S 1636

Ensuring Innovation Act

Congress: 116 (2019–2021, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 23, 2019
Current Status: Held at the desk.
Latest Action: Held at the desk. (Dec 15, 2020)
Official Text: https://www.congress.gov/bill/116th-congress/senate-bill/1636

Sponsor

Name: Sen. Roberts, Pat [R-KS]
Party: Republican • **State:** KS • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Cassidy, Bill [R-LA]	R · LA		May 23, 2019
Sen. Smith, Tina [D-MN]	D · MN		May 23, 2019

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Discharged From	Dec 15, 2020

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 HR 19	Related bill	**Dec 19, 2019:** Referred to the Subcommittee on Antitrust, Commercial, and Administrative Law.
116 HR 4955	Related bill	**Nov 1, 2019:** Referred to the Subcommittee on Health.
116 S 1895	Related bill	**Jul 8, 2019:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 133.

Summary (as of Dec 14, 2020)

This bill provides statutory authority for the existing Food and Drug Administration (FDA) practice of defining *active ingredient* more narrowly as *active moiety* in certain situations, such as when determining whether a new drug is entitled to a market exclusivity period or providing priority review of drugs for treating rare pediatric diseases.

Generally, the FDA defines *active moiety* as the core molecule or ion in a drug responsible for the relevant physiological or pharmacological action. By contrast, the FDA defines an *active ingredient* as a component in a drug that is intended to furnish pharmacological activity or other direct effect. The FDA's existing practice of interpreting *active ingredient* as *active moiety* in certain situations, as statutorily authorized by this bill, tends to exclude some drugs from market exclusivity.

The bill replaces references to *active ingredient* with *active moiety* in various statutes authorizing FDA activities.

Actions Timeline

- **Dec 15, 2020:** Message on Senate action sent to the House.
- **Dec 15, 2020:** Received in the House.
- **Dec 15, 2020:** Held at the desk.
- **Dec 14, 2020:** Senate Committee on Health, Education, Labor, and Pensions discharged by Unanimous Consent.
- **Dec 14, 2020:** Measure laid before Senate by unanimous consent. (consideration: CR S7470)
- **Dec 14, 2020:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.(text of amendment in the nature of a substitute: CR S7470)
- **Dec 14, 2020:** Passed Senate with an amendment by Unanimous Consent. (text of amendment in the nature of a substitute: CR S7470)
- **May 23, 2019:** Introduced in Senate
- **May 23, 2019:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.