I

110TH CONGRESS
2D SESSION

H. R. 6498

To secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 15, 2008

Mr. KENNEDY introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments, 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 ''Genomics and Personalized Medicine Act of 2008''.

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) The completion of the Human Genome Project in 2003 paved the way for a more sophisticated understanding of diseases and drug responses, which has contributed to the advent of ''personalized medicine''.

(2) Personalized medicine is the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, help determine a person's predisposition to a particular disease or condition, and identify any targeted prevention strategies for that predisposition.

(3) Many commonly-used drugs are typically effective in only 40 to 60 percent of the patient population.

(4) In the United States, up to 15 percent of hospitalized patients experience a serious adverse drug reaction, and as many as 100,000 deaths are attributed annually to such reactions.

(5) Pharmacogenomics has the potential to dramatically increase the efficacy and safety of drugs and reduce health care costs, and is fundamental to the practice of genome-based personalized medicine.

(6) Pharmacogenomics is the study of drug response in the context of the entire genome. This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop safer and more effective medications and dosing regimens that will be tailored to an individual's genetic makeup.

(7) The cancer drug Gleevec was developed based on knowledge of the chromosomal translocation that causes chronic myelogenous leukemia, which is characterized by an abnormal growth in the number of white blood cells. The mean 5-year survival for affected patients who are treated with Gleevec is 95 percent, which contrasts to a 5-year survival of 50 percent for patients treated with older therapies.

(8) The ERBB2 gene helps cells grow, divide, and repair themselves. One in 4 breast cancers are characterized by extra copies of this gene, which causes uncontrolled and rapid tumor growth. Pharmacogenomics research led to both the development of the test for this type of breast cancer as well as an effective biologic, Herceptin.

(9) Warfarin, a blood thinner used to prevent the formation of life-threatening clots, significantly

elevates patient risk for bleeding in the head or gas trointestinal tract, both of which are associated with increased rates of hospitalization, disability, and death. Pharmacogenomic researchers have identified and developed tests for genetic variants in the cytochrome P450 metabolizing enzyme (CYP2C9) and vitamin K epoxide reductase complex that increase risk for these adverse events. By using a companion diagnostic test for these two genes, physicians can modify the dosing regimen and decrease the likelihood of adverse events.

(10) Although the cancer drug 6-mercaptopurine (6–MP) cures 85 percent of children with acute lymphoblastic leukemia, historically, a significant number of patients would die inexplicably from the drug. Researchers later discovered that 1 in 300 individuals have only a non-functional form of the metabolizing enzyme thiopurine methyltransferase (TPMT) and, as a result, should receive only a fraction of the standard dose of 6

(11) Research into the genetics of breast cancer identified two pivotal genes, BRCA1 and BRCA2, mutations which correspond to a significantly increased lifetime risk of developing breast and ovarian cancer. Individuals in affected families or with

specific risk factors may use genetic testing to identify whether they carry mutations in these genes and to inform their decisions about treatment options, including prophylactic mastectomy and oophorectomy.

(12) Realizing the promise of personalized medicine will require continued Federal leadership and agency collaboration, expansion, and acceleration of genomics research, a capable genomics workforce, incentives to encourage development and collection of data on the analytic and clinical validity and clinical utility of genomic tests and therapies, and improved regulation over the quality of genetic tests, direct-to consumer advertising of genetic tests, and use of personal genomic information.

SEC. 3. DEFINITIONS.

In this Act:

(1) BIOBANK.—The term ''biobank'' means a shared repository of human biological specimens that may also include data associated with such specimens collected for medical or research purposes. Human biological specimens may include body fluids, tissues, blood, cells, or materials derived from these sources, and data associated with such speci-

mens may include health information or environmental data.

(2) BIOMARKER.—The term ''biomarker'' means an analyte found in or derived from a patient specimen that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

(3) CLIA.—The term ''CLIA'' means section 353 of the Public Health Service Act (42 U.S.C. 263a; commonly referred to as the ''Clinical Laboratory Improvement Amendments of 1988'').

