HR 4128

VALID Act of 2021

Congress: 117 (2021–2023, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 24, 2021
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 25, 2021)
Official Text: https://www.congress.gov/bill/117th-congress/house-bill/4128

Sponsor

Name: Rep. DeGette, Diana [D-CO-1]
Party: Democratic • **State:** CO • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bucshon, Larry [R-IN-8]	R · IN		Jun 24, 2021

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 25, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 S 2209	Identical bill	**Jun 24, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 24, 2021)

Verifying Accurate Leading-edge IVCT Development Act of 2021 or the VALID Act of 2021

This bill requires the Food and Drug Administration (FDA) to regulate in vitro clinical tests (IVCTs).

Currently, the FDA and the Centers for Medicare & Medicaid Services have authority to regulate in vitro diagnostic devices. The bill defines IVCTs, which includes in vitro diagnostic devices, as tests intended for the collection, preparation, analysis, or in vitro clinical examination of specimens from the human body to provide information about a disease, condition, or treatment.

An IVCT may not be introduced into interstate commerce unless it has received FDA premarket approval or is covered by certain exemptions, such as an exemption for a test that (1) was developed and introduced before this bill's enactment and meets certain requirements, (2) is a low-risk test, (3) is solely for public health surveillance, (4) is covered by a technology certification issued under this bill, or (5) has received a humanitarian exemption or emergency use authorization.

The FDA may grant upon application a technology certification. Generally, such a certification covers a group of tests that use a single technology and may be evaluated using a representative test. While such a certification is valid, a qualifying IVCT that falls within the scope of the certification shall be cleared for interstate commerce.

The bill also imposes various requirements related to IVCTs, including those related to quality control, labeling, and reporting adverse events.

The FDA shall have various enforcement authority, including authority to order the recall of an IVCT with a reasonable probability of causing serious adverse health consequences.

Actions Timeline

- **Jun 25, 2021:** Referred to the Subcommittee on Health.
- **Jun 24, 2021:** Introduced in House
- **Jun 24, 2021:** Referred to the House Committee on Energy and Commerce.