109TH CONGRESS
2D 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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Genomics and Personalized Medicine Act of 2006''.

SEC. 2. FINDINGS.

Congress makes the following findings:

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

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

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

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

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

(6) Pharmacogenomics is the study of how genes affect a person's response to drugs. This relatively new field combines pharmacology (the science

of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and dosing regimens that will be tailored to an individual's genetic makeup.

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

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

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

death. Pharmacogenomic researchers have identified and developed tests for genetic variants in the cytochrome P450 metabolizing enzyme (CYP2C9) and vitamin K epoxide reductase complex that increase risk for these adverse events. By using a companion diagnostic test for these two genes, physicians can modify the dosing regimen and decrease the likelihood of adverse events.

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

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

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

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

SEC. 3. DEFINITIONS.

In this Act:

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

(2) LABORATORY-DEVELOPED GENETIC TEST.—The term ''laboratory-developed genetic test'' means a molecular genetic test that is designed, validated, conducted, and offered as a service by a clinical laboratory subject to the Clinical Lab-

oratory Improvement Amendments (referred to in this Act as ''CLIA'') using either commercially available analyte specific reagents (FDA-regulated) or reagents prepared by the laboratory (not FDA-regulated), or some combination thereof.

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

(4) PHARMACOGENETIC TEST.—The term ''pharmacogenetic test'' means a molecular genetic test intended to identify individual variations in DNA sequence related to drug absorption and disposition (pharmacokinetics) or drug action (pharmacodynamics), including polymorphic variation in the genes that encode the functions of transporters, receptors, metabolizing enzymes, and other proteins.

(5) PHARMACOGENOMIC TEST.—

(A) IN GENERAL.—The term ''pharmacogenomic test'' means a molecular genetic test intended to identify individual variations in single-nucleotide polymorphisms, haplotype markers, or alterations in gene expression or inac-

tivation, that may be correlated with pharmacological function and therapeutic response.

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

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

SEC. 4. GENOMICS AND PERSONALIZED MEDICINE INTERAGENCY WORKING GROUP.

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

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

(1)(A) enhancing communication about current and proposed activities and areas of focus by the Department of Health and Human Services and other relevant Federal departments and agencies, including communication focused on findings and recommendations from—

(i) the advisory groups on genetics of the Secretary, including the Secretary's Advisory Committee on Genetics, Health, and Society, and the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; and

(ii) the National Academies of Science, including the Institute of Medicine; and

(B) identifying areas of need and opportunity; and

(2) facilitating collaboration, coordination, and integration of activities, within the Federal agencies, and among such agencies and their public and private partners to leverage resources and avoid duplication of effort.

(c) IWG CHAIRPERSON.—The Secretary shall serve as chairperson of the IWG. The Secretary may not designate another person to serve as a chairperson of the IWG.

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

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

the National Center on Minority Health and Health Disparities;

(2) Centers for Disease Control and Prevention, including the Office of Genomics and Disease Prevention;

(3) Food and Drug Administration, including the Office of Clinical Pharmacology and Biopharmaceutics Review and the Office of In Vitro Diagnostics;

(4) Health Resources and Services Administration, including the genetic services branch of the Maternal and Child Health Bureau and the Bureau of Health Professions;

(5) Office of Minority Health;

(6) Agency for Healthcare Research and Quality;

(7) Centers for Medicare & Medicaid Services;

(8) Veterans Health Administration;

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

(10) Department of Energy, including the Human Genome Program and Joint Genome Institute of the Office of Science; and

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

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

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

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

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

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

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

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

(a) GENETICS AND GENOMICS RESEARCH.—

(1) IN GENERAL.—The Secretary shall expand and accelerate research and programs to collect genetic and genomic data that will advance the field of

genomics and personalized medicine, with prioritized focus on—

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

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

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

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

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

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

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

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

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

(2) BIOBANKING.—

(A) NATIONAL BIOBANKING RESEARCH INITIATIVE.—The Secretary, in collaboration with the IWG, shall develop a plan for a national biobanking research initiative that—

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

(ii) builds upon current genomic research initiatives (existing as of the date the plan is issued) domestically and, as practicable, internationally;

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

(iv) takes into consideration public review and comment;

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

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

(vii) ensures diverse representation of individuals in the research or data collection that would allow statistically significant analyses of population subgroups as appropriate; and

(viii) reflects public-private partnership.

