

HR 2547

Surrogate Endpoint Improvement and Utilization Act of 2015

Congress: 114 (2015–2017, Ended)

Chamber: House

Policy Area: Health

Introduced: May 21, 2015

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (May 22, 2015)

Official Text: <https://www.congress.gov/bill/114th-congress/house-bill/2547>

Sponsor

Name: Rep. McMorris Rodgers, Cathy [R-WA-5]

Party: Republican • **State:** WA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 22, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 6	Related bill	Jul 13, 2015: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Surrogate Endpoint Improvement and Utilization Act of 2015

This bill amends the Federal Food, Drug, and Cosmetic Act to allow the sponsor of a drug that is eligible for accelerated approval to request that the Food and Drug Administration (FDA) agree to an accelerated approval development plan that includes a surrogate endpoint for the study of the drug and a magnitude of drug effect that is sufficient to claim the drug is effective. (Accelerated approval is an FDA process for approving a new drug for a serious medical condition at a point in the study of the drug that is reasonably likely to predict a clinical benefit instead of at a later point when a clinical benefit can be confirmed.)

The FDA may require the sponsor to modify or terminate an agreed upon plan if additional information indicates that the plan is no longer sufficient to demonstrate the safety and effectiveness of the drug or the drug is no longer eligible for accelerated approval.

Actions Timeline

- **May 22, 2015:** Referred to the Subcommittee on Health.
- **May 21, 2015:** Introduced in House
- **May 21, 2015:** Referred to the House Committee on Energy and Commerce.