

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Genomics and Person-
5 alized Medicine Act of 2008”.

1 **SEC. 2. FINDINGS.**

2 The Congress makes the following findings:

3 (1) The completion of the Human Genome
4 Project in 2003 paved the way for a more sophisti-
5 cated understanding of diseases and drug responses,
6 which has contributed to the advent of “personalized
7 medicine”.

8 (2) Personalized medicine is the application of
9 genomic and molecular data to better target the de-
10 livery of health care, facilitate the discovery and clin-
11 ical testing of new products, help determine a per-
12 son’s predisposition to a particular disease or condi-
13 tion, and identify any targeted prevention strategies
14 for that predisposition.

15 (3) Many commonly-used drugs are typically ef-
16 fective in only 40 to 60 percent of the patient popu-
17 lation.

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

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

1 (6) Pharmacogenomics is the study of drug re-
2 sponse in the context of the entire genome. This rel-
3 atively new field combines pharmacology (the science
4 of drugs) and genomics (the study of genes and
5 their functions) to develop safer and more effective
6 medications and dosing regimens that will be tai-
7 lored to an individual's genetic makeup.

8 (7) The cancer drug Gleevec was developed
9 based on knowledge of the chromosomal trans-
10 location that causes chronic myelogenous leukemia,
11 which is characterized by an abnormal growth in the
12 number of white blood cells. The mean 5-year sur-
13 vival for affected patients who are treated with
14 Gleevec is 95 percent, which contrasts to a 5-year
15 survival of 50 percent for patients treated with older
16 therapies.

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

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

1 elevates patient risk for bleeding in the head or gas
2 trointestinal tract, both of which are associated with
3 increased rates of hospitalization, disability, and
4 death. Pharmacogenomic researchers have identified
5 and developed tests for genetic variants in the
6 cytochrome P450 metabolizing enzyme (CYP2C9)
7 and vitamin K epoxide reductase complex that in-
8 crease risk for these adverse events. By using a com-
9 panion diagnostic test for these two genes, physi-
10 cians can modify the dosing regimen and decrease
11 the likelihood of adverse events.

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

21 (11) Research into the genetics of breast cancer
22 identified two pivotal genes, BRCA1 and BRCA2,
23 mutations which correspond to a significantly in-
24 creased lifetime risk of developing breast and ovar-
25 ian cancer. Individuals in affected families or with

1 specific risk factors may use genetic testing to iden-
2 tify whether they carry mutations in these genes and
3 to inform their decisions about treatment options,
4 including prophylactic mastectomy and oopho-
5 rectomy.

6 (12) Realizing the promise of personalized med-
7 icine will require continued Federal leadership and
8 agency collaboration, expansion, and acceleration of
9 genomics research, a capable genomics workforce, in-
10 centives to encourage development and collection of
11 data on the analytic and clinical validity and clinical
12 utility of genomic tests and therapies, and improved
13 regulation over the quality of genetic tests, direct-to-
14 consumer advertising of genetic tests, and use of
15 personal genomic information.

16 **SEC. 3. DEFINITIONS.**

17 In this Act:

18 (1) **BIOBANK.**—The term “biobank” means a
19 shared repository of human biological specimens that
20 may also include data associated with such speci-
21 mens collected for medical or research purposes.
22 Human biological specimens may include body
23 fluids, tissues, blood, cells, or materials derived from
24 these sources, and data associated with such speci-

1 mens may include health information or environ-
2 mental data.

3 (2) BIOMARKER.—The term “biomarker”
4 means an analyte found in or derived from a patient
5 specimen that is objectively measured and evaluated
6 as an indicator of normal biologic processes, patho-
7 genic processes, or pharmacologic responses to a
8 therapeutic intervention.

9 (3) CLIA.—The term “CLIA” means section
10 353 of the Public Health Service Act (42 U.S.C.
11 263a; commonly referred to as the “Clinical Labora-
12 tory Improvement Amendments of 1988”).

13 (4) ENVIRONMENT.—The term “environment”
14 means conditions or circumstances that are non-
15 genetic but may have a health impact.

