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S. 976

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.

IN THE SENATE OF THE UNITED STATES

MARCH 23, 2007

Mr. OBAMA (for himself and Mr. BURR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

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 2007”.

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 diseases and drug responses,
4 which has contributed to the advent of “personalized
5 medicine”.

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 person’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 health care costs, and is fundamental to
22 the practice of genome-based personalized medicine.

23 (6) Pharmacogenomics is the study of how ge-
24 netic variation affects a person’s response to drugs.
25 This relatively new field combines pharmacology (the

1 science of drugs) and genomics (the study of genes
2 and their functions) to develop safer and more effective
3 medications and dosing regimens that will be
4 tailored to an individual's genetic makeup.

5 (7) The cancer drug Gleevec was developed
6 based on knowledge of the chromosomal
7 translocation that causes chronic myelogenous leukemia,
8 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 extra copies of this gene, which
17 causes uncontrolled and rapid tumor growth.
18 Pharmacogenomics research led to both the development
19 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 gastrointestinal tract,
24 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 300 individuals inherit an inactive version of the
15 gene encoding the metabolizing enzyme thiopurine
16 methyltransferase (TPMT) from both their mother
17 and father and, as a result, should receive only a
18 fraction of the standard dose of purine drugs. In ad-
19 dition, 1 in 10 individuals have only 1 copy of the
20 gene with variable function, and the dosage of 6-MP
21 must be adjusted for a subset of these patients. Phy-
22 sicians now are able to screen for TPMT gene
23 variants before administering these drugs.

24 (11) Research into the genetics of breast cancer
25 identified two pivotal genes, BRCA1 and BRCA2,

1 mutations in which correspond to a significantly in-
2 creased lifetime risk of developing breast and ovar-
3 ian cancer. Individuals in affected families or with
4 specific risk factors may use genetic testing to iden-
5 tify whether they carry mutations in these genes and
6 to inform their decisions about treatment options,
7 including prophylactic mastectomy and oophorectomy.

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

18 **SEC. 3. DEFINITIONS.**

19 In this Act:

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

1 these sources, and data associated with such speci-
2 mens may include health information or environ-
3 mental data.

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

10 (3) CLIA.—The term “CLIA” means the Clin-
11 ical Laboratory Improvement Amendments of 1988
12 (42 U.S.C. 263a).

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 and bio-
20 chemical changes.

21 (6) LABORATORY-DEVELOPED GENETIC
22 TEST.—The term “laboratory-developed genetic
23 test” means a genetic test that is designed, vali-
24 dated, conducted, and offered as a service by a clin-
25 ical laboratory subject to CLIA using either com-

1 mercially available analyte specific reagents (FDA-
2 regulated) or reagents prepared by the laboratory
3 (not FDA-regulated), or some combination thereof.

4 (7) PHARMACOGENETIC TEST.—The term
5 “pharmacogenetic test” means a genetic test in-
6 tended to identify individual variations in DNA se-
7 quence related to drug absorption and disposition
8 (pharmacokinetics) or drug action
9 (pharmacodynamics), including polymorphic vari-
10 ation in the genes that encode the functions of
11 transporters, receptors, metabolizing enzymes, and
12 other proteins.

13 (8) PHARMACOGENOMIC TEST.—

14 (A) IN GENERAL.—The term
15 “pharmacogenomic test” means a genetic test
16 intended to identify individual variations in sin-
17 gle-nucleotide polymorphisms, haplotype mark-
18 ers, or alterations in gene expression or inac-
19 tivation, that may be correlated with pharma-
20 cological function and therapeutic response.

21 (B) VARIATIONS AND ALTERATIONS.—For
22 purposes of this paragraph, the variations or al-
23 terations referred to in subparagraph (A) may
24 be a pattern or profile of change, rather than
25 a change in an individual marker.

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

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

5 (a) IN GENERAL.—Not later than 90 days after the
6 date of enactment of this Act, the Secretary shall establish
7 within the Department of Health and Human Services the
8 Genomics and Personalized Medicine Interagency Working
9 Group (referred to in this Act as the “IWG”).