(4) ENVIRONMENT.—The term ''environment'' means conditions or circumstances that are nongenetic but may have a health impact.

(5) GENETIC TEST.—The term ''genetic test'' means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(6) IWG.—The term ''IWG'' means the Genomics and Personalized Medicine Interagency Working Group established pursuant to section 4.

(7) PHARMACOGENETIC TEST.—

(A) IN GENERAL.—The term ''pharmacogenetic test'' means a genetic test intended to

identify individual variations in DNA sequence related to drug absorption and disposition (pharmacokinetics) or drug action (pharmacodynamics), including polymorphic variation in the genes that encode the functions of transporters, receptors, metabolizing enzymes, and other proteins, or other genomic variations, including rearrangements, insertions, and deletions, or alterations in gene expression or inactivation, that may be correlated with pharmacological function and therapeutic response.

(B) VARIATIONS AND ALTERATIONS.—For purposes of this paragraph, the variations or alterations referred to in subparagraph (A) may be a pattern or profile of change, rather than a change in an individual marker.

(8) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 4. GENOMICS AND PERSONALIZED MEDICINE INTER AGENCY WORKING GROUP.

(a) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary shall establish within the Department of Health and Human Services the Genomics and Personalized Medicine Interagency Working Group (''IWG'').

(b) DUTIES.—The IWG shall facilitate collaboration, coordination, and integration of activities within the Department of Health and Human Services and other Federal agencies, and among such agencies and relevant public and private entities, by—

(1) reviewing current and proposed genomic initiatives, in order to identify shared interests and leverage resources;

(2) prioritizing new genomic initiatives, based on areas of need as measured by public health impact;

(3) reaching consensus on standardized genomic terminology, definitions, and data code sets for adoption and use in federally conducted or supported programs;

(4) establishing and disseminating quality standards and guidelines for the collection, processing, archiving, storage, and dissemination of genomic samples and data for research and clinical purposes;

(5) developing and promulgating guidelines regarding procedures, protocols, and policies for the safeguarding of the privacy of biobank subjects, in accordance with the Office for Human Research Protection and Clinical Research Policy Analysis and

Coordination Program at the National Institutes of Health, and other guidelines as appropriate;

(6) reviewing and making recommendations to address ownership and patient access issues with respect to genomic samples and analyses;

(7) developing and promulgating guidelines regarding procedures, protocols, and policies for access to patient data, genomic samples, and associated health information by nongovernmental entities for research purposes;

(8) developing and disseminating guidelines for constructing informed consent forms that ensure patient privacy and confidentiality of associated clinical data and information, understanding of research procedures, benefits, risks, rights, and responsibilities, and continuous voluntary participation; and

(9) providing recommendations for the establishment of a distributed database, pursuant to section 5.

(c) IWG CHAIRPERSON.—The Secretary, or his or her designee, shall serve as chairperson of the IWG.

(d) MEMBERS.—In addition to the Secretary, the IWG shall include members from—

(1) the National Institutes of Health;

(2) the Centers for Disease Control and Prevention;

(3) the Food and Drug Administration;

(4) the Health Resources and Services Administration;

(5) the Office of Minority Health;

(6) the Agency for Healthcare Research and Quality;

(7) the Centers for Medicare & Medicaid Services;

(8) the Veterans Health Administration;

(9) the Office of the National Coordinator for Health Information Technology;

(10) the Department of Energy;

(11) the Armed Forces Institute of Pathology;

(12) the Indian Health Service;

(13) other Federal departments; and

(14) such other agencies as determined appropriate by the Secretary.

(e) PUBLIC INPUT.—The IWG shall solicit input from relevant stakeholders with respect to meeting the duties described in subsection (b).

(f) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall prepare and submit a report to the appropriate committees

of the Congress and to the public on IWG deliberations, activities, and recommendations with respect to meeting the duties described in subsection (b).

