

HR 3423

Medical Device User Fee Stabilization Act of 2005

Congress: 109 (2005–2007, Ended)

Chamber: House

Policy Area: Health

Introduced: Jul 25, 2005

Current Status: Became Public Law No: 109-43.

Latest Action: Became Public Law No: 109-43. (Aug 1, 2005)

Law: 109-43 (Enacted Aug 1, 2005)

Official Text: <https://www.congress.gov/bill/109th-congress/house-bill/3423>

Sponsor

Name: Rep. Pitts, Joseph R. [R-PA-16]

Party: Republican • State: PA • Chamber: House

Cosponsors (10 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bono, Mary [R-CA-45]	R · CA		Jul 25, 2005
Rep. Davis, Jim [D-FL-11]	D · FL		Jul 25, 2005
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Jul 25, 2005
Rep. Ferguson, Mike [R-NJ-7]	R · NJ		Jul 25, 2005
Rep. Norwood, Charles W. [R-GA-9]	R · GA		Jul 25, 2005
Rep. Pickering, Charles W. "Chip" [R-MS-3]	R · MS		Jul 25, 2005
Rep. Strickland, Ted [D-OH-6]	D · OH		Jul 25, 2005
Rep. Upton, Fred [R-MI-6]	R · MI		Jul 25, 2005
Rep. Whitfield, Ed [R-KY-1]	R · KY		Jul 25, 2005
Rep. Inslee, Jay [D-WA-1]	D · WA		Jul 26, 2005

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 29, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 S 1420	Related bill	Jul 25, 2005: Placed on Senate Legislative Calendar under General Orders. Calendar No. 173.

(This measure has not been amended since it was introduced. The summary of that version is repeated here.)

Medical Device User Fee Stabilization Act of 2005 - Amends the Federal Food, Drug, and Cosmetic Act to adjust medical device user fees (e.g., premarket application, premarket report, supplement, and submission fees).

Repeals the fee revenue target amounts for FY2006 and FY2007.

Eliminates the inflation, workload, compensating, and final year adjustments of revenues used for setting fees.

Sets the premarket application fee for devices for FY2006 and FY2007.

Allows the Secretary of Health and Human Services to use unobligated carryover balances from fees collected in previous fiscal years with notice to the appropriate congressional committees.

Increases the annual gross receipts or sales threshold below which businesses are eligible for reduced fees or a waiver of fees by the Secretary.

Removes the prohibition against the Secretary assessing fees unless certain cumulative fee revenues were met for FY2003 through 2006.

Requires the Secretary to include in annual reports to Congress: (1) information on the number and total amount of fees paid for each different type of application or notification from small businesses; and (2) a certification that the amounts obligated for the performance of functions other than the review of device applications is not less than such amount for FY2002 multiplied by the adjustment factor.

Deems as branded any reprocessed single use device unless it identifies the manufacturer, but allows such information to be provided by a detachable label intended to be affixed to the medical record of a patient.

Actions Timeline

- **Aug 1, 2005:** Signed by President.
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- **Aug 1, 2005:** Became Public Law No: 109-43.
- **Aug 1, 2005:** Became Public Law No: 109-43.
- **Jul 29, 2005:** Referred to the Subcommittee on Health.
- **Jul 29, 2005:** Presented to President.
- **Jul 29, 2005:** Presented to President.
- **Jul 28, 2005:** Message on Senate action sent to the House.
- **Jul 27, 2005:** Passed/agreed to in Senate: Received in the Senate, read twice, considered, read the third time, and passed without amendment by Unanimous Consent.(consideration: CR S9196-9197)
- **Jul 27, 2005:** Received in the Senate, read twice, considered, read the third time, and passed without amendment by Unanimous Consent. (consideration: CR S9196-9197)
- **Jul 27, 2005:** Cleared for White House.
- **Jul 26, 2005:** Committee on Energy and Commerce discharged.
- **Jul 26, 2005:** Committee on Energy and Commerce discharged.
- **Jul 26, 2005:** Considered by unanimous consent. (consideration: CR H6510-6511)
- **Jul 26, 2005:** Mr. Deal (GA) asked unanimous consent to discharge from committee and consider.
- **Jul 26, 2005:** Passed/agreed to in House: On passage Passed without objection.(text: CR H6510-6511)
- **Jul 26, 2005:** On passage Passed without objection. (text: CR H6510-6511)
- **Jul 26, 2005:** Motion to reconsider laid on the table Agreed to without objection.
- **Jul 25, 2005:** Introduced in House
- **Jul 25, 2005:** Introduced in House
- **Jul 25, 2005:** Referred to the House Committee on Energy and Commerce.