

109TH CONGRESS
2^D SESSION

S. 3822

To improve access to and appropriate utilization of valid, reliable and accurate molecular genetic tests by all populations thus helping to secure the promise of personalized medicine for all Americans.

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2006

Mr. OBAMA introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To improve access to and appropriate utilization of valid, reliable and accurate molecular genetic tests by all populations thus helping to secure the promise of personalized medicine for all Americans.

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 2006”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) The completion of the Human Genome
2 Project in 2003 paved the way for a more sophisti-
3 cated understanding of disease causation, which has
4 contributed to the advent of “personalized medi-
5 cine”.

6 (2) Personalized medicine is the application of
7 genomic and molecular data to better target the de-
8 livery of health care, facilitate the discovery and clin-
9 ical testing of new products, and help determine a
10 patient’s predisposition to a particular disease or
11 condition.

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

15 (4) In the United States, up to 15 percent of
16 hospitalized patients experience a serious adverse
17 drug reaction, and more than 100,000 deaths are at-
18 tributed annually to such reactions.

19 (5) Pharmacogenomics has the potential to dra-
20 matically increase the efficacy and safety of drugs
21 and reduce healthcare costs, and is fundamental to
22 the practice of genome-based personalized medicine.

23 (6) Pharmacogenomics is the study of how
24 genes affect a person’s response to drugs. This rel-
25 atively new field combines pharmacology (the science

1 of drugs) and genomics (the study of genes and
2 their functions) to develop effective, safe medications
3 and dosing regimens that will be tailored to an indi-
4 vidual's genetic makeup.

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

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

21 (9) Warfarin, a blood thinner used to prevent
22 the formation of life-threatening clots, significantly
23 elevates patient risk for bleeding in the head or gas-
24 trointestinal tract, both of which are associated with
25 increased rates of hospitalization, disability and

1 death. Pharmacogenomic researchers have identified
2 and developed tests for genetic variants in the
3 cytochrome P450 metabolizing enzyme (CYP2C9)
4 and vitamin K epoxide reductase complex that in-
5 crease risk for these adverse events. By using a com-
6 panion diagnostic test for these two genes, physi-
7 cians can modify the dosing regimen and decrease
8 the likelihood of adverse events.

9 (10) Although the cancer drug 6-
10 mercaptopurine (6-MP) cures 85 percent of children
11 with acute lymphoblastic leukemia, historically, a
12 significant number of patients would die inexplicably
13 from the drug. Researchers later discovered that 1
14 in 10 individuals has an under-active version of the
15 metabolizing enzyme thiopurine methyltransferase
16 (TPMT) and should receive only a fraction of the
17 standard dose of purine drugs. Physicians now are
18 able to screen for TPMT gene variants before ad-
19 ministering these drugs.

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

1 tify whether they carry mutations in these genes and
2 to inform their decisions about treatment options,
3 including mastectomy and oophorectomy.

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

13 **SEC. 3. DEFINITIONS.**

14 In this Act:

15 (1) **BIOMARKER.**—The term “biomarker”
16 means an analyte found in a patient specimen that
17 is objectively measured and evaluated as an indi-
18 cator of normal biologic processes, pathogenic proc-
19 esses, or pharmacologic responses to a therapeutic
20 intervention.

21 (2) **LABORATORY-DEVELOPED GENETIC**
22 **TEST.**—The term “laboratory-developed genetic
23 test” means a molecular genetic test that is de-
24 signed, validated, conducted, and offered as a service
25 by a clinical laboratory subject to the Clinical Lab-

1 oratory Improvement Amendments (referred to in
2 this Act as “CLIA”) using either commercially avail-
3 able analyte specific reagents (FDA-regulated) or re-
4 agents prepared by the laboratory (not FDA-regu-
5 lated), or some combination thereof.

6 (3) MOLECULAR GENETIC TEST.—The term
7 “molecular genetic test” means an analysis of
8 human DNA, RNA, chromosomes, proteins, or me-
9 tabolites, that detects genotypes, mutations, or chro-
10 mosomal and biochemical changes.

11 (4) PHARMACOGENETIC TEST.—The term
12 “pharmacogenetic test” means a molecular genetic
13 test intended to identify individual variations in
14 DNA sequence related to drug absorption and dis-
15 position (pharmacokinetics) or drug action
16 (pharmacodynamics), including polymorphic vari-
17 ation in the genes that encode the functions of
18 transporters, receptors, metabolizing enzymes, and
19 other proteins.