(g) TERMINATION.—The IWG shall terminate after submitting the report described in subsection (f), or later at the discretion of the Secretary.

(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $5,000,000 for each of fiscal years 2009 and 2010.

SEC. 5. EXPANSION AND ACCELERATION OF GENETIC AND GENOMICS RESEARCH.

(a) GENETICS AND GENOMICS RESEARCH.—The Secretary shall expand and accelerate research and programs to collect genetic and genomic data that will advance the field of genomics and personalized medicine, with prioritized focus on—

(1) studies of diseases and health conditions with substantial public health impact;

(2) population-based studies of genotype prevalence, gene-disease association, gene-drug response association, and gene-environment interactions;

(3) systematic review and synthesis of the results of population-based studies using methods of human genome epidemiology;

(4) translation of genomic information into molecular genetic screening tools, diagnostics, and therapeutics, through well-conducted clinical trials and studies;

(5) translation of genomic information into tools for public health investigations and ongoing biosurveillance and monitoring;

(6) systematic review of data on analytic validity and clinical validity of molecular genetic tests;

(7) comprehensive studies of clinical utility, including cost-effectiveness and cost-benefit analyses, of molecular genetic tests and therapeutics;

(8) population-based studies to assess the awareness, knowledge, and use of genetic tests and their impact on the population health and health disparities; and

(9) methods to enhance provider uptake or adoption of pharmacogenomic products into practice.

(b) NATIONAL BIOBANKING INITIATIVE.—

(1) IN GENERAL.—The Secretary shall advance the field of genomics and personalized medicine through establishment of a national biobanking distributed database for the collection and integration of genomic data, and associated environmental and

clinical health information, which shall facilitate synthesis and pooled analysis of such data.

(2) DATABASE.—With respect to the national biobanking distributed database, the Secretary shall—

(A) adhere to relevant guidelines, policies, and recommendations of the IWG, pursuant to section 4;

(B) establish, directly or by contract, a single point of authority to manage operations of the database;

(C) incorporate biobanking data from federally conducted or supported genomics initiatives, as feasible;

(D) encourage voluntary submission of biobanking data obtained or analyzed with private or non-Federal funds;

(E) facilitate submission of data, including secure and efficient electronic submission;

(F) allow public use of data only—

(i) with appropriate privacy safeguards in place; and

(ii) for health research purposes;

(G) determine appropriate procedures for access by nongovernmental entities to biobank

data for research and development of new or improved tests and treatments, and submission of data generated from such samples to the Food and Drug Administration as part of the approval process for drugs and devices;

(H) conduct, directly or by contract, analytical research, including clinical, epidemiological, and social research, using biobank data; and

(I) make analytic findings from biobanking initiatives supported by Federal funding publicly available within an appropriate timeframe to be determined by the Secretary.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the submission or acceptance of biological specimens.

(c) BIOBANK INITIATIVES GRANTS.—

(1) IN GENERAL.—The Secretary shall establish a grant program for eligible entities to develop or expand biobanking initiatives to increase understanding of how genomics interacts with environmental factors to cause disease, and to accelerate the development of genomic-based tests and treatments.

(2) ELIGIBLE ENTITIES.—

(A) IN GENERAL.—For purposes of this subsection, eligible entities include academic medical centers and other entities determined appropriate by the Secretary. Eligible entities desiring a grant under this subsection shall submit an application to the Secretary in accordance with this subsection, at such time, in such manner, and containing such additional information as the Secretary may require.

(B) PRIORITY.—Academic medical centers that partner with health care professionals within their communities in order to obtain diverse genomic samples shall be given priority for awards made under this subsection.