16 (5) GENETIC TEST.—The term “genetic test”
17 means an analysis of human DNA, RNA, chro-
18 mosomes, proteins, or metabolites, that detects
19 genotypes, mutations, or chromosomal changes.

20 (6) IWG.—The term “IWG” means the
21 Genomics and Personalized Medicine Interagency
22 Working Group established pursuant to section 4.

23 (7) PHARMACOGENETIC TEST.—

24 (A) IN GENERAL.—The term “pharma-
25 cogenetic test” means a genetic test intended to

1 identify individual variations in DNA sequence
2 related to drug absorption and disposition
3 (pharmacokinetics) or drug action (pharmaco-
4 dynamics), including polymorphic variation in
5 the genes that encode the functions of trans-
6 porters, receptors, metabolizing enzymes, and
7 other proteins, or other genomic variations, in-
8 cluding rearrangements, insertions, and dele-
9 tions, or alterations in gene expression or inac-
10 tivation, that may be correlated with pharma-
11 cological function and therapeutic response.

12 (B) VARIATIONS AND ALTERATIONS.—For
13 purposes of this paragraph, the variations or al-
14 terations referred to in subparagraph (A) may
15 be a pattern or profile of change, rather than
16 a change in an individual marker.

17 (8) SECRETARY.—The term “Secretary” means
18 the Secretary of Health and Human Services.

19 **SEC. 4. GENOMICS AND PERSONALIZED MEDICINE INTER**
20 **AGENCY WORKING GROUP.**

21 (a) IN GENERAL.—Not later than 90 days after the
22 date of the enactment of this Act, the Secretary shall es-
23 tablish within the Department of Health and Human
24 Services the Genomics and Personalized Medicine Inter-
25 agency Working Group (“IWG”).

1 (b) DUTIES.—The IWG shall facilitate collaboration,
2 coordination, and integration of activities within the De-
3 partment of Health and Human Services and other Fed-
4 eral agencies, and among such agencies and relevant pub-
5 lic and private entities, by—

6 (1) reviewing current and proposed genomic ini-
7 tiatives, in order to identify shared interests and le-
8 verage resources;

9 (2) prioritizing new genomic initiatives, based
10 on areas of need as measured by public health im-
11 pact;

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

16 (4) establishing and disseminating quality
17 standards and guidelines for the collection, proc-
18 essing, archiving, storage, and dissemination of
19 genomic samples and data for research and clinical
20 purposes;

21 (5) developing and promulgating guidelines re-
22 garding procedures, protocols, and policies for the
23 safeguarding of the privacy of biobank subjects, in
24 accordance with the Office for Human Research
25 Protection and Clinical Research Policy Analysis and

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

3 (6) reviewing and making recommendations to
4 address ownership and patient access issues with re-
5 spect to genomic samples and analyses;

6 (7) developing and promulgating guidelines re-
7 garding procedures, protocols, and policies for access
8 to patient data, genomic samples, and associated
9 health information by nongovernmental entities for
10 research purposes;

11 (8) developing and disseminating guidelines for
12 constructing informed consent forms that ensure pa-
13 tient privacy and confidentiality of associated clinical
14 data and information, understanding of research
15 procedures, benefits, risks, rights, and responsibil-
16 ities, and continuous voluntary participation; and

17 (9) providing recommendations for the estab-
18 lishment of a distributed database, pursuant to sec-
19 tion 5.

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

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

24 (1) the National Institutes of Health;

1 (2) the Centers for Disease Control and Preven-
2 tion;

3 (3) the Food and Drug Administration;

4 (4) the Health Resources and Services Adminis-
5 tration;

6 (5) the Office of Minority Health;

7 (6) the Agency for Healthcare Research and
8 Quality;

9 (7) the Centers for Medicare & Medicaid Serv-
10 ices;

11 (8) the Veterans Health Administration;

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

14 (10) the Department of Energy;

15 (11) the Armed Forces Institute of Pathology;

16 (12) the Indian Health Service;

17 (13) other Federal departments; and

18 (14) such other agencies as determined appro-
19 priate by the Secretary.

20 (e) PUBLIC INPUT.—The IWG shall solicit input
21 from relevant stakeholders with respect to meeting the du-
22 ties described in subsection (b).