20 (5) PHARMACOGENOMIC TEST.—

21 (A) IN GENERAL.—The term “pharmaco-
22 genomic test” means a molecular genetic test
23 intended to identify individual variations in sin-
24 gle-nucleotide polymorphisms, haplotype mark-
25 ers, or alterations in gene expression or inac-

1 tivation, that may be correlated with pharma-
2 cological function and therapeutic response.

3 (B) VARIATIONS AND ALTERATIONS.—For
4 purposes of this paragraph, the variations or al-
5 terations referred to in subparagraph (A) may
6 be a pattern or profile of change, rather than
7 a change in an individual marker.

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

10 **SEC. 4. GENOMICS AND PERSONALIZED MEDICINE INTER-**
11 **AGENCY WORKING GROUP.**

12 (a) IN GENERAL.—The Secretary shall establish
13 within the Department of Health and Human Services the
14 Genomics and Personalized Medicine Interagency Working
15 Group (referred to in this Act as the “IWG”).

16 (b) PURPOSE.—It shall be the purpose of the IWG
17 to expand and accelerate genetics and genomics research,
18 and the translation of findings from such research into
19 clinical and public health application, by—

20 (1)(A) enhancing communication about current
21 and proposed activities and areas of focus by the
22 Department of Health and Human Services and
23 other relevant Federal departments and agencies, in-
24 cluding communication focused on findings and rec-
25 ommendations from—

1 (i) the advisory groups on genetics of the
2 Secretary, including the Secretary's Advisory
3 Committee on Genetics, Health, and Society,
4 and the Advisory Committee on Heritable Dis-
5 orders and Genetic Diseases in Newborns and
6 Children; and

7 (ii) the National Academies of Science, in-
8 cluding the Institute of Medicine; and

9 (B) identifying areas of need and opportunity;
10 and

11 (2) facilitating collaboration, coordination, and
12 integration of activities, within the Federal agencies,
13 and among such agencies and their public and pri-
14 vate partners to leverage resources and avoid dupli-
15 cation of effort.

16 (c) IWG CHAIRPERSON.—The Secretary shall serve
17 as chairperson of the IWG. The Secretary may not des-
18 ignate another person to serve as a chairperson of the
19 IWG.

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

22 (1) National Institutes of Health, including the
23 National Human Genome Research Institute, the
24 National Institute of Environmental Health
25 Sciences, the Department of Clinical Bioethics, and

1 the National Center on Minority Health and Health
2 Disparities;

3 (2) Centers for Disease Control and Prevention,
4 including the Office of Genomics and Disease Pre-
5 vention;

6 (3) Food and Drug Administration, including
7 the Office of Clinical Pharmacology and Biopharma-
8 ceutics Review and the Office of In Vitro
9 Diagnostics;

10 (4) Health Resources and Services Administra-
11 tion, including the genetic services branch of the
12 Maternal and Child Health Bureau and the Bureau
13 of Health Professions;

14 (5) Office of Minority Health;

15 (6) Agency for Healthcare Research and Qual-
16 ity;

17 (7) Centers for Medicare & Medicaid Services;

18 (8) Veterans Health Administration;

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

21 (10) Department of Energy, including the
22 Human Genome Program and Joint Genome Insti-
23 tute of the Office of Science; and

24 (11) other Federal departments and agencies as
25 determined appropriate by the Secretaries.

1 (e) DUTIES OF THE IWG.—In fulfilling the purpose
2 described in subsection (b), members of the IWG shall—

3 (1) meet not less frequently than twice each
4 year or at the call of the chairperson;

5 (2) draft recommendations for various heads of
6 Federal departments and agencies; and

7 (3) provide opportunities for public input and
8 comment on the deliberations and activities of the
9 IWG, as appropriate.

10 (f) REPORT.—Not later than 1 year after the date
11 of enactment of this Act, and biennially thereafter, the
12 Secretary shall report to the appropriate committees of
13 Congress and to the public on IWG activities, with respect
14 to meeting the purpose described in subsection (b) and
15 carrying out the duties described in subsection (e).

16 (g) AUTHORIZATION OF APPROPRIATIONS.—There is
17 authorized to be appropriated to carry out this section,
18 \$5,000,000 for fiscal year 2007, and such sums as may
19 be necessary for each of fiscal years 2008 through 2012.