(3) REQUIREMENTS.—The Secretary shall ensure that biobanks supported by grant awards under this subsection—

(A) adhere to guidelines and recommendations developed pursuant to section 4;

(B) are established to complement activities related to the implementation of current Federal biobanking research initiatives, as feasible;

(C) are based on well-defined populations, including population-based registries of disease and family-based registries;

(D) collect data from participants with diverse genomic profiles, demographics, environmental exposures, and presence or absence of health conditions and diseases, as appropriate;

(E) meet quality standards developed by the IWG pursuant to section 4 for the collection, processing, archiving, storage, and dissemination of data;

(F) have practical experience and demonstrated expertise in genomics and its clinical and public health applications;

(G) establish mechanisms to ensure patient privacy and protection of information from non-health applications and, as feasible, patient access to genomic samples for clinical testing purposes; and

(H) contribute genomic and associated clinical and environmental data and analyses to the national biobanking distributed database, established pursuant to subsection (b).

(4) USE OF FUNDS.—An eligible entity that receives a grant under this subsection shall use the

grant funds to develop or expand a biobanking initiative, which may include the following activities:

(A) Support for scientific and community advisory committees.

(B) Recruitment and education of participants.

(C) Development of consent protocols.

(D) Obtaining genetic samples and associated environmental and clinical information.

(E) Establishment and maintenance of secure storage for genetic samples and clinical information.

(F) Conduct of data analyses and evidence-based systemic reviews that allow for the following:

(i) Identification of biomarkers and other surrogate markers to improve predictions of onset of disease, response to therapy, and clinical outcomes.

(ii) Increased understanding of gene environment interactions.

(iii) Development of genetic screening, diagnostic, and therapeutic interventions.

(iv) Genotypic characterization of tissue samples.

(G) Other activities, as determined appropriate by the Secretary.

(5) QUALITY ASSURANCE.—The Secretary may enter into a contract with an external entity to evaluate grantees under this subsection to ensure that quality standards are met.

(d) APPLICATION OF PRIVACY RULES.—Nothing in this Act or the amendments made by this Act shall be construed to supercede the requirements for the protection of patient privacy under—

(1) the Federal regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note);

(2) sections 552 and 552a of title 5, United States Code (5 U.S.C. App.); or

(3) the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233).

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $150,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2014.

SEC. 6. GENOMICS WORKFORCE AND TRAINING.

(a) GENETICS AND GENOMICS TRAINING.—The Secretary, directly or through contracts or grants to eligible

entities, which shall include professional genetics and genomics societies, academic institutions, and other entities as determined appropriate by the Secretary, shall improve the adequacy of genetics and genomics training for diagnosis, treatment, and counseling of adults and children for both rare and common disorders, through support of efforts to—

(1) develop and disseminate model training program and residency curricula and teaching materials that reflect the new knowledge and evolving practice of genetics and genomics;

(2) assist the review of board and other certifying examinations by professional societies and accreditation bodies to ensure adequate focus on the fundamental principles of genomics; and

(3) identify and evaluate options for distance or on-line learning for degree or continuing education programs.

(b) INTEGRATION.—The Secretary, in collaboration with medical professional societies and accreditation bodies and associations of health professional schools, shall support initiatives to increase the integration of genetics and genomics into all aspects of clinical and public health practice by promoting genetics and genomics competency across all clinical, public health, and laboratory disciplines

through the development and dissemination of health professional guidelines which shall—

(1) include focus on appropriate techniques for collection and storage of genomics samples, administration and interpretation of genetic and genomic tests, and subsequent clinical and public health decisionmaking; and

(2) specifically target health professionals without formal training or experience in the field of genomics.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2014.

SEC. 7. REALIZING THE POTENTIAL OF PERSONALIZED MEDICINE.

(a) PUBLIC REGISTRY OF INFORMATION ON VALIDITY OF LABORATORY-DEVELOPED GENETIC TESTS.—

(1) REGISTRY.—

(A) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

''(o) REGISTRY ON ANALYTICAL AND CLINICAL VALIDITY OF LABORATORY-DEVELOPED GENETIC TESTS.—

''(1) The Secretary shall establish and maintain a registry on the analytical and clinical validity of laboratory-developed genetic tests.