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

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

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

7 (h) AUTHORIZATION OF APPROPRIATIONS.—There is
8 authorized to be appropriated to carry out this section,
9 \$5,000,000 for each of fiscal years 2009 and 2010.

10 **SEC. 5. EXPANSION AND ACCELERATION OF GENETIC AND**
11 **GENOMICS RESEARCH.**

12 (a) GENETICS AND GENOMICS RESEARCH.—The Sec-
13 retary shall expand and accelerate research and programs
14 to collect genetic and genomic data that will advance the
15 field of genomics and personalized medicine, with
16 prioritized focus on—

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

19 (2) population-based studies of genotype preva-
20 lence, gene-disease association, gene-drug response
21 association, and gene-environment interactions;

22 (3) systematic review and synthesis of the re-
23 sults of population-based studies using methods of
24 human genome epidemiology;

1 (4) translation of genomic information into mo-
2 lecular genetic screening tools, diagnostics, and
3 therapeutics, through well-conducted clinical trials
4 and studies;

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

8 (6) systematic review of data on analytic valid-
9 ity and clinical validity of molecular genetic tests;

10 (7) comprehensive studies of clinical utility, in-
11 cluding cost-effectiveness and cost-benefit analyses,
12 of molecular genetic tests and therapeutics;

13 (8) population-based studies to assess the
14 awareness, knowledge, and use of genetic tests and
15 their impact on the population health and health dis-
16 parities; and

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

19 (b) NATIONAL BIOBANKING INITIATIVE.—

20 (1) IN GENERAL.—The Secretary shall advance
21 the field of genomics and personalized medicine
22 through establishment of a national biobanking dis-
23 tributed database for the collection and integration
24 of genomic data, and associated environmental and

1 clinical health information, which shall facilitate syn-
2 thesis and pooled analysis of such data.

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

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

9 (B) establish, directly or by contract, a sin-
10 gle point of authority to manage operations of
11 the database;

12 (C) incorporate biobanking data from fed-
13 erally conducted or supported genomics initia-
14 tives, as feasible;

15 (D) encourage voluntary submission of bio-
16 banking data obtained or analyzed with private
17 or non-Federal funds;

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

20 (F) allow public use of data only—

21 (i) with appropriate privacy safe-
22 guards in place; and

23 (ii) for health research purposes;

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

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

6 (H) conduct, directly or by contract, ana-
7 lytical research, including clinical, epidemiolog-
8 ical, and social research, using biobank data;
9 and

10 (I) make analytic findings from biobanking
11 initiatives supported by Federal funding pub-
12 licly available within an appropriate timeframe
13 to be determined by the Secretary.

14 (3) RULE OF CONSTRUCTION.—Nothing in this
15 subsection shall be construed to require the submis-
16 sion or acceptance of biological specimens.

17 (c) BIOBANK INITIATIVES GRANTS.—

18 (1) IN GENERAL.—The Secretary shall establish
19 a grant program for eligible entities to develop or ex-
20 pand biobanking initiatives to increase under-
21 standing of how genomics interacts with environ-
22 mental factors to cause disease, and to accelerate
23 the development of genomic-based tests and treat-
24 ments.

25 (2) ELIGIBLE ENTITIES.—

1 (A) IN GENERAL.—For purposes of this
2 subsection, eligible entities include academic
3 medical centers and other entities determined
4 appropriate by the Secretary. Eligible entities
5 desiring a grant under this subsection shall
6 submit an application to the Secretary in ac-
7 cordance with this subsection, at such time, in
8 such manner, and containing such additional
9 information as the Secretary may require.

10 (B) PRIORITY.—Academic medical centers
11 that partner with health care professionals
12 within their communities in order to obtain di-
13 verse genomic samples shall be given priority
14 for awards made under this subsection.

