S 1508

A bill to provide for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.

Congress: 117 (2021–2023, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 29, 2021
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. (Apr 29, 2021)
Official Text: https://www.congress.gov/bill/117th-congress/senate-bill/1508

Sponsor

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

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Cassidy, Bill [R-LA]	R · LA		Apr 29, 2021
Sen. Smith, Tina [D-MN]	D · MN		Apr 29, 2021

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 29, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 29, 2021)

This bill establishes that certain data and determinations from a request for emergency use authorization for a drug, biological product, or medical device may apply to later regulatory procedures for that product.

Specifically, data generated to support a request for emergency use authorization may constitute valid scientific evidence to be considered for various later submissions to the Food and Drug Administration (FDA), including a request for market approval.

Also, when granting emergency use authorization for a medical device, if the FDA determines that the device performs certain simple low-risk examinations, that determination shall apply to certain other regulatory submissions unless additional information contradicts that determination.

Actions Timeline

- **Apr 29, 2021:** Introduced in Senate
- **Apr 29, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.