(B) NATIONAL BIOBANKING DISTRIBUTED DATABASE.—

(i) IN GENERAL.—The Secretary, acting through the Director of the National Human Genome Research Institute at the National Institutes of Health and the Director of the Office of Genomics and Disease Prevention at the Centers for Disease Control and Prevention, shall establish a system for the integration of data, including genomic data and associated environmental and clinical health information, which shall facilitate the pooled analysis and synthesis of such data.

(ii) DISTRIBUTED DATABASE.—With respect to such national biobanking database, the Secretary shall—

(I) establish a grant program for local or regional biobanking initiatives, in accordance with subparagraph (C), with priority given for local or regional biobanks that—

(aa) are established or complement activities related to the implementation of the national biobanking research initiative, pursuant to subparagraph (A);

(bb) are based on well-defined populations, such as cohorts of newborn infants screened by State health departments for metabolic disorders, population-based registries of cancer and other diseases, and family-based registries;

(cc) collect data from participants with diverse genetic profiles, environmental exposures,

and health conditions and diseases; and

(dd) participate in and contribute data to consortia established to develop and apply best practices and standards in the research area of such consortium;

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

(III) develop and promulgate guidelines regarding procedures, protocols, and policies for access of data by non-governmental entities and the safeguarding of the privacy of biobank subjects, in accordance with the Office for Human Research Protection and Clinical Research Policy Analysis and Coordination program at the National Institutes of Health, and other guidelines as appropriate;

(IV) review and make recommendations to address ownership

issues with respect to genomic samples and analyses;

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

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

(VII) incorporate data from Federal surveys, such as the National Health and Nutrition Examination Survey;

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

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

(X) allow public use of data only—

(aa) with appropriate privacy safeguards in place; and

(bb) for health research purposes;

(XI) determine appropriate procedures for industry access to biobank data for research and development of new or improved tests and treatments, and submission of data generated from such samples to the Food and Drug Administration as part of the approval process for drugs and devices; and

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

(iii) NATIONAL RESOURCES.—The IWG shall sponsor national efforts to bring together the consortia described in clause (ii)(I)(dd) to build national data resources.

(C) BIOBANK INITIATIVES GRANTS.—

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

tutions to enable the institutions to develop or expand biobanking initiatives to advance the application of genomics to the practice of medicine and contribute to the understanding of the genetic causes of disease.

(ii) ELIGIBILITY.—An academic medical center or other institution shall be eligible for a grant under this subparagraph if the center or institution has—

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

(II) an established scientific advisory committee to—

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

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

(cc) provide a forum for evidence-based reviews and integration of research findings to determine if and how such findings

may be used in health care and disease prevention;

(III) an established community advisory committee comprised of community advocates, potential study participants, and other stakeholders, to—

(aa) provide a non-scientific perspective on the biobanking initiative;

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

(cc) support outreach to minority and other underserved communities; and

(dd) provide a forum for the discussion of ethical, social, and legal issues pertaining to the biobanking initiative;

(IV) mechanisms to ensure patient privacy and protection of information from non-health applications; and

(V) a demonstrated ability to recruit patients from diverse cultural backgrounds.

(iii) USE OF FUNDS.—An eligible institution that receives a grant under this subparagraph shall use the grant funds to develop or expand a biobanking initiative, which may include the following activities:

(I) Support for advisory committees.

(II) Recruitment and education of patients.

(III) Development of consent protocols.

(IV) Obtaining genetic samples and clinical information.

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

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

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

(bb) Increased understanding of gene-environment interactions.

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

(dd) Genotypic characterization of tissue samples.

(VII) Support for participation in research consortia concerned with establishing and developing best practices and standards in the relevant research areas.

(VIII) Development and implementation of protocols for external researchers to access non-identifiable patient samples and associated health information for research activities.

