HR 3493

Medical Devices Technical Corrections Act

Congress: 108 (2003–2005, Ended)
Chamber: House
Policy Area: Health
Introduced: Nov 17, 2003
Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and
Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jan 28, 2004)
Official Text: https://www.congress.gov/bill/108th-congress/house-bill/3493

Sponsor

Name: Rep. Greenwood, James C. [R-PA-8]
Party: Republican • **State:** PA • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Nov 17, 2003

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 4, 2003
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jan 28, 2004

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 S 1881	Related bill	**Apr 1, 2004:** Became Public Law No: 108-214.

Summary (as of Jan 27, 2004)

Medical Devices Technical Corrections Act - Amends the Federal Food, Drug, and Cosmetic Act (as amended by the Medical Device User Fee and Modernization Act of 2002) to revise provisions concerning medical devices user fees.

Prohibits the Secretary of Health and Human Services from collecting fees to defray costs in any fiscal year where the amount appropriated is more than five percent below the costs of the resources allocated for the review of device applications.

Allows the Secretary to withdraw the accreditation to inspect from any person where the Secretary has information indicating a relationship between the company and the accredited inspector that may create a conflict of interest.

Permits a company that markets at least one medical device in the United States and one medical device in another country to use an accredited third party inspector if the company certifies that the foreign country recognizes inspections by: (1) the Food and Drug Administration (FDA); and/or (2) the third party inspector. (Current law requires a country to recognize both types of inspections.)

Allows the Secretary to withdraw eligibility for third party inspections from a company if the Secretary obtains information indicating significant deviations from compliance with the Act or implementing regulations.

Allows electronic labeling for prescription devices intended for use by health care professionals and for in vitro diagnostic devices intended for use by health care professionals or in blood establishments.

Delays by 18 additional months the effective date of the provision deeming a device misbranded if the identification of the manufacturer is not conspicuously displayed.

Directs the Secretary to submit a report to the relevant committees on the barriers to the availability of devices intended for treatment or diagnosis of diseases or conditions that affect children.

Actions Timeline

- **Jan 28, 2004:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Jan 27, 2004:** Mr. Greenwood moved to suspend the rules and pass the bill.
- **Jan 27, 2004:** Considered under suspension of the rules. (consideration: CR H109-112)
- **Jan 27, 2004:** DEBATE - The House proceeded with forty minutes of debate on H.R. 3493.
- **Jan 27, 2004:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **Jan 27, 2004:** Considered as unfinished business. (consideration: CR H113)
- **Jan 27, 2004:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 333 - 0 (Roll no. 7).(CR H109-110)
- **Jan 27, 2004:** On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 333 - 0 (Roll no. 7). (CR H109-110)
- **Jan 27, 2004:** Motion to reconsider laid on the table Agreed to without objection.
- **Dec 4, 2003:** Referred to the Subcommittee on Health.
- **Nov 17, 2003:** Introduced in House
- **Nov 17, 2003:** Introduced in House
- **Nov 17, 2003:** Referred to the House Committee on Energy and Commerce.