20 **SEC. 5. EXPANSION AND ACCELERATION OF GENETIC AND**
21 **GENOMICS RESEARCH.**

22 (a) GENETICS AND GENOMICS RESEARCH.—

23 (1) IN GENERAL.—The Secretary shall expand
24 and accelerate research and programs to collect ge-
25 netic and genomic data that will advance the field of

1 genomics and personalized medicine, with prioritized
2 focus on—

3 (A) studies of diseases and health condi-
4 tions with substantial public health impact;

5 (B) population-based studies of genotype
6 prevalence, gene-disease association, gene-drug
7 response association, and gene-environment
8 interactions;

9 (C) systematic review and synthesis of the
10 results of population-based studies using meth-
11 ods of human genome epidemiology;

12 (D) translation of genomic information
13 into molecular genetic screening tools,
14 diagnostics, and therapeutics, through well-con-
15 ducted clinical trials and studies;

16 (E) translation of genomic information
17 into tools for public health investigations and
18 ongoing biosurveillance and monitoring;

19 (F) systematic review of data on analytic
20 validity and clinical validity of molecular genetic
21 tests;

22 (G) comprehensive studies of clinical util-
23 ity, including cost-effectiveness and cost-benefit
24 analyses, of molecular genetic tests and thera-
25 peutics;

1 (H) population based studies to assess the
2 awareness, knowledge, and use of genetic tests
3 and their impact on the population health and
4 health disparities; and

5 (I) methods to enhance provider uptake or
6 adoption of pharmacogenomic products into
7 practice.

8 (2) BIOBANKING.—

9 (A) NATIONAL BIOBANKING RESEARCH
10 INITIATIVE.—The Secretary, in collaboration
11 with the IWG, shall develop a plan for a na-
12 tional biobanking research initiative that—

13 (i) addresses priority areas of focus,
14 as described in paragraph (1);

15 (ii) builds upon current genomic re-
16 search initiatives (existing as of the date
17 the plan is issued) domestically and, as
18 practicable, internationally;

19 (iii) is prospective and long-term in
20 design;

21 (iv) takes into consideration public re-
22 view and comment;

23 (v) is designed to support collection
24 and synthesis of evidence for public health
25 and clinical applications;

1 (vi) meets rigorous standards and
2 guidelines regarding ethics, legality, and
3 social issues;

4 (vii) ensures diverse representation of
5 individuals in the research or data collec-
6 tion that would allow statistically signifi-
7 cant analyses of population subgroups as
8 appropriate; and

9 (viii) reflects public-private partner-
10 ship.

11 (B) NATIONAL BIOBANKING DISTRIBUTED
12 DATABASE.—

13 (i) IN GENERAL.—The Secretary, act-
14 ing through the Director of the National
15 Human Genome Research Institute at the
16 National Institutes of Health and the Di-
17 rector of the Office of Genomics and Dis-
18 ease Prevention at the Centers for Disease
19 Control and Prevention, shall establish a
20 system for the integration of data, includ-
21 ing genomic data and associated environ-
22 mental and clinical health information,
23 which shall facilitate the pooled analysis
24 and synthesis of such data.

1 (ii) DISTRIBUTED DATABASE.—With
2 respect to such national biobanking data-
3 base, the Secretary shall—

4 (I) establish a grant program for
5 local or regional biobanking initia-
6 tives, in accordance with subpara-
7 graph (C), with priority given for local
8 or regional biobanks that—

9 (aa) are established or com-
10 plement activities related to the
11 implementation of the national
12 biobanking research initiative,
13 pursuant to subparagraph (A);

14 (bb) are based on well-de-
15 fined populations, such as co-
16 horts of newborn infants
17 screened by State health depart-
18 ments for metabolic disorders,
19 population-based registries of
20 cancer and other diseases, and
21 family-based registries;

22 (cc) collect data from par-
23 ticipants with diverse genetic pro-
24 files, environmental exposures,

1 and health conditions and dis-
2 eases; and

3 (dd) participate in and con-
4 tribute data to consortia estab-
5 lished to develop and apply best
6 practices and standards in the re-
7 search area of such consortium;

8 (II) assist in the development of
9 uniform standards and guidelines for
10 the collection, submission, and storage
11 of biobank data;

12 (III) develop and promulgate
13 guidelines regarding procedures, pro-
14 tocols, and policies for access of data
15 by non-governmental entities and the
16 safeguarding of the privacy of biobank
17 subjects, in accordance with the Office
18 for Human Research Protection and
19 Clinical Research Policy Analysis and
20 Coordination program at the National
21 Institutes of Health, and other guide-
22 lines as appropriate;

23 (IV) review and make rec-
24 ommendations to address ownership

1 issues with respect to genomic sam-
2 ples and analyses;

3 (V) encourage voluntary submis-
4 sion of biobanking data obtained or
5 analyzed with private or non-Federal
6 funds;

7 (VI) facilitate submission of data,
8 including secure and efficient elec-
9 tronic submission;

