrick [D-NY-18]
Party: Democratic • **State:** NY • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Apr 18, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Apr 20, 2016
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 12, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 S 524	Related bill	**Jul 22, 2016:** Became Public Law No: 114-198.
114 HR 5189	Related bill	**Jun 7, 2016:** Referred to the Subcommittee on Military Personnel.

Summary (as of May 11, 2016)

(This measure has not been amended since it was introduced. The expanded summary of the House reported version is repeated here.)

Opioid Review Modernization Act of 2016

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to refer new drug applications for opioids (drugs with effects similar to opium, such as certain pain medications) to an advisory committee before approval, unless the FDA finds that such a referral is scientifically unnecessary and not in the interest of protecting and promoting public health and the FDA notifies Congress of its rationale.

The FDA must convene an advisory committee on labeling opioids for pediatric use before approving any such labeling.

(Sec. 3) As part of its evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, the FDA must develop recommendations regarding education programs for prescribers of opioids.
(Sec. 4) The FDA must finalize the draft guidance entitled "General Principals for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products."

Actions Timeline

- **May 12, 2016:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **May 11, 2016:** Mr. Guthrie moved to suspend the rules and pass the bill.
- **May 11, 2016:** Considered under suspension of the rules. (consideration: CR H2254-2256)
- **May 11, 2016:** DEBATE - The House proceeded with forty minutes of debate on H.R. 4976.
- **May 11, 2016:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H2254-2256)
- **May 11, 2016:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H2254-2256)
- **May 11, 2016:** Motion to reconsider laid on the table Agreed to without objection.
- **May 10, 2016:** Reported by the Committee on Energy and Commerce. H. Rept. 114-557.
- **May 10, 2016:** Placed on the Union Calendar, Calendar No. 431.
- **Apr 27, 2016:** Committee Consideration and Mark-up Session Held.
- **Apr 27, 2016:** Ordered to be Reported by Voice Vote.
- **Apr 26, 2016:** Committee Consideration and Mark-up Session Held.
- **Apr 25, 2016:** Committee Consideration and Mark-up Session Held.
- **Apr 20, 2016:** Subcommittee Consideration and Mark-up Session Held.
- **Apr 20, 2016:** Forwarded by Subcommittee to Full Committee by Voice Vote .
- **Apr 18, 2016:** Introduced in House
- **Apr 18, 2016:** Referred to the House Committee on Energy and Commerce.
- **Apr 18, 2016:** Referred to the Subcommittee on Health.