S 822

Scientific EXPERT Act of 2025

Congress: 119 (2025–2027, Current)
Chamber: Senate
Policy Area: Health
Introduced: Mar 3, 2025
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 3, 2025)
Official Text: https://www.congress.gov/bill/119th-congress/senate-bill/822

Sponsor

Name: Sen. Klobuchar, Amy [D-MN]
Party: Democratic • **State:** MN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Wicker, Roger F. [R-MS]	R · MS		Mar 3, 2025

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 3, 2025

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
119 HR 1532	Related bill	**Feb 24, 2025:** Referred to the House Committee on Energy and Commerce.

Summary (as of Mar 3, 2025)

Scientific External Process for Educated Review of Therapeutics Act of 2025 or the Scientific EXPERT Act of 2025

This bill requires the Food and Drug Administration (FDA) to facilitate and participate in externally led, science-focused drug development meetings to discuss the development of treatments for rare diseases and conditions.

The FDA must enter into an arrangement with the Reagan-Udall Foundation for the FDA under which the foundation agrees to convene such meetings. Meetings must be held at least four times a year, and each meeting must focus on a different rare disease or condition.

The foundation must establish a permanent steering committee to review and recommend topics for each meeting. In evaluating potential topics, the committee must consider unmet therapeutic needs, patient population sizes for different diseases and conditions, and whether a disease or condition would benefit from clarity and alignment on drug development questions, among other factors.

In planning each meeting, the foundation must develop a list of medical experts, drug sponsors, scientific organizations, patient organizations, and other entities to be invited to participate. Representatives of the FDA's review divisions must attend each meeting.

After each meeting, the foundation must make available a summary of the meeting noting areas of consensus, areas where additional clarification or information is needed, and next steps agreed upon with the FDA.

The bill also requires the FDA to indicate whether it incorporated any input from these meetings when approving a new drug or biologic.

Actions Timeline

- **Mar 3, 2025:** Introduced in Senate
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