10 (VII) incorporate data from Fed-
11 eral surveys, such as the National
12 Health and Nutrition Examination
13 Survey;

14 (VIII) develop and disseminate
15 standard consent forms, including
16 those that allow multiple uses of data
17 for research purposes;

18 (IX) conduct, directly or by con-
19 tract, analytical research, including
20 clinical, epidemiological, and social re-
21 search, using biobank data;

22 (X) allow public use of data
23 only—

24 (aa) with appropriate pri-
25 vacy safeguards in place; and

1 (bb) for health research pur-
2 poses;

3 (XI) determine appropriate pro-
4 cedures for industry access to biobank
5 data for research and development of
6 new or improved tests and treatments,
7 and submission of data generated
8 from such samples to the Food and
9 Drug Administration as part of the
10 approval process for drugs and de-
11 vices; and

12 (XII) make analytic findings
13 from biobanking initiatives supported
14 by Federal funding publicly available
15 within an appropriate timeframe to be
16 determined by the Secretary, which
17 findings shall not contain identifiable
18 information of patients.

19 (iii) NATIONAL RESOURCES.—The
20 IWG shall sponsor national efforts to bring
21 together the consortia described in clause
22 (ii)(I)(dd) to build national data resources.
23 (C) BIOBANK INITIATIVES GRANTS.—

24 (i) IN GENERAL.—The Secretary shall
25 establish a grant program for eligible insti-

1 tutions to enable the institutions to develop
2 or expand biobanking initiatives to advance
3 the application of genomics to the practice
4 of medicine and contribute to the under-
5 standing of the genetic causes of disease.

6 (ii) ELIGIBILITY.—An academic med-
7 ical center or other institution shall be eli-
8 gible for a grant under this subparagraph
9 if the center or institution has—

10 (I) practical experience and dem-
11 onstrated expertise in genomics and
12 its clinical and public health applica-
13 tions;

14 (II) an established scientific advi-
15 sory committee to—

16 (aa) advise staff on genomic
17 issues, including related ethical,
18 legal, and social issues;

19 (bb) evaluate and approve
20 research studies utilizing the
21 biobank data; and

22 (cc) provide a forum for evi-
23 dence-based reviews and integra-
24 tion of research findings to deter-
25 mine if and how such findings

1 may be used in health care and
2 disease prevention;

3 (III) an established community
4 advisory committee comprised of com-
5 munity advocates, potential study par-
6 ticipants, and other stakeholders, to—

7 (aa) provide a non-scientific
8 perspective on the biobanking ini-
9 tiative;

10 (bb) guide the development
11 of patient-oriented materials;

12 (cc) support outreach to mi-
13 nority and other underserved
14 communities; and

15 (dd) provide a forum for the
16 discussion of ethical, social, and
17 legal issues pertaining to the bio-
18 banking initiative;

19 (IV) mechanisms to ensure pa-
20 tient privacy and protection of infor-
21 mation from non-health applications;
22 and

23 (V) a demonstrated ability to re-
24 cruit patients from diverse cultural
25 backgrounds.

1 (iii) USE OF FUNDS.—An eligible in-
2 stitution that receives a grant under this
3 subparagraph shall use the grant funds to
4 develop or expand a biobanking initiative,
5 which may include the following activities:

6 (I) Support for advisory commit-
7 tees.

8 (II) Recruitment and education
9 of patients.

10 (III) Development of consent
11 protocols.

12 (IV) Obtaining genetic samples
13 and clinical information.

14 (V) Establishment and mainte-
15 nance of secure storage for genetic
16 samples and clinical information.

17 (VI) Conduct of data analyses
18 and evidence-based systemic reviews
19 that allow for the following:

20 (aa) Identification of bio-
21 markers and other surrogate
22 markers to improve predictions of
23 onset of disease, response to
24 therapy, and clinical outcomes.

1 (bb) Increased under-
2 standing of gene-environment
3 interactions.

4 (cc) Development of molec-
5 ular genetic screening, diagnostic,
6 and therapeutic interventions.

7 (dd) Genotypic characteriza-
8 tion of tissue samples.

9 (VII) Support for participation in
10 research consortia concerned with es-
11 tablishing and developing best prac-
12 tices and standards in the relevant re-
13 search areas.

14 (VIII) Development and imple-
15 mentation of protocols for external re-
16 searchers to access non-identifiable
17 patient samples and associated health
18 information for research activities.

19 (IX) Other activities, as deter-
20 mined appropriate by the Secretary.

