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108TH CONGRESS
1ST SESSION

H. R. 2356

To require the National Institutes of Health to conduct research, and the Agency for Healthcare Research and Quality to conduct studies, on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of expenditures or use by individuals in federally funded health programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 2003

Mr. ALLEN (for himself, Mrs. EMERSON, Mr. BERRY, Mr. BEREUTER, Mr. WAXMAN, Mr. BURTON of Indiana, Mr. DAVIS of Florida, Mr. GUTKNECHT, Mr. SNYDER, Mrs. BONO, Mr. COOPER, and Mr. WAMP) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the National Institutes of Health to conduct research, and the Agency for Healthcare Research and Quality to conduct studies, on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of expenditures or use by individuals in federally funded health programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Comparative Effectiveness Act of 2003''.

SEC. 2. NIH RESEARCH AND AHRQ STUDY ON EFFECTIVENESS OF CERTAIN PRESCRIPTION DRUGS.

(a) IN GENERAL.—

(1) RESEARCH BY NIH.—The Director of the National Institutes of Health, in coordination with the Director of the Agency for Healthcare Research and Quality, shall conduct research, which may include clinical research, to develop valid scientific evidence regarding the comparative effectiveness, cost-effectiveness, and, where appropriate, comparative safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition.

(2) ANALYSIS BY AHRQ.—

(A) IN GENERAL.—The Director of the Agency for Healthcare Research and Quality, taking into consideration the research of the National Institutes of Health under this section, shall use evidence-based practice centers to conduct studies or other analyses of the comparative effectiveness, cost-effectiveness, and, where appropriate, comparative safety of covered prescription drugs relative to other drugs

and treatments for the same disease or condition.

(B) SAFETY.—In any analysis of comparative effectiveness or cost-effectiveness under this subparagraph, the Director of the Agency for Healthcare Research and Quality shall include a discussion of available information on relative safety.

(3) STANDARDS.—The Director of the Agency for Healthcare Research and Quality, in consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and stakeholders, shall develop standards for the design and conduct of cost-effectiveness studies under this subsection.

(b) COVERED PRESCRIPTION DRUGS.—For purposes of this section, the term ''covered prescription drugs'' means prescription drugs that, as determined by the Director of the Agency for Healthcare Research and Quality in consultation with the Administrator of the Centers for Medicare & Medicaid Services, account for high levels of expenditures or use by individuals in federally funded health programs, including Medicare and Medicaid.

(c) ANNUAL REPORT.—Each year the Director of the Agency for Healthcare Research and Quality shall prepare

a report on the results of the research, studies, and analyses conducted by the National Institutes of Health and the Agency for Healthcare Research and Quality under this section and submit the report to the following:

(1) The Congress.

(2) The Secretary of Defense.

(3) The Secretary of Health and Human Services.

(4) The Secretary of Veterans Affairs.

(5) The Administrator of the Centers for Medicare & Medicaid Services.

(6) The Director of the Indian Health Service.

(7) The Director of the National Institutes of Health.

(8) The Director of the Office of Personnel Management.

(d) REPORTS FOR PRACTITIONERS.—As soon as possible, but not later than a year after the completion of any study pursuant to subsection (a)(2), the Director of the Agency for Healthcare Research and Quality shall—

(1) prepare a report on the results of such study for the purpose of informing health care practitioners; and

(2) transmit the report to the Director of the National Institutes of Health.

(e) NIH INTERNET SITE.—The Director of the National Institutes of Health shall publish on the Institutes' Internet site, and through other means that will facilitate access by practitioners, each report prepared under subsection (c) or (d) by the Director of the Agency for Healthcare Research and Quality.

(f) EVIDENCE.—In carrying out this section, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality shall consider only methodologically sound studies, giving preference to studies for which the Directors have access to sufficient underlying data and analysis to address any significant concerns about methodology or the reliability of data.

(g) AUTHORIZATIONS OF APPROPRIATIONS.—

(1) NIH.—There are authorized to be appropriated to the National Institutes of Health to carry out this section $50,000,000 for fiscal year 2004, and such sums as may be necessary for fiscal years thereafter.

(2) AHRQ.—There are authorized to be appropriated to the Agency for Healthcare Research and Quality to carry out this section $25,000,000 for fiscal year 2004, and such sums as may be necessary for fiscal years thereafter.

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