HR 4955

Protecting Access to Safe and Effective Medicines Act of 2019

Congress: 116 (2019–2021, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 31, 2019
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Nov 1, 2019)
Official Text: https://www.congress.gov/bill/116th-congress/house-bill/4955

Sponsor

Name: Rep. Engel, Eliot L. [D-NY-16]
Party: Democratic • **State:** NY • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Guthrie, Brett [R-KY-2]	R · KY		Oct 31, 2019
Rep. Hudson, Richard [R-NC-8]	R · NC		Oct 31, 2019
Rep. Schrader, Kurt [D-OR-5]	D · OR		Oct 31, 2019

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Nov 1, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 S 1636	Related bill	**Dec 15, 2020:** Held at the desk.
116 HR 19	Related bill	**Dec 19, 2019:** Referred to the Subcommittee on Antitrust, Commercial, and Administrative Law.
116 S 1895	Related bill	**Jul 8, 2019:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 133.

Summary (as of Oct 31, 2019)

Protecting Access to Safe and Effective Medicines Act of 2019

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

- **Nov 1, 2019:** Referred to the Subcommittee on Health.
- **Oct 31, 2019:** Introduced in House
- **Oct 31, 2019:** Referred to the House Committee on Energy and Commerce.