21 (b) RACE, GENOMICS, AND HEALTH.—

22 (1) IN GENERAL.—The Secretary shall expand
23 and intensify efforts to increase knowledge about
24 the—

1 (A) interaction between genetics and the
2 environment, and the influence of such inter-
3 action on the causality and treatment of dis-
4 eases common in racial and ethnic minority
5 populations; and

6 (B) ways in which molecular genetic
7 screening, diagnostics, and treatments may be
8 used to improve the health and health care of
9 racial and ethnic minority populations.

10 (2) RACE AND GENOMICS.—Not later than 1
11 year after the date of enactment of this Act, the
12 Secretary, in collaboration with the IWG, shall pre-
13 pare, with public input, and publish trans-agency
14 guidance regarding the following:

15 (A) An appropriate definition for race and
16 ethnicity for use in genomic research and pro-
17 grams operated or supported by the Federal
18 Government.

19 (B) Guiding ethics, principles, and proto-
20 cols for the inclusion and designation of racial
21 and ethnic populations in genomics research
22 and programs operated or supported by the
23 Federal Government.

1 (C) Ways to increase access to effective
2 pharmacogenomic and other clinical genetic
3 services for minority populations.

4 (D) Research opportunities and funding
5 support in the area of race and genomics that
6 may improve the health and health care of mi-
7 nority populations.

8 (E) Ways to enhance integration of Fed-
9 eral Government-wide efforts and activities per-
10 taining to race, genomics, and health.

11 (F) Any needs for additional privacy pro-
12 tections in preventing stigmatization and inap-
13 propriate use of genetic information.

14 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
15 authorized to be appropriated to carry out this section,
16 \$150,000,000 for fiscal year 2007, and such sums as may
17 be necessary for each of fiscal years 2008 through 2012.

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

19 (a) IN GENERAL.—The Secretary, acting through the
20 Administrator of the Health Resources and Services Ad-
21 ministration and the Director of the Centers for Disease
22 Control and Prevention, and in collaboration with the
23 IWG, shall expand and intensify efforts to—

1 (1) support efforts to recruit and retain health
2 professionals from diverse backgrounds in the
3 genomics workforce;

4 (2) in collaboration with appropriate profes-
5 sional accreditation organizations, assess and make
6 recommendations to improve the quality of genomics
7 training; and

8 (3) develop a plan to integrate genomics into all
9 aspects of health professional training.

10 (b) ELIGIBLE ENTITY.—For purposes of this section,
11 the term “eligible entity” includes professional genetics
12 and genomics societies and academic institutions deter-
13 mined appropriate by the Secretary.

14 (c) RECRUITMENT AND RETENTION.—The Secretary
15 shall provide financial and technical support to eligible en-
16 tities to increase recruitment and retention of trainees in
17 genetics and genomics by—

18 (1) providing education and awareness opportu-
19 nities, practical and research experiences, and finan-
20 cial incentives such as scholarships or loan repay-
21 ment;

22 (2) considering development of genomic sub-
23 specialty fellowships or concentrations within genet-
24 ics training programs;

1 (3) considering development of combined resi-
2 dency programs or joint subspecialty fellowships
3 with other specialties;

4 (4) providing support for laboratory-based ge-
5 netics or genomics fellowships for medical and other
6 health professional students; and

7 (5) carrying out other activities determined ap-
8 propriate by the Secretary.

9 (d) GENETICS AND GENOMICS TRAINING.—The Sec-
10 retary, directly or through contracts or grants to eligible
11 entities, shall ensure the adequacy of genetics and
12 genomics training for diagnosis, treatment, and counseling
13 of adults and children for both rare and common dis-
14 orders, through support of efforts to—

15 (1) strengthen the core training content of the
16 various clinical disciplines to reflect new knowledge
17 and evolving practice of genetics and genomics;

18 (2) develop and disseminate model residency
19 and other training program curricula and teaching
20 materials that integrate and broaden the base of
21 medical genetics and genomics training;

22 (3) assist the review of board and other certi-
23 fying examinations by professional societies and ac-
24 creditation bodies to ensure adequate focus on the
25 fundamental principles of genomics; and

1 (4) explore options for distance or on-line learn-
2 ing for degree or continuing education programs.

3 (e) INTEGRATION.—The Secretary shall support ini-
4 tiatives to increase the integration of genetics and
5 genomics into all aspects of clinical and public health prac-
6 tice by—

7 (1) generating greater awareness of the rel-
8 evance and application of genetics and genomics to
9 common disorders; and

10 (2) promoting genetics and genomics com-
11 petency across all clinical, public health and labora-
12 tory disciplines through the development and dis-
13 semination of health professional guidelines which
14 shall—

15 (A) include focus on appropriate adminis-
16 tration and interpretation of genomic tests, and
17 subsequent clinical and public health decision-
18 making; and

19 (B) specifically target health professionals
20 without formal training or experience in the
21 field of genomics.