15 (3) REQUIREMENTS.—The Secretary shall en-
16 sure that biobanks supported by grant awards under
17 this subsection—

18 (A) adhere to guidelines and recommenda-
19 tions developed pursuant to section 4;

20 (B) are established to complement activi-
21 ties related to the implementation of current
22 Federal biobanking research initiatives, as fea-
23 sible;

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

4 (D) collect data from participants with di-
5 verse genomic profiles, demographics, environ-
6 mental exposures, and presence or absence of
7 health conditions and diseases, as appropriate;

8 (E) meet quality standards developed by
9 the IWG pursuant to section 4 for the collec-
10 tion, processing, archiving, storage, and dis-
11 semination of data;

12 (F) have practical experience and dem-
13 onstrated expertise in genomics and its clinical
14 and public health applications;

15 (G) establish mechanisms to ensure patient
16 privacy and protection of information from non-
17 health applications and, as feasible, patient ac-
18 cess to genomic samples for clinical testing pur-
19 poses; and

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

24 (4) USE OF FUNDS.—An eligible entity that re-
25 ceives a grant under this subsection shall use the

1 grant funds to develop or expand a biobanking ini-
2 tiative, which may include the following activities:

3 (A) Support for scientific and community
4 advisory committees.

5 (B) Recruitment and education of partici-
6 pants.

7 (C) Development of consent protocols.

8 (D) Obtaining genetic samples and associ-
9 ated environmental and clinical information.

10 (E) Establishment and maintenance of se-
11 cure storage for genetic samples and clinical in-
12 formation.

13 (F) Conduct of data analyses and evidence-
14 based systemic reviews that allow for the fol-
15 lowing:

16 (i) Identification of biomarkers and
17 other surrogate markers to improve pre-
18 dictions of onset of disease, response to
19 therapy, and clinical outcomes.

20 (ii) Increased understanding of gene
21 environment interactions.

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

24 (iv) Genotypic characterization of tis-
25 sue samples.

1 (G) Other activities, as determined appro-
2 priate by the Secretary.

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

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

11 (1) the Federal regulations promulgated under
12 section 264(c) of the Health Insurance Portability
13 and Accountability Act of 1996 (42 U.S.C. 1320d–
14 2 note);

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

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

19 (e) AUTHORIZATION OF APPROPRIATIONS.—There
20 are authorized to be appropriated to carry out this section,
21 \$150,000,000 for fiscal year 2009, and such sums as may
22 be necessary for each of fiscal years 2010 through 2014.

23 **SEC. 6. GENOMICS WORKFORCE AND TRAINING.**

24 (a) GENETICS AND GENOMICS TRAINING.—The Sec-
25 retary, directly or through contracts or grants to eligible

1 entities, which shall include professional genetics and
2 genomics societies, academic institutions, and other enti-
3 ties as determined appropriate by the Secretary, shall im-
4 prove the adequacy of genetics and genomics training for
5 diagnosis, treatment, and counseling of adults and chil-
6 dren for both rare and common disorders, through support
7 of efforts to—

8 (1) develop and disseminate model training pro-
9 gram and residency curricula and teaching materials
10 that reflect the new knowledge and evolving practice
11 of genetics and genomics;

12 (2) assist the review of board and other certi-
13 fying examinations by professional societies and ac-
14 creditation bodies to ensure adequate focus on the
15 fundamental principles of genomics; and

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

19 (b) INTEGRATION.—The Secretary, in collaboration
20 with medical professional societies and accreditation bod-
21 ies and associations of health professional schools, shall
22 support initiatives to increase the integration of genetics
23 and genomics into all aspects of clinical and public health
24 practice by promoting genetics and genomics competency
25 across all clinical, public health, and laboratory disciplines

1 through the development and dissemination of health pro-
2 fessional guidelines which shall—

3 (1) include focus on appropriate techniques for
4 collection and storage of genomics samples, adminis-
5 tration and interpretation of genetic and genomic
6 tests, and subsequent clinical and public health deci-
7 sionmaking; and

8 (2) specifically target health professionals with-
9 out formal training or experience in the field of
10 genomics.

11 (c) AUTHORIZATION OF APPROPRIATIONS.—There
12 are authorized to be appropriated to carry out this section
13 \$10,000,000 for fiscal year 2009, and such sums as may
14 be necessary for each of fiscal years 2010 through 2014.