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

(b) RACE, GENOMICS, AND HEALTH.—

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

(A) interaction between genetics and the environment, and the influence of such interaction on the causality and treatment of diseases common in racial and ethnic minority populations; and

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

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

(A) An appropriate definition for race and ethnicity for use in genomic research and programs operated or supported by the Federal Government.

(B) Guiding ethics, principles, and protocols for the inclusion and designation of racial and ethnic populations in genomics research and programs operated or supported by the Federal Government.

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

(D) Research opportunities and funding support in the area of race and genomics that may improve the health and health care of minority populations.

(E) Ways to enhance integration of Federal Government-wide efforts and activities pertaining to race, genomics, and health.

(F) Any needs for additional privacy protections in preventing stigmatization and inappropriate use of genetic information.

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

SEC. 6. GENOMICS WORKFORCE AND TRAINING.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention, and in collaboration with the IWG, shall expand and intensify efforts to—

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

(2) in collaboration with appropriate professional accreditation organizations, assess and make recommendations to improve the quality of genomics training; and

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

(b) ELIGIBLE ENTITY.—For purposes of this section, the term ''eligible entity'' includes professional genetics and genomics societies and academic institutions determined appropriate by the Secretary.

(c) RECRUITMENT AND RETENTION.—The Secretary shall provide financial and technical support to eligible entities to increase recruitment and retention of trainees in genetics and genomics by—

(1) providing education and awareness opportunities, practical and research experiences, and financial incentives such as scholarships or loan repayment;

(2) considering development of genomic subspecialty fellowships or concentrations within genetics training programs;

(3) considering development of combined residency programs or joint subspecialty fellowships with other specialties;

(4) providing support for laboratory-based genetics or genomics fellowships for medical and other health professional students; and

(5) carrying out other activities determined appropriate by the Secretary.

(d) GENETICS AND GENOMICS TRAINING.—The Secretary, directly or through contracts or grants to eligible entities, shall ensure the adequacy of genetics and genomics training for diagnosis, treatment, and counseling of adults and children for both rare and common disorders, through support of efforts to—

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

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

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

(4) explore options for distance or on-line learning for degree or continuing education programs.

(e) INTEGRATION.—The Secretary shall support initiatives to increase the integration of genetics and genomics into all aspects of clinical and public health practice by—

(1) generating greater awareness of the relevance and application of genetics and genomics to common disorders; and

(2) promoting genetics and genomics competency across all clinical, public health and laboratory disciplines through the development and dissemination of health professional guidelines which shall—

(A) include focus on appropriate administration and interpretation of genomic tests, and subsequent clinical and public health decision-making; and

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

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

SEC. 7. REALIZING THE POTENTIAL OF PERSONALIZED MEDICINE.

(a) INCENTIVES.—

(1) TAX CREDIT FOR RESEARCH AND DEVELOPMENT RELATED TO COMPANION DIAGNOSTIC TESTS.—

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

"SEC. 45N. COMPANION DIAGNOSTIC TEST CREDIT.

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

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

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

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

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

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

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

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

''(e) NO DOUBLE BENEFIT.—

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

''(2) RESEARCH AND DEVELOPMENT COSTS.—

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

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

''(B) COSTS TAKEN INTO ACCOUNT IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any amount taken into account in determining the amount of the credit under subsection (a) for any taxable year shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

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

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

(B) CREDIT TREATED AS PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986 is amended by striking ''and'' at the end of paragraph (29), by

striking the period at the end of paragraph (30) and inserting ", plus", and by adding at the end the following new paragraph:

"(31) the companion diagnostic test credit determined under section 45N(a).".

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

"Sec. 45N. Companion diagnostic test credit.".

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

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

(A) co-development of companion diagnostic testing by a drug sponsor;

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

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

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

(b) GENETIC TEST QUALITY.—

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

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

(3) DECISION MATRIX.—

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

(2), shall develop a decision matrix (referred to in this section as the ''matrix'') to improve the oversight and regulation of genetic tests, including pharmacogenomics and pharmacogenetic tests by—

(i) determining the classification of genetic tests that have not yet been classified, or of which the classification is unclear, questioned, or challenged;

(ii) determining which types of tests, including laboratory-developed tests, require review and the level of review needed for such tests;

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

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

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

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

(ii) intended use of the test;

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

(iv) social consequences of the test.