22 (f) AUTHORIZATION OF APPROPRIATIONS.—There
23 are authorized to be appropriated to carry out this section
24 \$10,000,000 for fiscal year 2007 and such sums as may
25 be necessary for each of fiscal years 2008 through 2012.

1 **SEC. 7. REALIZING THE POTENTIAL OF PERSONALIZED**
2 **MEDICINE.**

3 (a) INCENTIVES.—

4 (1) TAX CREDIT FOR RESEARCH AND DEVELOP-
5 MENT RELATED TO COMPANION DIAGNOSTIC
6 TESTS.—

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

11 **“SEC. 45N. COMPANION DIAGNOSTIC TEST CREDIT.**

12 “(a) ALLOWANCE OF CREDIT.—For purposes of sec-
13 tion 38, in the case of an eligible taxpayer, the companion
14 diagnostic test credit for any taxable year is an amount
15 equal to the qualified research expenses paid or incurred
16 by the taxpayer during the taxable year in connection with
17 the development of a qualified companion diagnostic test
18 .

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

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

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

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

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

10 “(2) is approved by the Secretary of Health and
11 Human Services.

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

15 “(e) NO DOUBLE BENEFIT.—

16 “(1) COORDINATION WITH OTHER DEDUCTIONS
17 AND CREDITS.—Except as provided in paragraph
18 (2), the amount of any deduction or other credit al-
19 lowable under this chapter for any expense taken
20 into account in determining the amount of the credit
21 under subsection (a) shall be reduced by the amount
22 of such credit attributable to such expense.

23 “(2) RESEARCH AND DEVELOPMENT COSTS.—

24 “(A) IN GENERAL.—Except as provided in
25 subparagraph (B), any amount which is taken

1 into account in determining the amount of the
2 credit under subsection (a) for any taxable year
3 shall not be taken into account for purposes of
4 determining the credit under section 41 for
5 such taxable year.

6 “(B) COSTS TAKEN INTO ACCOUNT IN DE-
7 TERMINING BASE PERIOD RESEARCH EX-
8 PENSES.—Any amount taken into account in
9 determining the amount of the credit under
10 subsection (a) for any taxable year shall be
11 taken into account in determining base period
12 research expenses for purposes of applying sec-
13 tion 41 to subsequent taxable years.

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

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

22 (B) CREDIT TREATED AS PART OF GEN-
23 ERAL BUSINESS CREDIT.—Section 38(b) of the
24 Internal Revenue Code of 1986 is amended by
25 striking “and” at the end of paragraph (29), by

1 striking the period at the end of paragraph (30)
2 and inserting “, plus”, and by adding at the
3 end the following new paragraph:

4 “(31) the companion diagnostic test credit de-
5 termined under section 45N(a).”.

6 (C) CLERICAL AMENDMENT.—The table of
7 sections for subpart D of subchapter A of chap-
8 ter 1 of the Internal Revenue Code of 1986 is
9 amended by adding at the end the following
10 new item:

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

11 (D) EFFECTIVE DATE.—The amendments
12 made by this paragraph shall apply to expenses
13 paid or incurred in taxable years beginning
14 after the date of enactment of this Act.

15 (2) NATIONAL ACADEMY OF SCIENCES
16 STUDY.—Not later than 6 months after the date of
17 enactment of this Act, the Secretary shall enter into
18 a contract with the National Research Council of the
19 National Academy of Sciences to study and rec-
20 ommend appropriate incentives to encourage—

21 (A) co-development of companion diag-
22 nostic testing by a drug sponsor;

23 (B) development of companion diagnostic
24 testing for already-approved drugs by the drug
25 sponsor;

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

4 (D) action on other issues determined ap-
5 propriate by the Secretary.

6 (b) GENETIC TEST QUALITY.—

7 (1) IN GENERAL.—The Secretary shall improve
8 the safety, efficacy, and availability of information
9 about genetic tests, including pharmacogenetic and
10 pharmacogenomic tests.

11 (2) INSTITUTE OF MEDICINE STUDY.—Not later
12 than 30 days after the date of enactment of this
13 Act, the Secretary shall enter into a contract with
14 the Institute of Medicine to conduct a study and a
15 prepare a report that includes recommendations to
16 improve Federal oversight and regulation of genetic
17 tests, with specific recommendations on the develop-
18 ment of the decision matrix under paragraph (3).
19 Such study shall be completed not later than 1 year
20 after the date on which such contract was entered
21 into.