10 (b) DUTIES.—The IWG shall facilitate collaboration,
11 coordination, and integration of activities within the De-
12 partment of Health and Human Services and other Fed-
13 eral agencies, and among such agencies and relevant pub-
14 lic and private entities, by—

15 (1) reviewing current and proposed genomic ini-
16 tiatives, in order to identify shared interests and le-
17 verage resources;

18 (2) prioritizing new genomic initiatives, based
19 on areas of need as measured by public health im-
20 pact;

21 (3) reaching consensus on standardized genomic
22 terminology, definitions, and data code sets for
23 adoption and use in Federally conducted or sup-
24 ported programs;

1 (4) establishing and disseminating quality
2 standards and guidelines for the collection, proc-
3 essing, archiving, storage, and dissemination of
4 genomic samples and data for research and clinical
5 purposes;

6 (5) developing and promulgating guidelines re-
7 garding procedures, protocols, and policies for the
8 safeguarding of the privacy of biobank subjects, in
9 accordance with the Office for Human Research
10 Protection and Clinical Research Policy Analysis and
11 Coordination Program at the National Institutes of
12 Health, and other guidelines as appropriate;

13 (6) reviewing and making recommendations to
14 address ownership and patient access issues with re-
15 spect to genomic samples and analyses;

16 (7) developing and promulgating guidelines re-
17 garding procedures, protocols, and policies for access
18 to patient data, genomic samples, and associated
19 health information by non-governmental entities for
20 research purposes;

21 (8) developing and disseminating guidelines for
22 constructing informed consent forms that ensure pa-
23 tient privacy and confidentiality of associated clinical
24 data and information, understanding of research

1 procedures, benefits, risks, rights, and responsibil-
2 ities, and continuous voluntary participation; and

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

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

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

10 (1) National Institutes of Health;

11 (2) Centers for Disease Control and Prevention;

12 (3) Food and Drug Administration;

13 (4) Health Resources and Services Administra-
14 tion;

15 (5) Office of Minority Health;

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

18 (7) Centers for Medicare & Medicaid Services;

19 (8) Veterans Health Administration;

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

22 (10) Department of Energy;

23 (11) Armed Forces Institute of Pathology;

24 (12) Indian Health Service; and

1 (13) other Federal departments and agencies as
2 determined appropriate by the Secretary.

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

6 (f) REPORT.—Not later than 18 months after the
7 date of enactment of this Act, the Secretary shall prepare
8 and submit a report to the appropriate committees of Con-
9 gress and to the public on IWG deliberations, activities,
10 and recommendations with respect to meeting the duties
11 described in subsection (b).

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

15 (h) AUTHORIZATION OF APPROPRIATIONS.—There
16 are authorized to be appropriated to carry out this section,
17 \$1,000,000 for fiscal years 2008 and 2009.

18 **SEC. 5. NATIONAL BIOBANKING INITIATIVE.**

19 (a) IN GENERAL.—The Secretary shall advance the
20 field of genomics and personalized medicine through estab-
21 lishment of a national biobanking distributed database for
22 the collection and integration of genomic data, and associ-
23 ated environmental and clinical health information, which
24 shall facilitate synthesis and pooled analysis of such data.

1 (b) DATABASE.—With respect to the national bio-
2 banking distributed database, the Secretary shall—

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

5 (2) establish, directly or by contract, a single
6 point of authority to manage operations of the data-
7 base;

8 (3) incorporate biobanking data from Federally
9 conducted or supported genomics initiatives, as fea-
10 sible;

11 (4) encourage voluntary submission of bio-
12 banking data obtained or analyzed with private or
13 non-Federal funds;

14 (5) facilitate submission of data, including se-
15 cure and efficient electronic submission;

16 (6) allow public use of data only—

17 (A) with appropriate privacy safeguards in
18 place; and

19 (B) for health research purposes;

20 (7) determine appropriate procedures for access
21 by nongovernmental entities to biobank data for re-
22 search and development of new or improved tests
23 and treatments, and submission of data generated
24 from such samples to the Food and Drug Adminis-

1 tration as part of the approval process for drugs and
2 devices;

3 (8) conduct, directly or by contract, analytical
4 research, including clinical, epidemiological, and so-
5 cial research, using biobank data; and

6 (9) make analytic findings from biobanking ini-
7 tiatives supported by Federal funding publicly avail-
8 able within an appropriate timeframe to be deter-
9 mined by the Secretary.

10 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to require the submission or ac-
12 ceptance of biological specimens.

13 (d) BIOBANK INITIATIVES GRANTS.—

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

21 (2) ELIGIBLE ENTITIES.—

22 (A) IN GENERAL.—For purposes of this
23 subsection, eligible entities include academic
24 medical centers and other entities determined
25 appropriate by the Secretary. Eligible entities

1 desiring a grant under this subsection shall
2 submit an application to the Secretary in ac-
3 cordance with this subsection, at such time, in
4 such manner, and containing such additional
5 information as the Secretary may require.