''(2) The registry under paragraph (1) shall consist of information on the analytical and clinical validity of laboratory-developed genetic tests submitted to the Secretary—

''(A) under section 510(c), 515, or 520 for clearance or approval of such tests (whether submitted before or after the date of the enactment of this subsection); and

''(B) under paragraph (3).

''(3)(A) Unless a laboratory-developed genetic test is cleared under section 510(k) or approved under section 515 or 520(m) for its intended use, the manufacturer of the test shall electronically submit to the Secretary information (in a form specified by the Secretary and certified as truthful and accurate) on the analytical and clinical validity of the test for its intended use.

''(B) If the intended use of a laboratory-developed genetic test is limited solely to the measurement of an analytical property or characteristic, the manufacturer of the test shall not submit any information with respect to the clinical validity of the test under subparagraph (A) other than the following statement: 'This test is intended to

measure only the property or characteristic that is reported as a result of use of the test. The test is not intended to be used to diagnose or screen for any disease or condition, or to otherwise aid in decisionmaking with respect to health, and this laboratory makes no representations as to its usefulness for any such purpose.'.

''(4) In this subsection:

''(A) The term 'genetic test' means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

''(B) The term 'laboratory-developed genetic test' means a genetic test that is designed, validated, conducted, and offered as a service by a clinical laboratory subject to section 353 of the Public Health Service Act (commonly referred to as the 'Clinical Laboratory Improvement Amendments of 1988') using either commercially available analyte specific reagents (Food and Drug Administration-regulated), reagents prepared by the laboratory (not Food and Drug Administration-regulated), or some combination thereof.''.

(B) CONFORMING AMENDMENT.—Section 501 of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is a laboratory-developed genetic test described in section 520(o)(4) and the manufacturer of the test fails to submit information with respect to the test as required by such section.''.

(2) COMPARATIVE ANALYSIS.—To inform implementation of the registry on laboratory-developed genetic tests under section 520(o) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), the Secretary shall undertake a comparative analysis of laboratory review requirements under CLIA and those of the Food and Drug Administration to—

(A) assess and reduce unnecessary differences in such requirements;

(B) eliminate redundancies and decrease the burden of review, as practicable; and

(C) specify which elements of the test constitute a device that may be regulated by the Food and Drug Administration and which elements comprise a service that may be regulated under CLIA.

(3) REGULATIONS.—Not later than 18 months after the date of the enactment of this Act, the Sec-

retary shall promulgate regulations to implement the registry on laboratory-developed genetic tests under section 520(o) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1).

(4) EFFECTIVE DATE OF SUBMISSION REQUIREMENTS.—The Secretary may not require a laboratory to submit information under section 520(o) of the Federal Food, Drug and Cosmetic Act, as added by paragraph (1), until the date that is 180 days after the regulations promulgated pursuant to paragraph (3) take effect.

(5) ADVERSE EVENTS.—The Secretary, acting through the Commissioner of Food and Drugs and the Administrator of the Centers for Medicare & Medicaid Services, shall—

(A) facilitate the use of genetic and genomic approaches, as feasible, to assess risk for, and reduce incidence of, adverse drug reactions;

(B) develop or expand adverse event reporting systems to encompass reports of adverse events resulting from genetic testing; and

(C) respond appropriately to any adverse events resulting from such testing.

(b) NATIONAL ACADEMY OF SCIENCES STUDY.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall enter into a contract with the National Research Council of the National Academy of Sciences to study and recommend appropriate incentives to encourage—

(1) codevelopment of companion diagnostic testing by a drug sponsor;

(2) development of companion diagnostic testing for already-approved drugs by the drug sponsor;

(3) companion diagnostic test development by device companies that are not affiliated with the drug sponsor; and

(4) action on other issues determined appropriate by the Secretary.