22 (3) DECISION MATRIX.—

23 (A) IN GENERAL.—The Secretary, taking
24 into consideration the recommendations of the
25 Institute of Medicine report under paragraph

1 (2), shall develop a decision matrix (referred to
2 in this section as the “matrix”) to improve the
3 oversight and regulation of genetic tests, includ-
4 ing pharmacogenomics and pharmacogenetic
5 tests by—

6 (i) determining the classification of
7 genetic tests that have not yet been classi-
8 fied, or of which the classification is un-
9 clear, questioned, or challenged;

10 (ii) determining which types of tests,
11 including laboratory-developed tests, re-
12 quire review and the level of review needed
13 for such tests;

14 (iii) determining which agency shall
15 have oversight over the review process of
16 such tests that are determined to require
17 review; and

18 (iv) determining, to the extent prac-
19 ticable, which requirements the agency
20 shall apply to the types of tests identified
21 in clause (ii).

22 (B) LEVEL OF REVIEW.—In determining
23 the level of review needed by a genetic test, the
24 Secretary shall take into consideration—

- 1 (i) characteristics of the test and its
2 target disease or condition;
- 3 (ii) intended use of the test;
- 4 (iii) potential for improved medical
5 conditions and patient harms; and
- 6 (iv) social consequences of the test.

7 (C) COMPARATIVE ANALYSIS.—To inform
8 development of the matrix, the Secretary shall
9 undertake a comparative analysis of laboratory
10 review requirements under the Clinical Labora-
11 tory Improvement Act and those of the Food
12 and Drug Administration to assess and reduce
13 differences in such requirements, and to elimi-
14 nate redundancies and decrease burden of re-
15 view, as practicable.

16 (D) REGULATIONS.—Not later than 30
17 months after the date of enactment of this Act,
18 the Secretary shall promulgate regulations to
19 implement the matrix.

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

1 (A) develop or expand adverse event re-
2 porting systems to encompass reports of ad-
3 verse events resulting from genetic testing; and

4 (B) respond appropriately to any adverse
5 events resulting from such testing.

6 (5) AUTHORIZATION OF APPROPRIATIONS.—

7 There is authorized to be appropriated to carry out
8 this subsection, \$10,000,000 for fiscal year 2007,
9 and such sums as may be necessary for each of fis-
10 cal years 2008 through 2012.

11 (c) FOOD AND DRUG ADMINISTRATION.—

12 (1) IN GENERAL.—

13 (A) SUMMARY INFORMATION.—If a genetic
14 test that is determined to be within the jurisdic-
15 tion of the Food and Drug Administration but
16 that does not require review, as determined
17 under the matrix, the sponsor of such test shall
18 provide the Secretary with summary informa-
19 tion on how the test was validated and its per-
20 formance characteristics, which information
21 shall be made easily accessible for the public.

22 (B) SOURCE OF INFORMATION.—The in-
23 formation described under subparagraph (A)
24 may be obtained from the labeling submitted
25 for CLIA complexity categorization.

1 (2) REQUIREMENT FOR COMPANION DIAG-
2 NOSTIC TESTING.—The Secretary may require the
3 sponsor of a drug or biological product—

4 (A) to codevelop a companion diagnostic
5 test, after filing an investigational new drug ap-
6 plication or a new drug application to address
7 significant safety concerns of the drug or bio-
8 logical product;

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

13 (C) to relabel the drug or biological prod-
14 uct to require validated companion diagnostic
15 testing when evidence of improved outcomes has
16 been established in practice or if data dem-
17 onstrate significant safety concerns with use of
18 such drug or biological product.

19 (3) PHARMACOGENOMIC DATA SUBMISSION.—
20 The Secretary shall encourage and facilitate vol-
21 untary pharmacogenomic data submission from drug
22 sponsors, which may include—

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

1 (B) the provision of technical assistance;

2 (C) the establishment of a mechanism to
3 store, maintain and analyze such data, in col-
4 laboration with the National Institutes of
5 Health and the Centers for Disease Control and
6 Prevention;

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

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

13 (F) other activities determined appropriate
14 by the Commissioner.

15 (4) LABELING FOR CERTAIN GROUPS.—Not
16 later than 6 months of enactment of this Act, the
17 Secretary shall prepare and publish guidance regard-
18 ing the approval, licensing, or clearance of any prod-
19 uct under the Federal Food, Drug and Cosmetic Act
20 (21 U.S.C. 301 et seq.) or section 351 of the Public
21 Health Service Act (42 U.S.C. 262) with an indica-
22 tion, contraindication, warning, or any other labeling
23 information that is specific to a racial or ethnic
24 group.