15 **SEC. 7. REALIZING THE POTENTIAL OF PERSONALIZED**
16 **MEDICINE.**

17 (a) PUBLIC REGISTRY OF INFORMATION ON VALID-
18 ITY OF LABORATORY-DEVELOPED GENETIC TESTS.—

19 (1) REGISTRY.—

20 (A) IN GENERAL.—Section 520 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C.
22 360j) is amended by adding at the end the fol-
23 lowing:

24 “(o) REGISTRY ON ANALYTICAL AND CLINICAL VA-
25 LIDITY OF LABORATORY-DEVELOPED GENETIC TESTS.—

1 “(1) The Secretary shall establish and maintain a
2 registry on the analytical and clinical validity of labora-
3 tory-developed genetic tests.

4 “(2) The registry under paragraph (1) shall consist
5 of information on the analytical and clinical validity of lab-
6 oratory-developed genetic tests submitted to the Sec-
7 retary—

8 “(A) under section 510(c), 515, or 520 for
9 clearance or approval of such tests (whether sub-
10 mitted before or after the date of the enactment of
11 this subsection); and

12 “(B) under paragraph (3).

13 “(3)(A) Unless a laboratory-developed genetic test is
14 cleared under section 510(k) or approved under section
15 515 or 520(m) for its intended use, the manufacturer of
16 the test shall electronically submit to the Secretary infor-
17 mation (in a form specified by the Secretary and certified
18 as truthful and accurate) on the analytical and clinical va-
19 lidity of the test for its intended use.

20 “(B) If the intended use of a laboratory-developed ge-
21 netic test is limited solely to the measurement of an ana-
22 lytical property or characteristic, the manufacturer of the
23 test shall not submit any information with respect to the
24 clinical validity of the test under subparagraph (A) other
25 than the following statement: ‘This test is intended to

1 measure only the property or characteristic that is re-
2 ported as a result of use of the test. The test is not in-
3 tended to be used to diagnose or screen for any disease
4 or condition, or to otherwise aid in decisionmaking with
5 respect to health, and this laboratory makes no represen-
6 tations as to its usefulness for any such purpose.’.

7 “(4) In this subsection:

8 “(A) The term ‘genetic test’ means an analysis
9 of human DNA, RNA, chromosomes, proteins, or
10 metabolites, that detects genotypes, mutations, or
11 chromosomal changes.

12 “(B) The term ‘laboratory-developed genetic
13 test’ means a genetic test that is designed, validated,
14 conducted, and offered as a service by a clinical lab-
15 oratory subject to section 353 of the Public Health
16 Service Act (commonly referred to as the ‘Clinical
17 Laboratory Improvement Amendments of 1988’)
18 using either commercially available analyte specific
19 reagents (Food and Drug Administration-regulated),
20 reagents prepared by the laboratory (not Food and
21 Drug Administration-regulated), or some combina-
22 tion thereof.”.

23 (B) CONFORMING AMENDMENT.—Section
24 501 of the Federal Food, Drug, and Cosmetic

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

3 “(j) If it is a laboratory-developed genetic test de-
4 scribed in section 520(o)(4) and the manufacturer of the
5 test fails to submit information with respect to the test
6 as required by such section.”.

7 (2) COMPARATIVE ANALYSIS.—To inform im-
8 plementation of the registry on laboratory-developed
9 genetic tests under section 520(o) of the Federal
10 Food, Drug, and Cosmetic Act, as added by para-
11 graph (1), the Secretary shall undertake a compara-
12 tive analysis of laboratory review requirements under
13 CLIA and those of the Food and Drug Administra-
14 tion to—

15 (A) assess and reduce unnecessary dif-
16 ferences in such requirements;

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

19 (C) specify which elements of the test con-
20 stitute a device that may be regulated by the
21 Food and Drug Administration and which ele-
22 ments comprise a service that may be regulated
23 under CLIA.

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

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

5 (4) EFFECTIVE DATE OF SUBMISSION REQUIRE-
6 MENTS.—The Secretary may not require a labora-
7 tory to submit information under section 520(o) of
8 the Federal Food, Drug and Cosmetic Act, as added
9 by paragraph (1), until the date that is 180 days
10 after the regulations promulgated pursuant to para-
11 graph (3) take effect.

