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109TH CONGRESS
2D SESSION

H. R. 5975

To require the Agency for Healthcare Research and Quality, in consultation with the Director of the National Institutes of Health, to conduct research to develop valid scientific evidence regarding comparative clinical effectiveness, outcomes, and appropriateness of prescription drugs, medical devices, and procedures, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2006

Mr. ALLEN (for himself, Mrs. EMERSON, Mr. WAXMAN, Mr. EHLERS, Mr. BERRY, Mr. BURTON of Indiana, Mr. BROWN of Ohio, and Mr. GUTKNECHT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Agency for Healthcare Research and Quality, in consultation with the Director of the National Institutes of Health, to conduct research to develop valid scientific evidence regarding comparative clinical effectiveness, outcomes, and appropriateness of prescription drugs, medical devices, and procedures, 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 2006''.

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

(a) IN GENERAL.—

(1) RESEARCH.—The Director of the Agency for Healthcare Research and Quality, in consultation with the Director of the National Institutes of Health, shall conduct or support research, which may include clinical research, to develop valid scientific evidence regarding comparative clinical effectiveness, outcomes, and appropriateness of prescription drugs, medical devices, and procedures. In conducting or supporting such research, particular consideration shall be given to treatments that involve high volume, high cost, or high risk to patients.

(2) SYSTEMATIC REVIEWS.—

(A) IN GENERAL.—The Director of the Agency for Healthcare Research and Quality shall conduct or support systematic reviews of existing evidence regarding comparative clinical effectiveness, outcomes, and appropriateness of prescription drugs, medical devices, and procedures. In conducting or supporting such reviews, particular consideration shall be given to

treatments that involve high volume, high cost, or high risk to patients.

(B) BETTER CLINICIAN AND PATIENT INFORMATION ON SAFETY.—Within 12 months of the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, shall develop a coordinated plan for research on the most appropriate methods for measuring and comparing adverse events associated with pharmaceuticals and other medical and surgical treatments so that clinicians and patients can evaluate the comparative safety as well as the comparative clinical effectiveness of the alternative treatment options.

(b) 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 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.

(c) REPORTS FOR PRACTITIONERS.—As soon as possible, but not later than a year after the completion of any systemic review conducted 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 systemic review for the purpose of informing health care practitioners; and

(2) identify treatment options for which comparative clinical effectiveness judgments could not be reached due to insufficient evidence and make such identifications available to the Director of the National Institutes of Health and other entities funding research.

(d) INFORMATION FOR PATIENTS.—The Director of the Agency for Healthcare Research and Quality shall create a version of each report prepared for practitioners under subsection (c)(1) in a form that is easily understood by the individuals receiving the treatments involved.

(e) AVAILABILITY.—The Director of the Agency for Healthcare Research and Quality—

(1) shall publish on the Agency's Internet site, and through other means that will facilitate access by practitioners, each report prepared under subsection (b), (c), or (d); and

(2) make the information in such reports available to the public through easily accessible and searchable electronic mechanisms, and in hard copy formats as appropriate.

(f) ACCOUNTABILITY.—In carrying out this subsection, the Secretary of Health and Human Services shall implement activities in a manner that makes publicly available all scientific evidence relied upon and the methodologies employed, provided such evidence and method are not protected from public disclosure by section 1905 of title 18, United States Code, or other applicable law, so that the results of the research, analyses, or syntheses involved can be evaluated and replicated.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated to the Agency for Healthcare Research and Quality and the National Institutes of Health $100,000,000 for fiscal year 2007 and such sums as may be necessary for fiscal year 2008 and each subsequent fiscal year.

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