(C) COMPARATIVE ANALYSIS.—To inform development of the matrix, the Secretary shall undertake a comparative analysis of laboratory review requirements under the Clinical Laboratory Improvement Act and those of the Food and Drug Administration to assess and reduce differences in such requirements, and to eliminate redundancies and decrease burden of review, as practicable.

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

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

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

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

(5) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $10,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2012.

(c) FOOD AND DRUG ADMINISTRATION.—

(1) IN GENERAL.—

(A) SUMMARY INFORMATION.—If a genetic test that is determined to be within the jurisdiction of the Food and Drug Administration but that does not require review, as determined under the matrix, the sponsor of such test shall provide the Secretary with summary information on how the test was validated and its performance characteristics, which information shall be made easily accessible for the public.

(B) SOURCE OF INFORMATION.—The information described under subparagraph (A) may be obtained from the labeling submitted for CLIA complexity categorization.

(2) REQUIREMENT FOR COMPANION DIAGNOSTIC TESTING.—The Secretary may require the sponsor of a drug or biological product—

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

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

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

(3) PHARMACOGENOMIC DATA SUBMISSION.—The Secretary shall encourage and facilitate voluntary pharmacogenomic data submission from drug sponsors, which may include—

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

(B) the provision of technical assistance;

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

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

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

(F) other activities determined appropriate by the Commissioner.

(4) LABELING FOR CERTAIN GROUPS.—Not later than 6 months of enactment of this Act, the Secretary shall prepare and publish guidance regarding the approval, licensing, or clearance of any product under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262) with an indication, contraindication, warning, or any other labeling information that is specific to a racial or ethnic group.

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

(d) CENTERS FOR MEDICARE & MEDICAID SERVICES.—

(1) IN GENERAL.—If a genetic test that is determined to be within the jurisdiction of the Centers for Medicare & Medicaid Services does not require review as determined under the matrix, the sponsor of such test shall provide the Administrator of the Centers for Medicare & Medicaid Services with summary information on how the test was validated and its performance characteristics, which information shall be made easily accessible for the public.

(2) SPECIALTY AREA.—To ensure the accuracy, validity, and reliability of clinical genetic tests that do not require premarket approval by or notification to the Food and Drug Administration, and to improve oversight of genetic test laboratories, the Director of the Division of Laboratory Services of the

Survey and Certification Group of the Center for Medicaid and State Operations of the Centers for Medicare & Medicaid Services, in collaboration with the Clinical Laboratory Improvement Advisory Committee at the Centers for Disease Control and Prevention, shall establish a specialty area for molecular and biochemical genetic tests, in order to—

(A) develop criteria for establishing analytic and clinical validity for genetic tests that are determined to require review under the matrix;

(B) specify requirements for proficiency testing for laboratories;

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

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

(i) laboratory certification; and

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

(E) conduct other activities at the discretion of the Administrator of the Centers for Medicare & Medicaid Services.

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

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

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

(e) CENTERS FOR DISEASE CONTROL AND PREVENTION.—

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

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

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

(C) make recommendations to Congress regarding necessary interventions to protect the public from potential harms of direct-to-consumer marketing and access to molecular genetic tests.

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

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

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

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

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

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

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

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

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

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

(3) accelerates development and rapid adoption by providers and payers as appropriate, of companion diagnostic testing that could significantly enhance the safety of a medication by identifying patients at risk for toxic events from use of such medication or by improving dosing regimens for such medication; and

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

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $30,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2012.

SEC. 8. SENSE OF THE SENATE REGARDING GENETIC NONDISCRIMINATION AND PRIVACY.

It is the sense of the Senate that—

(1) in order for personalized medicine to advance and achieve success in both reducing the burden of disease and reducing health care costs, strong privacy protections, including protections against genetic discrimination, must be enacted and implemented;

(2) without a Federal law banning genetic discrimination, people may fear losing their health insurance and their employment, and subsequently—

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

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

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

(4) adequate privacy protections, including a Federal prohibition against genetic discrimination, are necessary prerequisites to advancing personalized medicine.

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