

111TH CONGRESS
2^D SESSION

H. R. 5440

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

IN THE HOUSE OF REPRESENTATIVES

MAY 27, 2010

Mr. KENNEDY (for himself and Ms. ESHOO) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Genomics and Personalized Medicine Act of 2010”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Definitions.

TITLE I—OFFICE OF PERSONALIZED HEALTHCARE

Sec. 101. Office of Personalized Healthcare.

TITLE II—EXPANSION AND ACCELERATION OF RESEARCH FOR GENOMICS AND PERSONALIZED MEDICINE

Subtitle A—Acceleration of Genomics and Personalized Medicine Research

- Sec. 201. Grants for research in genomics and personalized medicine.
- Sec. 202. National biobank.
- Sec. 203. Biobank initiative grants.
- Sec. 204. Authorization of appropriations.

Subtitle B—Committee on the Evaluation of Genomic Applications in Practice and Prevention

Sec. 211. Establishment.

TITLE III—GENOMICS AND PERSONALIZED MEDICINE IN CLINICAL PRACTICE AND PUBLIC HEALTH

Sec. 301. Genomics and personalized medicine education and training.

TITLE IV—REALIZING THE POTENTIAL OF PERSONALIZED MEDICINE

- Sec. 401. Reducing the redundancy of clinical laboratory requirements.
- Sec. 402. Committee on public engagement.
- Sec. 403. Study by the Institute of Medicine.
- Sec. 404. Food and Drug Administration.
- Sec. 405. Adverse events.
- Sec. 406. Termination of certain advertising campaigns.
- Sec. 407. Centers for Disease Control and Prevention.
- Sec. 408. Authorization of appropriations.

1 **SEC. 2. DEFINITIONS.**

2 In this Act:

3 (1) **BIOBANK.**—The term “biobank” means a
 4 shared repository of human biological specimens col-
 5 lected for medical or research purposes that may in-
 6 clude biobank data.

7 (2) **BIOBANK DATA.**—The term “biobank
 8 data”—

1 (A) means data associated with a human
2 biological specimen stored in a biobank collected
3 for medical or research purposes; and

4 (B) includes, if feasible, health informa-
5 tion, demographic, genotype, and molecular pro-
6 file data, and environmental data associated
7 with a specimen.

8 (3) BIOMARKER.—The term “biomarker”
9 means a substance or chemical constituent found in
10 or derived from a human biological specimen that is
11 objectively measured and evaluated as an indicator
12 of normal biologic processes, pathogenic processes,
13 or pharmacologic responses to a therapeutic inter-
14 vention.

15 (4) ENVIRONMENT; ENVIRONMENTAL.—The
16 terms “environment” and “environmental” refer to
17 conditions or circumstances that are nongenetic, but
18 may have a health impact and affect the expression
19 of genes.

20 (5) CEGAPP.—The term “CEGAPP” means
21 the Committee on the Evaluation of Genomic Appli-
22 cations in Practice and Prevention established under
23 section 211.

24 (6) CLIA.—The term “CLIA” means section
25 353 of the Public Health Service Act (42 U.S.C. 18

1 263a; commonly referred to as the “Clinical Labora-
2 tory Improvement Amendments of 1988”).

3 (7) COMPANION DIAGNOSTIC TEST.—The term
4 “companion diagnostic test” means a genetic or
5 genomic test used in conjunction with a specific
6 treatment that measures and evaluates a specific
7 biomarker as an indicator of normal biologic proc-
8 esses, pathogenic processes, or pharmacologic re-
9 sponses to a therapeutic intervention for an individ-
10 ual’s condition.

11 (8) GENETIC AND GENOMIC TESTS.—

12 (A) IN GENERAL.—The term “genetic or
13 genomic tests” means analyses of human chro-
14 mosomes, deoxyribonucleic acid, ribonucleic
15 acid, genes, gene products (such as enzymes
16 and other types of proteins), or metabolites,
17 that—

18 (i) are predominately used to detect
19 heritable or somatic mutations,
20 genotypes, or phenotypes related to disease
21 and health; and

22 (ii) may be used to screen newborns,
23 identify carriers of inherited mutations,
24 predict risk of disease, establish prenatal
25 or clinical diagnoses, provide prognostic in-

1 formation, diagnose malignancies, guide
2 clinical management, identify targets for
3 therapy, monitor results to therapy, and
4 evaluate for early relapse.

