CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 9, 2008

H.R. 1014
Heart Disease Education, Analysis Research, and Treatment for Women Act

As passed by the House of Representatives on September 25, 2008

SUMMARY

H.R. 1014 would amend the Federal Food, Drug, and Cosmetic Act to require the submission of specific clinical effectiveness data with drug, device, and biologic approval applications. The act also would authorize a variety of activities related to the prevention and treatment of cardiovascular disease in women. CBO estimates that implementing the act would cost $16 million in 2009 and $179 million over the 2009-2013 period, assuming the appropriation of the necessary amounts.

H.R. 1014 would impose a number of mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on the private sector. Entities submitting applications for the approval of new drugs, the use of certain devices, and the licensing of biological products would be required to include information regarding the drug or device stratified by gender, race, and ethnicity, including differences in safety and effectiveness. CBO estimates that the aggregate cost of complying with those mandates would not exceed the threshold established by UMRA for private-sector mandates ($136 million in 2008, adjusted annually for inflation).

H.R. 1014 contains no intergovernmental mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated cost of H.R. 1014 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2009	2010	2011	2012	2013	2009-2013
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
CDC						
Authorization Level	37	39	41	43	45	205
Estimated Outlays	7	28	36	40	42	153
AHRQ						
Estimated Authorization Level	1	2	1	1	2	7
Estimated Outlays	1	2	1	1	2	7
FDA						
Estimated Authorization Level	4	2	2	2	2	12
Estimated Outlays	4	2	2	2	2	12
HHS						
Estimated Authorization Level	2	0	0	0	0	2
Estimated Outlays	1	1	0	0	0	2
HRSA						
Estimated Authorization Level	5	0	0	0	0	5
Estimated Outlays	3	2	0	0	0	5
Total Changes						
Estimated Authorization Level	49	43	44	46	49	231
Estimated Outlays	16	35	39	43	46	179

Note: CDC = Centers for Disease Control and Prevention; AHRQ = Agency for Healthcare Research and Quality; FDA = Food and Drug Administration; HHS = Department of Health and Human Services; HRSA = Health Resources and Services Administration.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 1014 will be enacted near the beginning of fiscal year 2009, that the necessary amounts will be appropriated each year, and that outlays will follow historical patterns for similar activities of the Department of Health and Human Services (HHS). CBO estimates that implementing H.R. 1014 would cost $16 million in 2009 and $179 million over the 2009-2013 period.

Reauthorization of the WISEWOMAN Program

The WISEWOMAN program provides chronic disease screening and educational services to low-income women between the ages of 40 and 64. H.R. 1014 would authorize the appropriation of $37 million for 2009, $39 million for 2010, $41 million for 2011, $43 million for 2012, and $45 million for 2013 to the Centers for Disease Control and Prevention to extend the WISEWOMAN Program. Assuming the appropriation of the specified amounts, CBO estimates that implementing this provision would cost $153 million over the 2009-2013 period.

Data Collection and Annual Report on Women and Heart Disease

H.R. 1014 would require the Agency for Healthcare Research and Quality (AHRQ) to ensure that non-identifiable patient data reported to patient safety databases be stratified by gender. Additionally, H.R. 1014 would require AHRQ to generate an annual report to the Congress pertaining to the quality of and access to care for women with cardiovascular disease. CBO estimates that implementing these provisions would cost $7 million over the 2009-2013 period.

Data Reporting Requirements in Applications for Drugs, Biologics and Devices

H.R. 1014 would require the Food and Drug Administration (FDA) to deny a new drug application or withhold approval of a proposed or ongoing clinical study for drugs, biologics, or devices if specific requirements regarding data on clinical effectiveness are not met. Applicants also would be required to report all clinical data on effectiveness by gender, age, and race. Upon approval of an application, the FDA would be required to make the data publicly available. CBO estimates that implementing this provision would cost $12 million over the 2009-2013 period.

Educational Campaigns

H.R. 1014 would authorize the Secretary of HHS to develop and distribute educational materials related to cardiovascular diseases in women. These materials would be distributed to health care professionals and women over the age of 65. The Health Resources and Services Administration (HRSA) would be responsible for conducting the campaign targeting health care professionals. HHS would be responsible for designating one of its divisions to conduct the campaign targeting women over the age of 65. CBO estimates the

HRSA and HHS components of this provision would cost $7 million over the 2009-2013 period.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 1014 contains no intergovernmental mandates as defined in UMRA. States that provide preventive health services and referrals would benefit from grant funds authorized in the act.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 1014 would impose a number of private-sector mandates, as defined in UMRA, on drug and device manufacturers submitting applications to the FDA. The act would require entities submitting applications for the approval of new drugs, the use of certain devices, and the licensing of biological products to include information regarding the drug or device stratified by gender, race, and ethnicity, including differences in safety and effectiveness. Clinical trials already collect data that can be stratified by gender, race, and ethnicity, but submissions to the FDA are not necessarily stratified by gender, race, and ethnicity. These provisions would require drug and device manufacturers to submit information with these stratifications. CBO estimates that the direct costs of those requirements would be below the threshold established by UMRA for private-sector mandates ($136 million in 2008, adjusted annually for inflation).

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