



**CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE**

July 26, 2005

S. 1420

Medical Device User Fee Stabilization Act of 2005

*As ordered reported by the Senate Committee on Health, Education, Labor,
and Pensions on July 20, 2005*

SUMMARY

S. 1420 would extend the medical device user fee program administered by the Food and Drug Administration (FDA) for fiscal years 2006 and 2007. (User fees defray FDA's costs of expediting the review of applications for approval to market medical devices.) Under current law, authorization for the user fee program through 2007 is contingent on minimum funding for activities related to regulating devices and radiological products (among other requirements). But because those appropriation targets have not been met on a cumulative basis (from 2003 through 2005), the program will sunset under current law at the end of 2005. S. 1420 would change the target formula and eliminate the early termination of the program.

CBO estimates that implementing S. 1420 would have no net budget impact over the 2006-2010 period, assuming appropriation action consistent with the bill. Such implementation would encompass the collection of \$64 million in new fees over the 2006-2007 period and the spending of such fees (over the 2006-2008 period). Both of those effects would be subject to appropriation action; enacting the bill would have no effect on direct spending or revenues.

S. 1420 would impose mandates as defined by the Unfunded Mandates Reform Act (UMRA) on the private sector and on state, local, or tribal governments that manufacture medical devices for commercial purposes. However, CBO estimates the costs of complying with the mandates would be minimal and would not exceed the thresholds for intergovernmental or private-sector entities established in that act (\$62 million and \$123 million, respectively, in 2005, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated cost of S. 1420 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2005	2006	2007	2008	2009	2010
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law for the MDUFMA Program						
Collection of MDUFMA User Fees						
Budget Authority ^a	-31	0	0	0	0	0
Estimated Outlays	-31	0	0	0	0	0
Spending of MDUFMA User Fees						
Budget Authority ^a	31	0	0	0	0	0
Estimated Outlays	32	10	0	0	0	0
Net Spending under Current Law						
Budget Authority	0	0	0	0	0	0
Estimated Outlays	1	10	0	0	0	0
Proposed Changes						
Collection of MDUFMA User Fees						
Estimated Authorization Level	0	-31	-33	0	0	0
Estimated Outlays	0	-31	-33	0	0	0
Spending of MDUFMA User Fees						
Estimated Authorization Level	0	31	33	0	0	0
Estimated Outlays	0	21	37	6	0	0
Net Changes						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	0	-10	4	6	0	0
Spending Under S. 1420 for the MDUFMA Program						
Collection of MDUFMA User Fees						
Estimated Authorization Level	-31	-31	-33	0	0	0
Estimated Outlays	-31	-31	-33	0	0	0

(Continued)

	By Fiscal Year, in Millions of Dollars					
	2005	2006	2007	2008	2009	2010
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Spending of MDUFMA User Fees						
Estimated Authorization Level	31	31	33	0	0	0
Estimated Outlays	32	31	37	6	0	0
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Total Net Spending under S. 1420						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	1	0	4	6	0	0

Note: MDUFMA = Medical Device User Fee and Modernization Act.

- a. The 2005 amount reflects the appropriation for the MDUFMA program in that year. In 2005, the amount appropriated for FDA for activities not supported by user fee programs is \$1.4 billion.

BASIS OF ESTIMATE

S. 1420 would extend FDA's device user fee program that is otherwise set to expire at the end of fiscal year 2005. Device user fees defray FDA's costs of expediting the review of applications for approval to market medical devices. Such fees are collected and made available for obligation only to the extent, and in the amounts, provided in advance in appropriations acts.

The Medical Device User Fee and Modernization Act (MDUFMA) authorizes FDA to collect user fees for certain medical device applications through fiscal year 2007 if certain conditions are met. However, amounts appropriated for FDA's device and radiological health program during the first three years of the user fee program (from 2003 through 2005) fell short of cumulative funding requirements. As a result, under current law, fees may not be assessed in 2006 or 2007. The bill would change the target formula and eliminate the shortfalls that trigger the early termination of the program. As a result, the program would be authorized to continue through 2007 (subject to modified funding targets).

The bill also would modify how fees paid by firms for the review of medical device applications are set. The bill would eliminate the use of aggregate "fee revenue" targets for annual fee-setting calculations. Instead, the bill would set the new rates for pre-market applications at \$259,600 for fiscal year 2006 and \$281,600 for fiscal year 2007. Fees for other device submissions are estimated as a percentage of pre-market application fees. Under the bill, there would be no additional adjustments to fees based on estimates of inflation, workload or other compensating factors.

The bill also would raise the threshold for small businesses to qualify for fee reductions on certain device applications; such a change would generate a higher number of reduced-fee applications submitted by small companies.

The bill would replace the authorization of appropriations for aggregate fee revenues in fiscal years 2006 and 2007 with the authorization of such sums as necessary to fund the user fee program in those years. Based on information provided by the FDA, CBO estimates that user fee collections under the bill would total \$31 million in 2006 and \$33 million in 2007. This estimate reflects the per-application fees specified in the bill and assumes the same number and mix of device applications in 2006 and 2007 as received by FDA in 2004. It also assumes future funding targets would be met.

CBO estimates that implementing S. 1420 would reduce net discretionary outlays by \$10 million in 2006, assuming appropriation action consistent with the bill. Spending of fees lags somewhat behind their collection. Lower spending would occur in 2006 primarily because we expect that FDA would spend less of the program's unobligated balances from prior-year resources under the bill compared with the amount of those balances that would be spent to terminate the program under current law. (In addition, the agency would not spend all of the 2006 collections in that year.) We estimate that the legislation would have no net budget impact over the 2006-2010 period.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

By ensuring the continuation of the user fee program, S. 1420 would extend a requirement to pay fees on state, local, or tribal governments that manufacture medical devices for commercial purposes. That requirement would be an intergovernmental mandate as defined in UMRA, but CBO is unaware of any case in which a state, local, or tribal entity manufactures such devices for commercial purposes. Thus, we estimate that the costs of complying with the mandate would be minimal and well below the threshold established in UMRA (\$62 million in 2005, adjusted annually for inflation.)

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 1420 would clarify the requirements of one private-sector mandate and extend for two years another mandate that would otherwise expire at the end of fiscal year 2005. In the first case, the bill would extend and strengthen labeling guidelines for reproprocessors, requiring them to prominently display the name of the manufacturer on each device. Since most reproprocessors currently label their devices in a way that would meet these guidelines, CBO estimates the increase in the cost of this labeling mandate would be small. In the second

case, the extension would require the producers of medical devices to continue to pay user fees to FDA when submitting applications for marketing approval and licensing. CBO estimates that the total cost of these two mandates would be well below the threshold specified in UMRA (\$123 million in 2005, adjusted annually for inflation) in each of the two years the mandates would be effective.

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