

S 1881

Medical Devices Technical Corrections Act

Congress: 108 (2003–2005, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Nov 18, 2003

Current Status: Became Public Law No: 108-214.

Latest Action: Became Public Law No: 108-214. (Apr 1, 2004)

Law: 108-214 (Enacted Apr 1, 2004)

Official Text: <https://www.congress.gov/bill/108th-congress/senate-bill/1881>

Sponsor

Name: Sen. Alexander, Lamar [R-TN]

Party: Republican • **State:** TN • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Enzi, Michael B. [R-WY]	R · WY		Nov 18, 2003
Sen. Gregg, Judd [R-NH]	R · NH		Nov 18, 2003
Sen. Murray, Patty [D-WA]	D · WA		Nov 18, 2003

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 17, 2003
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Nov 24, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 HR 3493	Related bill	Jan 28, 2004: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

(This measure has not been amended since it was reported to the House on March 9, 2004. The summary of that version is repeated here.)

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 accreditation to inspect from any person where the Secretary determines that there is a conflict of interest between the company and the accredited inspector.

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 determines that the company is substantially not in compliance with the Act.

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

- **Apr 1, 2004:** Signed by President.
- **Apr 1, 2004:** Became Public Law No: 108-214.
- **Mar 22, 2004:** Presented to President.
- **Mar 15, 2004:** Message on Senate action sent to the House.
- **Mar 12, 2004:** Resolving differences -- Senate actions: Senate agreed to House amendment by Unanimous Consent.(text as Senate agreed to House amendment: CR S2821-2822)
- **Mar 12, 2004:** Senate agreed to House amendment by Unanimous Consent. (text as Senate agreed to House amendment: CR S2821-2822)
- **Mar 11, 2004:** Message on House action received in Senate and at desk: House amendment to Senate bill.
- **Mar 10, 2004:** Considered as unfinished business. (consideration: CR H931-932)
- **Mar 10, 2004:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by the Yeas and Nays: (2/3 required): 396 - 0 (Roll no. 46).(text: CR 3/9/2004 H890-891)
- **Mar 10, 2004:** On motion to suspend the rules and pass the bill, as amended Agreed to by the Yeas and Nays: (2/3 required): 396 - 0 (Roll no. 46). (text: CR 3/9/2004 H890-891)
- **Mar 10, 2004:** Motion to reconsider laid on the table Agreed to without objection.
- **Mar 9, 2004:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 108-433.
- **Mar 9, 2004:** Placed on the Union Calendar, Calendar No. 250.
- **Mar 9, 2004:** Mr. Greenwood moved to suspend the rules and pass the bill, as amended.
- **Mar 9, 2004:** Considered under suspension of the rules. (consideration: CR H890-892)
- **Mar 9, 2004:** DEBATE - The House proceeded with forty minutes of debate on S. 1881.
- **Mar 9, 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.
- **Mar 3, 2004:** Committee Consideration and Mark-up Session Held.
- **Mar 3, 2004:** Ordered to be Reported (Amended) by Voice Vote.
- **Dec 17, 2003:** Referred to the Subcommittee on Health.
- **Dec 8, 2003:** Received in the House.
- **Dec 8, 2003:** Message on Senate action sent to the House.
- **Dec 8, 2003:** Referred to the House Committee on Energy and Commerce.
- **Nov 25, 2003:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.(consideration: CR S16057-16060; text of measure as reported to Senate: CR S16058-16060)
- **Nov 25, 2003:** Passed Senate with an amendment by Unanimous Consent. (consideration: CR S16057-16060; text of measure as reported to Senate: CR S16058-16060)
- **Nov 24, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with an amendment in the nature of a substitute. Without written report.
- **Nov 24, 2003:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 412.
- **Nov 21, 2003:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Nov 18, 2003:** Introduced in Senate
- **Nov 18, 2003:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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