5 (B) EXCLUSIONS.—The term “genetic and
6 genomic tests” excludes—

7 (i) tests conducted exclusively for fo-
8 rensic and identity purposes;

9 (ii) tests conducted purely for re-
10 search purposes;

11 (iii) tests that are used primarily for
12 other purposes but that may contribute to
13 diagnosing a genetic disease or disorder
14 (such as blood smears and certain serum
15 chemistries);

16 (iv) an analysis of proteins or metabo-
17 lites that does not indicate genotypes,
18 mutations, or chromosomal changes; or

19 (v) an analysis of proteins or metabo-
20 lites that is directly related to a manifested
21 disease, disorder, or pathological condition
22 that could reasonably be detected by a
23 health care professional with appropriate
24 training and expertise in the field of medi-
25 cine involved.

1 (9) HUMAN BIOLOGICAL SPECIMEN.—The term
2 “human biological specimen” means any human
3 body fluid, tissue, blood, or cell; any material derived
4 from any human body fluid, tissue, blood, or cell;
5 and, as feasible, any data associated with such speci-
6 mens including associated health information, demo-
7 graphic, genotype, and molecular profile data, and
8 environmental data.

9 (10) OPH.—The term “OPH” means the Of-
10 fice of Personalized Healthcare established under
11 section 101.

12 (11) PERSONALIZED MEDICINE.—The term
13 “personalized medicine” means any clinical practice
14 model that emphasizes the systematic use of preven-
15 tive, diagnostic, and therapeutic interventions that
16 use genome and family history information to im-
17 prove health outcomes.

18 (12) PHARMACOGENOMICS.—

19 (A) IN GENERAL.—The term
20 “pharmacogenomics” means the study of indi-
21 vidual variations in DNA and RNA characteris-
22 tics and sequences and the relationship of such
23 variations to drug response, including absorp-
24 tion, distribution, metabolism, and elimination
25 (pharmacokinetics) or drug action

1 (pharmacodynamics). Such variations include
2 nucleotide polymorphism rearrangements, inser-
3 tions, and deletions. Such variations may also
4 include alterations in gene expression or inac-
5 tivation in the genes encoding drug trans-
6 porters, receptors, metabolizing enzymes, or any
7 other proteins that are implicated in pharma-
8 cological function and therapeutic response.

9 (B) VARIATIONS.—For purposes of this
10 paragraph, the variations referred to in sub-
11 paragraph (A) may affect a single nucleotide or
12 more than one region in a single gene or reflect
13 alterations in more than one gene.

14 (13) SACGHS.—The term “SACGHS” means
15 the Secretary’s Advisory Committee on Genomics,
16 Health, and Society.

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

19 **TITLE I—OFFICE OF** 20 **PERSONALIZED HEALTHCARE**

21 **SEC. 101. OFFICE OF PERSONALIZED HEALTHCARE.**

22 (a) IN GENERAL.—The Secretary shall establish the
23 Office of Personalized Healthcare within the Office of the
24 Secretary.

1 (b) DIRECTOR.—The OPH shall be headed by a di-
2 rector, to be appointed by the Secretary.

3 (c) PURPOSE.—The purpose of the OPH is to coordi-
4 nate the activities related to genomics and personalized
5 medicine of the Department of Health and Human Serv-
6 ices with those of other relevant agencies and public and
7 private entities to ensure that personalized medicine meets
8 the highest standards of safety, efficacy, and clinical valid-
9 ity and utility.