1 (5) TERMINATION OF CERTAIN ADVERTISING
2 CAMPAIGNS.—The Food and Drug Administration
3 shall collaborate with the Federal Trade Commission
4 to identify and terminate, pursuant to section 5 of
5 the Federal Trade Commission Act (15 U.S.C. 45),
6 advertising campaigns that make false, misleading,
7 deceptive, or unfair claims about molecular genetic
8 tests.

9 (d) CENTERS FOR MEDICARE & MEDICAID SERV-
10 ICES.—

11 (1) IN GENERAL.—If a genetic test that is de-
12 termined to be within the jurisdiction of the Centers
13 for Medicare & Medicaid Services does not require
14 review as determined under the matrix, the sponsor
15 of such test shall provide the Administrator of the
16 Centers for Medicare & Medicaid Services with sum-
17 mary information on how the test was validated and
18 its performance characteristics, which information
19 shall be made easily accessible for the public.

20 (2) SPECIALTY AREA.—To ensure the accuracy,
21 validity, and reliability of clinical genetic tests that
22 do not require premarket approval by or notification
23 to the Food and Drug Administration, and to im-
24 prove oversight of genetic test laboratories, the Di-
25 rector of the Division of Laboratory Services of the

1 Survey and Certification Group of the Center for
2 Medicaid and State Operations of the Centers for
3 Medicare & Medicaid Services, in collaboration with
4 the Clinical Laboratory Improvement Advisory Com-
5 mittee at the Centers for Disease Control and Pre-
6 vention, shall establish a specialty area for molecular
7 and biochemical genetic tests, in order to—

8 (A) develop criteria for establishing ana-
9 lytic and clinical validity for genetic tests that
10 are determined to require review under the ma-
11 trix;

12 (B) specify requirements for proficiency
13 testing for laboratories;

14 (C) provide guidance regarding the scope
15 of duty for laboratory directors;

16 (D) make information easily accessible to
17 the public about—

18 (i) laboratory certification; and

19 (ii) analytic and clinical validity for
20 genetic tests that are determined to require
21 high level review under the matrix; and

22 (E) conduct other activities at the discre-
23 tion of the Administrator of the Centers for
24 Medicare & Medicaid Services.

1 (3) REIMBURSEMENT.—To foster adoption of
2 molecular genetic screening tools, the Administrator
3 of the Centers for Medicare & Medicaid Services
4 shall—

5 (A) assess and update current procedure
6 terminology codes as warranted; and

7 (B) determine and implement fair and rea-
8 sonable coverage policies and reimbursement
9 rates for medically necessary genetic and
10 genomic treatments and services, including lab-
11 oratory testing.

12 (e) CENTERS FOR DISEASE CONTROL AND PREVEN-
13 TION.—

14 (1) DIRECT-TO-CONSUMER MARKETING.—Not
15 later than 12 months after the date of enactment of
16 this Act, the Director of the Centers for Disease
17 Control and Prevention, with respect to molecular
18 genetic tests for which consumers have direct access,
19 shall—

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

24 (B) analyze the validity of claims made in
25 direct-to-consumer marketing; and

1 (C) make recommendations to Congress re-
2 garding necessary interventions to protect the
3 public from potential harms of direct-to-con-
4 sumer marketing and access to molecular ge-
5 netic tests.

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

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

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

20 (3) AUTHORIZATION OF APPROPRIATIONS.—
21 There is authorized to be appropriated to carry out
22 this subsection, \$30,000,000 for fiscal year 2007,
23 and such sums as may be necessary for each of fis-
24 cal years 2008 through 2012.

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

8 (1) develops standardized tools and methodolo-
9 gies to assess the cost-effectiveness of such tests, as
10 well as criteria for use;

11 (2) establishes and validates drug dosing algo-
12 rithms for which such tests can improve outcomes,
13 taking into consideration—

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

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

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

1 (2) without a Federal law banning genetic dis-
2 crimination, people may fear losing their health in-
3 surance and their employment, and subsequently—

4 (A) avoid participating in research that
5 collects genetic information; and

6 (B) even decline clinical molecular testing
7 that may provide lifesaving information;

8 (3) fear of genetic discrimination will slow the
9 pace of discovery in research and hinder the uptake
10 of molecular testing in a clinical setting, both of
11 which will undermine efforts to translate and apply
12 personalized medicine technology; and

13 (4) adequate privacy protections, including a
14 Federal prohibition against genetic discrimination,
15 are necessary prerequisites to advancing personal-
16 ized medicine.

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