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

11 (3) REQUIREMENTS.—The Secretary shall en-
12 sure that biobanks supported by grant awards under
13 this section—

14 (A) adhere to guidelines and recommenda-
15 tions developed pursuant to section 4;

16 (B) are established to complement activi-
17 ties related to the implementation of current
18 Federal biobanking research initiatives, as fea-
19 sible;

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

23 (D) collect data from participants with di-
24 verse genomic profiles, demographics, environ-

1 mental exposures, and presence or absence of
2 health conditions and diseases, as appropriate;

3 (E) meet quality standards for the collec-
4 tion, processing, archiving, storage, and dis-
5 semination of data, which shall be developed by
6 the IWG;

7 (F) have practical experience and dem-
8 onstrated expertise in genomics and its clinical
9 and public health applications;

10 (G) establish mechanisms to ensure patient
11 privacy and protection of information from non-
12 health applications and, as feasible, patient ac-
13 cess to genomic samples for clinical testing pur-
14 poses; and

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

19 (4) USE OF FUNDS.—An eligible entity that re-
20 ceives a grant under this subsection shall use the
21 grant funds to develop or expand a biobanking ini-
22 tiative, which may include the following activities:

23 (A) Support for scientific and community
24 advisory committees.

1 (B) Recruitment and education of partici-
2 pants.

3 (C) Development of consent protocols.

4 (D) Obtaining genetic samples and associ-
5 ated environmental and clinical information.

6 (E) Establishment and maintenance of se-
7 cure storage for genetic samples and clinical in-
8 formation.

9 (F) Conduct of data analyses and evidence-
10 based systemic reviews that allow for the fol-
11 lowing:

12 (i) Identification of biomarkers and
13 other surrogate markers to improve pre-
14 dictions of onset of disease, response to
15 therapy, and clinical outcomes.

16 (ii) Increased understanding of gene-
17 environment interactions.

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

20 (iv) Genotypic characterization of tis-
21 sue samples.

22 (G) Other activities, as determined appro-
23 priate by the Secretary.

24 (5) QUALITY ASSURANCE.—The Secretary may
25 enter into a contract with an external entity to

1 evaluate grantees under this subsection to ensure
2 that quality standards are met.

3 (e) APPLICATION OF PRIVACY RULES.—Nothing in
4 this Act shall be construed to supercede the requirements
5 for the protection of patient privacy under—

6 (1) the Federal regulations promulgated under
7 section 264(c) of the Health Insurance Portability
8 and Accountability Act of 1996 (42 U.S.C. 1320d–
9 2 note); or

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

12 (f) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this section,
14 \$75,000,000 for fiscal year 2009, and such sums as may
15 be necessary for each of fiscal years 2010 through 2014.

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

17 (a) GENETICS AND GENOMICS TRAINING.—The Sec-
18 retary, directly or through contracts or grants to eligible
19 entities, which shall include professional genetics and
20 genomics societies, academic institutions, and other enti-
21 ties as determined appropriate by the Secretary, shall im-
22 prove the adequacy of genetics and genomics training for
23 diagnosis, treatment, and counseling of adults and chil-
24 dren for both rare and common disorders, through support
25 of efforts to—

1 (1) develop and disseminate model training pro-
2 gram and residency curricula and teaching materials
3 that reflect the new knowledge and evolving practice
4 of genetics and genomics;

5 (2) assist the review of board and other certi-
6 fying examinations by professional societies and ac-
7 creditation bodies to ensure adequate focus on the
8 fundamental principles of genomics; and

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

12 (b) INTEGRATION.—The Secretary, in collaboration
13 with medical professional societies and accreditation bod-
14 ies and associations of health professional schools, shall
15 support initiatives to increase the integration of genetics
16 and genomics into all aspects of clinical and public health
17 practice by promoting genetics and genomics competency
18 across all clinical, public health, and laboratory disciplines
19 through the development and dissemination of health pro-
20 fessional guidelines which shall—

21 (1) include focus on appropriate techniques for
22 collection and storage of genomics samples, adminis-
23 tration and interpretation of genetic and genomic
24 tests, and subsequent clinical and public health deci-
25 sionmaking; and

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

4 (c) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this section
6 \$5,000,000 for fiscal year 2008 and such sums as may
7 be necessary for each of fiscal years 2009 through 2013.

8 **SEC. 7. REALIZING THE POTENTIAL OF PERSONALIZED**
9 **MEDICINE.**

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

16 (1) codevelopment of companion diagnostic test-
17 ing by a drug sponsor;

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

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

23 (4) action on other issues determined appro-
24 priate by the Secretary.

25 (b) GENETIC TEST QUALITY.—

1 (1) IN GENERAL.—The Secretary shall improve
2 the availability of information on, and safety and ef-
3 ficacy of, genetic tests, including pharmacogenetic
4 and pharmacogenomic tests.