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

16 (A) facilitate the use of genetic and
17 genomic approaches, as feasible, to assess risk
18 for, and reduce incidence of, adverse drug reac-
19 tions;

20 (B) develop or expand adverse event re-
21 porting systems to encompass reports of ad-
22 verse events resulting from genetic testing; and

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

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

7 (1) codevelopment of companion diagnostic test-
8 ing by a drug sponsor;

9 (2) development of companion diagnostic test-
10 ing for already-approved drugs by the drug sponsor;

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

14 (4) action on other issues determined appro-
15 priate by the Secretary.

16 (c) FOOD AND DRUG ADMINISTRATION.—

17 (1) ENCOURAGEMENT OF COMPANION DIAG-
18 NOSTIC TESTING.—The Secretary, acting through
19 the Commissioner of Food and Drugs, may encour-
20 age the sponsor of a drug or biological product—

21 (A) to codevelop a companion diagnostic
22 test, after filing an investigational new drug ap-
23 plication or a new drug application to address
24 significant safety concerns of the drug or bio-
25 logical product;

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

5 (C) to relabel the drug or biological prod-
6 uct to require validated companion diagnostic
7 testing when evidence of improved outcomes has
8 been established in practice or if data dem-
9 onstrate significant safety concerns with use of
10 such drug or biological product.

11 (2) PHARMACOGENOMIC DATA SUBMISSION.—
12 The Secretary, acting through the Commissioner of
13 Food and Drugs, shall encourage and facilitate vol-
14 untary pharmacogenomic data submission from drug
15 sponsors, which may include—

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

19 (B) the provision of technical assistance;

20 (C) the establishment of a mechanism to
21 store, maintain, and analyze such data, in col-
22 laboration with the National Institutes of
23 Health and the Centers for Disease Control and
24 Prevention;

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

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

7 (F) other activities determined appropriate
8 by the Commissioner.

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

17 (d) CENTERS FOR MEDICARE & MEDICAID SERV-
18 ICES.—To foster adoption of genetic screening tools, the
19 Administrator of the Centers for Medicare & Medicaid
20 Services shall—

21 (1) assess and update current procedure termi-
22 nology codes to encourage the rapid review and cov-
23 erage of novel tests through the creation of new
24 Healthcare Common Procedures Coding System
25 (“HCPCS”) codes and adoption of new current pro-

1 cedural terminology (“CPT”) codes and without
2 undue reliance on national coverage determinations;
3 and

4 (2) determine and implement fair and reason-
5 able coverage policies and reimbursement rates for
6 medically necessary genetic and genomic treatments
7 and services, including laboratory testing.

8 (e) CENTERS FOR DISEASE CONTROL AND PREVEN-
9 TION.—

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

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

20 (B) analyze the validity of claims made in
21 direct-to-consumer marketing to determine
22 whether such claims are substantiated by com-
23 petent and reliable scientific evidence; and

24 (C) make recommendations to the Sec-
25 retary regarding necessary interventions to pro-

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

4 (2) PUBLIC AWARENESS.—The Director shall
5 expand efforts to educate and increase awareness of
6 the general public about genomics and its applica-
7 tions to improve health, prevent disease, and elimi-
8 nate health disparities. Such efforts shall include
9 the—

10 (A) ongoing collection of data on the
11 awareness, knowledge, and use of genetic tests
12 through public health surveillance systems, and
13 analysis of the impact of such tests on popu-
14 lation health; and

15 (B) integration of the use of validated ge-
16 netic and genomic tests in public health pro-
17 grams as appropriate.

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

1 (1) develops standardized tools and methodolo-
2 gies to assess the clinical utility and cost-effective-
3 ness of such tests, as well as criteria for use;

4 (2) establishes and validates drug dosing algo-
5 rithms for which such tests can improve outcomes,
6 taking into consideration—

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

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

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

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

21 (4) prioritizes the development of such tests for
22 diseases and health conditions that have a signifi-
23 cant public health impact because of prevalence, risk
24 of complications from treatment, and other factors
25 determined appropriate by the Director.