(c) FOOD AND DRUG ADMINISTRATION.—

(1) ENCOURAGEMENT OF COMPANION DIAGNOSTIC TESTING.—The Secretary, acting through the Commissioner of Food and Drugs, may encourage the sponsor of a drug or biological product—

(A) to codevelop a companion diagnostic test, after filing an investigational new drug application or a new drug application to address significant safety concerns of the drug or biological product;

(B) to develop a companion diagnostic test if phase IV data demonstrate significant safety or effectiveness concerns with use of the drug or biological product; and

(C) to relabel the drug or biological product to require validated companion diagnostic testing when evidence of improved outcomes has been established in practice or if data demonstrate significant safety concerns with use of such drug or biological product.

(2) PHARMACOGENOMIC DATA SUBMISSION.—The Secretary, acting through the Commissioner of Food and Drugs, shall encourage and facilitate voluntary pharmacogenomic data submission from drug sponsors, which may include—

(A) the development and dissemination of guidance on relevant policies, procedure and practice regarding such submission;

(B) the provision of technical assistance;

(C) the establishment of a mechanism to store, maintain, and analyze such data, in collaboration with the National Institutes of Health and the Centers for Disease Control and Prevention;

(D) determining when such data may be used to support an investigational new drug or a new drug application;

(E) the conduct of a study of the use of genomic approaches to understand and reduce adverse drug reactions; and

(F) other activities determined appropriate by the Commissioner.

(3) TERMINATION OF CERTAIN ADVERTISING CAMPAIGNS.—The Commissioner of Food and Drugs shall collaborate with the Federal Trade Commission to identify and terminate, pursuant to section 5 of the Federal Trade Commission Act (15 U.S.C. 45), advertising campaigns that make false, misleading, deceptive, or unfair claims about the benefits or risks of genetic tests.

(d) CENTERS FOR MEDICARE & MEDICAID SERVICES.—To foster adoption of genetic screening tools, the Administrator of the Centers for Medicare & Medicaid Services shall—

(1) assess and update current procedure terminology codes to encourage the rapid review and coverage of novel tests through the creation of new Healthcare Common Procedures Coding System (''HCPCS'') codes and adoption of new current pro-

cedural terminology (''CPT'') codes and without undue reliance on national coverage determinations; and

(2) determine and implement fair and reasonable coverage policies and reimbursement rates for medically necessary genetic and genomic treatments and services, including laboratory testing.

(e) CENTERS FOR DISEASE CONTROL AND PREVENTION.—

(1) DIRECT-TO-CONSUMER MARKETING.—Not later than 2 years after the date of the enactment of this Act, the Director of the Centers for Disease Control and Prevention (in this subsection referred to as the ''Director''), with respect to genetic tests for which consumers have direct access, shall—

(A) conduct an analysis of the public health impact of direct-to-consumer marketing to the extent possible from available data sources;

(B) analyze the validity of claims made in direct-to-consumer marketing to determine whether such claims are substantiated by competent and reliable scientific evidence; and

(C) make recommendations to the Secretary regarding necessary interventions to pro-

tect the public from potential harms of direct to-consumer marketing and access to genetic tests.

(2) PUBLIC AWARENESS.—The Director shall expand efforts to educate and increase awareness of the general public about genomics and its applications to improve health, prevent disease, and eliminate health disparities. Such efforts shall include the—

(A) ongoing collection of data on the awareness, knowledge, and use of genetic tests through public health surveillance systems, and analysis of the impact of such tests on population health; and

(B) integration of the use of validated genetic and genomic tests in public health programs as appropriate.

(f) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.—The Director of the Agency for Healthcare Research and Quality, after consultation with the IWG and other public and private organizations based in the United States and abroad, as appropriate, shall support the assessment of the clinical utility and cost-effectiveness of companion diagnostic tests that guide prescribing decisions, through research that—

(1) develops standardized tools and methodologies to assess the clinical utility and cost-effectiveness of such tests, as well as criteria for use;

(2) establishes and validates drug dosing algorithms for which such tests can improve outcomes, taking into consideration—

(A) a reduction in toxicity, adverse events, and mortality;

(B) improved clinical outcomes and quality of life, including decreased requirements for monitoring and laboratory testing; and

(C) the impact on the direct and indirect costs of health care, which may include costs due to length of hospital stay, length of time to identify safe and effective dosing for patients, toxicity and adverse events, and other measures of health care utilization and outcomes;

(3) supports and expedites the development of clinical decision tools for clinical use of genetic tests, as warranted; and

(4) prioritizes the development of such tests for diseases and health conditions that have a significant public health impact because of prevalence, risk of complications from treatment, and other factors determined appropriate by the Director.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out subsections (a), (c), (d), and (f), there are authorized to be appropriated $30,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2014.