5 (2) INSTITUTE OF MEDICINE STUDY.—Not later
6 than 30 days after the date of enactment of this
7 Act, the Secretary shall enter into a contract with
8 the Institute of Medicine to conduct a study and
9 prepare a report that includes recommendations to
10 improve Federal oversight and regulation of genetic
11 tests, with specific recommendations on the imple-
12 mentation of the decision matrix under paragraph
13 (3). Such study shall take into consideration rel-
14 evant reports by the Secretary’s Advisory Committee
15 on Genetic Testing and other groups and shall be
16 completed not later than 1 year after the date on
17 which the Secretary entered into such contract.

18 (3) DECISION MATRIX.—

19 (A) IN GENERAL.—Not later than 18
20 months after the date of enactment of this Act,
21 the Secretary, taking into consideration the rec-
22 ommendations of the Institute of Medicine re-
23 port under paragraph (2), shall implement a de-
24 cision matrix (referred to in this section as the
25 “matrix”) to improve the oversight and regula-

1 tion of genetic tests, including
2 pharmacogenomic and pharmacogenetic tests by
3 determining—

4 (i) the classification of all genetic
5 tests;

6 (ii) which categories of tests, includ-
7 ing laboratory-developed tests, require re-
8 view and the level of review needed for
9 such categories of tests;

10 (iii) which agency shall have oversight
11 over the review process of such categories
12 of tests that are determined to require re-
13 view; and

14 (iv) to the extent practicable, which
15 requirements the agency shall apply to the
16 types of tests identified in clause (ii).

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

20 (i) performance characteristics of the
21 test and its target disease or condition;

22 (ii) intended use of the test;

23 (iii) potential for improved medical
24 conditions and patient harms; and

25 (iv) social consequences of the test.

1 (C) COMPARATIVE ANALYSIS.—To inform
2 implementation of the matrix, the Secretary
3 shall undertake a comparative analysis of lab-
4 oratory review requirements under CLIA and
5 those of the Food and Drug Administration
6 to—

7 (i) assess and reduce unnecessary dif-
8 ferences in such requirements;

9 (ii) eliminate redundancies and de-
10 crease burden of review, as practicable;
11 and

12 (iii) specify which elements of the test
13 constitute a device that may be regulated
14 by the Food and Drug Administration and
15 which elements comprise a service that
16 may be regulated under CLIA.

17 (D) REGULATIONS.—The Secretary shall
18 promulgate regulations to implement the matrix
19 not later than the date specified under subpara-
20 graph (A).

21 (E) TRANSITION PERIOD.—The Secretary
22 may not require a laboratory to submit a report
23 under section 510(k) or an application under
24 section 515 of the Federal Food, Drug and
25 Cosmetic Act (21 U.S.C. 301 et seq.) until 180

1 days after the regulations promulgated under
2 subparagraph (D) take effect.

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

7 (A) develop or expand adverse event re-
8 porting systems to encompass reports of ad-
9 verse events resulting from genetic testing;

10 (B) respond appropriately to any adverse
11 events resulting from such testing; and

12 (C) facilitate the use of genetic and
13 genomic approaches, as feasible, to assess risk
14 for, and reduce incidence of, adverse drug reac-
15 tions.

16 (5) AUTHORIZATION OF APPROPRIATIONS.—
17 There are authorized to be appropriated to carry out
18 this subsection, \$6,000,000 for fiscal year 2008, and
19 such sums as may be necessary for each of fiscal
20 years 2009 through 2013.

21 (c) FOOD AND DRUG ADMINISTRATION.—

22 (1) IN GENERAL.—

23 (A) SUMMARY INFORMATION.—If a genetic
24 test that is determined to be within the jurisdic-
25 tion of the Food and Drug Administration but

1 that does not require review as determined
2 under the matrix, the sponsor of such test shall
3 provide the Secretary with summary informa-
4 tion on how such test was validated and its per-
5 formance characteristics. Such information shall
6 be in a standardized format and with standard-
7 ized content as specified by the Food and Drug
8 Administration, and shall be made easily acces-
9 sible to the public.

10 (B) SOURCE OF INFORMATION.—The in-
11 formation described under subparagraph (A)
12 may be obtained from the labeling submitted
13 for CLIA complexity categorization.