1 (g) AUTHORIZATION OF APPROPRIATIONS.—

2 (1) IN GENERAL.—To carry out subsections (a),
3 (c), (d), and (f), there are authorized to be appro-
4 priated \$30,000,000 for fiscal year 2009, and such
5 sums as may be necessary for each of fiscal years
6 2010 through 2014.

7 (2) REGISTRY ON ANALYTICAL AND CLINICAL
8 VALIDITY OF LABORATORY-DEVELOPED GENETIC
9 TESTS; ADVERSE EVENT REPORTING.—To carry out
10 subsection (b), there are authorized to be appro-
11 priated \$10,000,000 for fiscal year 2009, and such
12 sums as may be necessary for each of fiscal years
13 2010 through 2014.

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

19 **SEC. 8. TAX CREDIT FOR RESEARCH AND DEVELOPMENT**
20 **RELATED TO COMPANION DIAGNOSTIC**
21 **TESTS.**

22 (a) IN GENERAL.—Subpart D of part IV of sub-
23 chapter A of chapter 1 of the Internal Revenue Code of
24 1986 is amended by adding at the end the following new
25 section:

1 **“SEC. 45Q. COMPANION DIAGNOSTIC TEST CREDIT.**

2 “(a) ALLOWANCE OF CREDIT.—For purposes of sec-
3 tion 38, in the case of an eligible taxpayer, the companion
4 diagnostic test credit for any taxable year is an amount
5 equal to the qualified research expenses paid or incurred
6 by the taxpayer during the taxable year in connection with
7 the development of a qualified companion diagnostic test.

8 “(b) ELIGIBLE TAXPAYER.—For purposes of this
9 section, the term ‘eligible taxpayer’ means a taxpayer who
10 has been requested to develop a qualified companion diag-
11 nostic test by the Secretary of Health and Human Serv-
12 ices in connection with a drug—

13 “(1) for which an application has been sub-
14 mitted under section 501(b)(1) of the Federal Food,
15 Drug, and Cosmetic Act, or

16 “(2) for which an application has been ap-
17 proved under such section.

18 “(c) QUALIFIED COMPANION DIAGNOSTIC TEST.—
19 For purposes of this section, the term ‘qualified com-
20 panion diagnostic test’ means a diagnostic test in connec-
21 tion with a drug which—

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

25 “(2) is approved by the Secretary of Health and
26 Human Services.

1 “(d) QUALIFIED RESEARCH EXPENSES.—For pur-
2 poses of this section, the term ‘qualified research expenses’
3 has the meaning given to such term under section 41(b).

4 “(e) NO DOUBLE BENEFIT.—

5 “(1) COORDINATION WITH OTHER DEDUCTIONS
6 AND CREDITS.—Except as provided in paragraph
7 (2), the amount of any deduction or other credit al-
8 lowable under this chapter for any expense taken
9 into account in determining the amount of the credit
10 under subsection (a) shall be reduced by the amount
11 of the credit under subsection (a) attributable to
12 such expense.

13 “(2) RESEARCH AND DEVELOPMENT COSTS.—

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

21 “(B) COSTS TAKEN INTO ACCOUNT IN DE-
22 TERMINING BASE PERIOD RESEARCH EX-
23 PENSES.—Any amount taken into account in
24 determining the amount of the credit under
25 subsection (a) for any taxable year shall be

1 taken into account in determining base period
2 research expenses for purposes of applying sec-
3 tion 41 to subsequent taxable years.

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

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

12 (b) CREDIT TREATED AS PART OF GENERAL BUSI-
13 NESS CREDIT.—Section 38(b) of the Internal Revenue
14 Code of 1986 is amended by striking “plus” at the end
15 of paragraph (32), by striking the period at the end of
16 paragraph (33) and inserting “, plus”, and by adding at
17 the end the following new paragraph:

18 “(34) the companion diagnostic test credit de-
19 termined under section 45Q(a).”.

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

“Sec. 45Q. Companion diagnostic test credit.”.

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

- 1 taxable years beginning after the date of the enactment
- 2 of this Act.

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