CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 1, 1997

H.R. 1710
Medical Device Regulatory Modernization Act of 1997

As ordered reported by the House Committee on Commerce on September 26, 1997

SUMMARY

H.R. 1710 would amend the Food, Drug and Cosmetic Act (FD&CA) and the Public Health Service Act to reform the Food and Drug Administration's (FDA's) regulatory and approval processes for devices. The bill would also require the FDA to meet statutory deadlines for approving some device applications. Finally, the FDA would be directed to accredit independent entities to review certain device applications. CBO estimates that enacting H.R.1710 would result in net additional discretionary spending of $13 million in 1998 and $70 million over the 1998-2002 period, assuming appropriation of the authorized amounts.

H.R. 1710 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would impost no costs on state, local, or tribal governments. The bill would reduce the costs of existing private-sector mandates.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1710 is shown in the following table. For the purposes of this estimate, CBO assumes that all amounts authorized in the bill would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns for the FDA. The costs of this legislation fall within budget function 550 (Health).

	By Fiscal Year, in Millions of Dollars						
	1996	1997	1998	1999	2000	2001	2002
SPENDING SUBJECT TO APPROPRIATION							
Spending by FDA Under Current Law							
Estimated Authorization Level	877	887	919	949	982	1016	1050
Estimated Outlays	866	895	914	937	971	1005	1038
Proposed Changes							
Estimated Authorization Level	0	0	13	14	13	14	16
Estimated Outlays	0	0	9	13	13	14	15
Spending by FDA Under H.R. 1710							
Estimated Authorization Level [a]	877	887	932	963	995	1030	1066
Estimated Outlays	866	895	923	950	984	1019	1053

a. The 1996 and 1997 levels are the amounts appropriated for those years.

BASIS OF ESTIMATE

H.R. 1710 would amend the FDA's approval and regulatory processes with the intent of accelerating product approvals and reducing regulatory requirements. Under this bill, manufacturers of class III devices could petition for the reclassification of their products. The bill would direct the FDA to comply with statutory deadlines for reviewing certain device applications and to accredit third-party reviewers. Finally, the proposal would require the FDA to establish an information system to track device applications and submissions. Other provisions of the bill would have no significant budgetary impact.

Reclassification of Class III Devices. H.R. 1710 would change the FDA's current practice of automatically designating as class III products new devices that are not substantially equivalent to a legally marketed predicate device. Sponsors of devices designated as class

III could submit to the FDA information supporting a class I or II determination, and could make a recommendation about the classification of their product. The FDA would have 60 days to make a final determination on the sponsor's recommendation. This provision would reduce the number of premarket applications reviewed by the FDA, saving $2 million in 1998 and $12 million over five years.

Enforced Deadlines for FDA Action on Submissions. Under this provision, the FDA would be directed to complete action on applications for premarket approval (PMA) of class III devices within 180 days. This provision would therefore bring the FDA into compliance with the statutory deadline for reviewing PMA applications.

Assuming that the volume and quality standards for reviews were to remain constant, the FDA would require additional staff and resources to reduce its current device review times significantly. Because H.R. 1710 would somewhat relax current FDA regulations, the number of product applications could increase, placing further demands on the agency's resources. CBO estimates that the additional personnel and resources necessary to meet the proposed deadlines would exceed any savings realized through regulatory relief offered by H.R. 1710. This provision would cost the federal government an estimated $11 million in 1998 and $66 million over five years.

Third-Party Review of Applications. This provision would require the FDA to accredit independent entities for reviewing and making initial classification recommendations on section 510(k) device submissions. Devices that are life-sustaining or life-supporting, intended for permanent implantation, or designated as class III devices would be exempted from this provision. The FDA could evaluate the performance of accredited reviewers and rescind their accreditation status when necessary. CBO estimates that this proposal would save approximately $1 million over five years.

Application Tracking System. H.R. 1710 would direct the FDA to establish an information system to track device applications and submissions. Based on information from the FDA, CBO estimates that the cost of developing and maintaining this system would be $4 million in 1998, and $17 million over five years.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 1710 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

In general, H.R. 1710 reduces the costs of existing private-sector mandates. In at least one instance (section 8, Scope of Review) it would replace an existing private-sector mandate with new, less burdensome requirements. CBO is uncertain whether other sections would add to the cost of complying with regulations governing the use of unapproved devices for humanitarian purposes. In total, however, CBO concludes that the direct cost of all private-sector mandates in this bill would be minimal and the total effect could be a net reduction in costs imposed on the private sector.

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