14 (2) ENCOURAGEMENT OF COMPANION DIAG-
15 NOSTIC TESTING.—The Secretary may encourage
16 the sponsor of a drug or biological product—

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

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

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

7 (3) PHARMACOGENOMIC DATA SUBMISSION.—
8 The Secretary shall encourage and facilitate vol-
9 untary pharmacogenomic data submission from drug
10 sponsors, which may include—

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

14 (B) the provision of technical assistance;

15 (C) the establishment of a mechanism to
16 store, maintain and analyze such data, in col-
17 laboration with the National Institutes of
18 Health and the Centers for Disease Control and
19 Prevention;

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

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

1 (F) other activities determined appropriate
2 by the Commissioner.

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

11 (d) CENTERS FOR MEDICARE & MEDICAID SERV-
12 ICES.—

13 (1) IN GENERAL.—If a genetic test that is de-
14 termined to be within the jurisdiction of the Centers
15 for Medicare & Medicaid Services but that does not
16 require review as determined under the matrix, the
17 sponsor of such test shall provide the Administrator
18 of the Centers for Medicare & Medicaid Services
19 with summary information on how the test was vali-
20 dated and its performance characteristics. Such in-
21 formation shall be in a standardized format and with
22 standardized content as specified by the Centers for
23 Medicare & Medicaid Services, and shall be made
24 easily accessible to the public.

1 (2) SPECIALTY AREA.—To ensure the accuracy,
2 validity, and reliability of clinical genetic tests that
3 do not require premarket approval by or notification
4 to the Food and Drug Administration, and to im-
5 prove oversight of genetic test laboratories, the Di-
6 rector of the Division of Laboratory Services of the
7 Survey and Certification Group of the Center for
8 Medicaid and State Operations of the Centers for
9 Medicare & Medicaid Services, in collaboration with
10 the Clinical Laboratory Improvement Advisory Com-
11 mittee at the Centers for Disease Control and Pre-
12 vention, shall establish a specialty area for molecular
13 and biochemical genetic tests, in order to—

14 (A) develop criteria for establishing ana-
15 lytic and clinical validity for genetic tests that
16 are determined to require review under the ma-
17 trix;

18 (B) specify requirements for proficiency
19 testing for laboratories;

20 (C) provide guidance regarding the scope
21 of duty for laboratory directors;

22 (D) make information easily accessible to
23 the public about—

24 (i) laboratory certification; and

1 (ii) analytic and clinical validity for
2 genetic tests that are determined to require
3 high level review under the matrix; and

4 (E) conduct other activities at the discre-
5 tion of the Administrator of the Centers for
6 Medicare & Medicaid Services.

7 (3) REIMBURSEMENT.—

8 (A) CODING.—To foster adoption of ge-
9 netic screening tools, the Administrator of the
10 Centers for Medicare & Medicaid Services
11 shall—

12 (i) assess and update current proce-
13 dure terminology codes to encourage the
14 rapid review and coverage of novel tests
15 through the creation of new HCPCS codes
16 and adoption of new CPT codes and with-
17 out undue reliance on national coverage
18 determinations; and

19 (ii) determine and implement fair and
20 reasonable coverage policies and reimburse-
21 ment rates for medically necessary genetic
22 and genomic treatments and services, in-
23 cluding laboratory testing.

24 (B) BUDGET NEUTRALITY.—Before en-
25 hancing payment for a year pursuant to this

1 paragraph, the Secretary shall, if necessary,
2 provide for an adjustment to payments made
3 under part B of title XVIII of the Social Secu-
4 rity Act (42 U.S.C. 1395j et seq.) in that year
5 to ensure that such payments shall be equal to
6 aggregate payments that would have been made
7 under such part in that year if this paragraph
8 had not been enacted.

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

11 (1) DIRECT-TO-CONSUMER MARKETING.—Not
12 later than 2 years after the date of enactment of
13 this Act, the Director of the Centers for Disease
14 Control and Prevention, 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 (3) AUTHORIZATION OF APPROPRIATIONS.—
19 There are authorized to be appropriated to carry out
20 this subsection, \$10,000,000 for fiscal year 2008,
21 and such sums as may be necessary for each of fis-
22 cal years 2009 through 2013.

23 (f) AGENCY FOR HEALTHCARE RESEARCH AND
24 QUALITY.—The Director of the Agency for Healthcare
25 Research and Quality, after consultation with the IWG

1 and other public and private organizations based in the
2 United States and abroad, as appropriate, shall support
3 the assessment of the clinical utility and cost-effectiveness
4 of companion diagnostic tests that guide prescribing deci-
5 sions, through research that—

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

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

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

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

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

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

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

6 (g) AUTHORIZATION OF APPROPRIATIONS.—There
7 are authorized to be appropriated to carry out this section,
8 \$10,000,000 for fiscal year 2008, and such sums as may
9 be necessary for each of fiscal years 2009 through 2013.

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