(2) REGISTRY ON ANALYTICAL AND CLINICAL VALIDITY OF LABORATORY-DEVELOPED GENETIC TESTS; ADVERSE EVENT REPORTING.—To carry out subsection (b), there are authorized to be appropriated $10,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2014.

(3) CDC PUBLIC AWARENESS ACTIVITIES.—To carry out subsection (e), there are authorized to be appropriated $30,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2014.

SEC. 8. TAX CREDIT FOR RESEARCH AND DEVELOPMENT RELATED TO COMPANION DIAGNOSTIC TESTS.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 45Q. COMPANION DIAGNOSTIC TEST CREDIT.

''(a) ALLOWANCE OF CREDIT.—For purposes of section 38, in the case of an eligible taxpayer, the companion diagnostic test credit for any taxable year is an amount equal to the qualified research expenses paid or incurred by the taxpayer during the taxable year in connection with the development of a qualified companion diagnostic test.

''(b) ELIGIBLE TAXPAYER.—For purposes of this section, the term 'eligible taxpayer' means a taxpayer who has been requested to develop a qualified companion diagnostic test by the Secretary of Health and Human Services in connection with a drug—

''(1) for which an application has been submitted under section 501(b)(1) of the Federal Food, Drug, and Cosmetic Act, or

''(2) for which an application has been approved under such section.

''(c) QUALIFIED COMPANION DIAGNOSTIC TEST.—For purposes of this section, the term 'qualified companion diagnostic test' means a diagnostic test in connection with a drug which—

''(1) is designed to provide information which can be used to increase the safety or effectiveness of the drug, and

''(2) is approved by the Secretary of Health and Human Services.

''(d) QUALIFIED RESEARCH EXPENSES.—For purposes of this section, the term 'qualified research expenses' has the meaning given to such term under section 41(b).

''(e) NO DOUBLE BENEFIT.—

''(1) COORDINATION WITH OTHER DEDUCTIONS AND CREDITS.—Except as provided in paragraph (2), the amount of any deduction or other credit allowable under this chapter for any expense taken into account in determining the amount of the credit under subsection (a) shall be reduced by the amount of the credit under subsection (a) attributable to such expense.

''(2) RESEARCH AND DEVELOPMENT COSTS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), any amount which is taken into account in determining the amount of the credit under subsection (a) for any taxable year shall not be taken into account for purposes of determining the credit under section 41 for such taxable year.

''(B) COSTS TAKEN INTO ACCOUNT IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any amount taken into account in determining the amount of the credit under subsection (a) for any taxable year shall be

taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(f) REGULATIONS.—The Secretary, in consultation with the Secretary of Health and Human Services, shall promulgate such regulations as are necessary to carry out the purposes of this section.

''(g) TERMINATION.—This section shall not apply to expenses paid or incurred in taxable years beginning after the date which is 5 years after the date of the enactment of this section.''.

(b) CREDIT TREATED AS PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986 is amended by striking ''plus'' at the end of paragraph (32), by striking the period at the end of paragraph (33) and inserting '', plus'', and by adding at the end the following new paragraph:

''(34) the companion diagnostic test credit determined under section 45Q(a).''.

(c) CLERICAL AMENDMENT.—The table of sections for subpart D of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 45Q. Companion diagnostic test credit.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to expenses paid or incurred in

taxable years beginning after the date of the enactment of this Act.

○