



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

October 19, 2000

H.R. 1798 **Clinical Research Enhancement Act of 1999**

As ordered reported by the House Committee on Commerce on September 26, 2000

SUMMARY

H.R. 1798 would authorize the National Institutes of Health (NIH) to provide grants to establish clinical research centers, fund clinical researchers and clinical research projects, and support students pursuing master's or doctoral degrees in clinical research.

The bill also would increase the numbers of scholarships under the Public Health Service Act, and would modify a loan repayment program. Under the current program, health professionals from disadvantaged backgrounds working at the NIH agree to conduct clinical research in return for an agreement that the federal government will repay up to \$35,000 of the principal and interest of educational loans for each year of service. The bill would expand the eligibility of who could qualify for loans and the sites at which these individuals could be employed. It would also require that at least half of the loan repayment contracts involve individuals from disadvantaged backgrounds. The program is currently paid out of appropriated funds and would continue to be operated in such a way under H.R. 1798.

Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 1798 would cost \$53 million in 2001 and \$814 million over the 2001-2005 period, assuming annual adjustments for inflation for the activities without specified authorization levels. The five-year total would be \$783 million if such inflation adjustments are not made. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 1798 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). To the extent that public and university hospital conduct clinical research eligible for grant assistance under the bill, those entities may receive additional funding.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1798 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2000	2001	2002	2003	2004	2005
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law						
Estimated Authorization Level ^a	229	0	0	0	0	0
Estimated Outlays	201	156	90	23	11	11
Proposed Changes ^b						
Estimated Authorization Level	0	230	236	242	249	256
Estimated Outlays	0	53	123	196	212	230
Spending Under H.R. 3250						
Estimated Authorization Level	229	230	236	242	249	256
Estimated Outlays	201	209	214	218	224	240

a. The 2000 level is the amount appropriated for that year for the agencies that would be affected by H.R. 1798.

b. The amounts shown reflect adjustments for anticipated inflation for those activities for which the bill would authorize such sums as necessary. Without such inflation adjustments, the five-year changes in authorization levels would total \$1.15 billion (instead of \$1.21 billion) and the changes in outlays would total \$783 million (instead of \$814 million).

BASIS OF ESTIMATE

The bill authorizes several grant programs to support clinical research that NIH already operates. It also increases the number of national research service awards under section 487(a)(1)(C) of the Public Health Service Act from 50 to 100 awards. The bill would also expand the criteria under which an individual could enter into a loan repayment contract with the federal government under section 487E of the Public Health Service Act. Under current law, only individuals from disadvantaged backgrounds employed by the NIH may qualify for loan repayment. The bill would expand the program to all individuals in a clinical research training position, with a requirement that half of the contracts must be to individuals from disadvantaged backgrounds.

Many of the grants, scholarships, and loan repayment contracts that would be authorized by H.R. 1798 are currently conducted within the NIH, and are reflected in the estimated changes

to both budget authority and outlays. The estimates of changes in budget authority and outlays of the proposal reflect the incremental cost of the increase in National Service Awards and the expansion of the loan repayment program.

PAY-AS-YOU-GO CONSIDERATIONS: None.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 1798 contains no intergovernmental or private-sector mandates as defined in the UMRA. To the extent that public and university hospital conduct clinical research eligible for grant assistance under the bill, those entities may receive additional funding.

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