10 (d) DUTIES.—The Secretary, acting through the Di-
11 rector of the OPH, shall coordinate cross-agency activities
12 and collaboration of the Department of Health and
13 Human Services related to genomics and personalized
14 medicine, and shall work with relevant departments and
15 agencies and representatives of the private sector to—

16 (1) develop a strategic, long-term plan to ad-
17 vance research and development relevant to person-
18 alized medicine for coordinating basic science and
19 translational research in personalized medicine;

20 (2) identify, prioritize, and address challenges
21 in translational research on products used for per-
22 sonalized medicine, including genetic and genomic
23 tests that impact both product development and reg-
24 ulation, including any ongoing initiatives;

1 (3) assure that coverage and reimbursement de-
2 cisions for products used for personalized medicine
3 take into account the best data available for such
4 decisions without violating the data sharing con-
5 straints;

6 (4) identify and prioritize gaps in the evidence
7 base concerning outcomes and cost-effectiveness of
8 genomics-based diagnostics and to develop research
9 or consensus development initiatives to address those
10 gaps;

11 (5) clarify and simplify the regulation of prod-
12 ucts used for personalized medicine to ensure that
13 guidelines are consistent and intra-agency regula-
14 tions do not conflict;

15 (6) educate and consult with developers of prod-
16 ucts used for personalized medicine concerning evi-
17 dence requirements for reimbursement and regu-
18 latory purposes, to facilitate development of more
19 cost-effective clinical trial programs for new prod-
20 ucts;

21 (7) ensure that the Federal regulatory approach
22 to information technology-based clinical decision
23 support systems is evidence based and appropriately
24 targeted;

1 (8) leverage and network existing agency and
2 private sector expertise to address the needs in
3 translating genomics into the implementation and
4 practice of personalized medicine, including the find-
5 ings and recommendations of the SACGHS and
6 CEGAPP or any other such council or committee es-
7 tablished for the purpose of advising the Secretary
8 on personalized medicine; and

9 (9) provide a forum and mechanism to coordi-
10 nate across agencies and the private sector with re-
11 gard to discussing genomics priorities and the stand-
12 ards needed for personalized medicine to become fea-
13 sible.

14 (e) ANNUAL REPORTS.—Not later than 24 months
15 after the date of the enactment of this Act, and annually
16 after submission of the initial report, the Director of the
17 OPH shall prepare and submit to the appropriate commit-
18 tees of the Congress a report. Each such report shall de-
19 scribe—

20 (1) progress of cross-agency coordination re-
21 lated to personalized medicine;

22 (2) innovations in genomics and personalized
23 medicine;

24 (3) emerging and persistent challenges related
25 to personalized medicine;

1 (4) key barriers in research, regulation, and re-
2 imbursement and their impact on innovation, devel-
3 opment, and implementation of medical product de-
4 velopment for personalized medicine;

5 (5) medical, ethical, legal, and social impacts of
6 personalized medicine; and

7 (6) the extent to which the findings and rec-
8 ommendations of the SACGHS, CEGAPP, and
9 other Federal entities are used to inform policy-
10 making on personalized medicine within the Depart-
11 ment of Health and Human Services.

12 (f) REPORT ON THE REGULATION OF PRODUCTS
13 USED FOR PERSONALIZED MEDICINE.—Not later than 18
14 months after the date of the enactment of this Act, the
15 Director of the OPH shall submit to the Secretary and
16 the appropriate committees of the Congress, and publish
17 a report on, recommendations for the regulation of prod-
18 ucts used for personalized medicine (including genetic and
19 genomic tests). Such report shall include recommendations
20 regarding—

21 (1) which products used for personalized medi-
22 cine should require regulation, and, for such prod-
23 ucts which are recommended in the report to require
24 regulation, recommendations regarding—

1 (A) the appropriate regulatory submission
2 requirements and timeframes for such submis-
3 sions;

4 (B) the appropriate level of evidence nec-
5 essary for approval of such products; and

6 (C) resubmission requirements for those
7 products used for personalized medicine that
8 undergo modifications;

9 (2) a clear delineation between the roles and re-
10 sponsibilities of the Food and Drug Administration
11 and the Centers for Medicare & Medicaid Services in
12 regulation and enforcement of products used for per-
13 sonalized medicine, including laboratory-developed
14 tests, and the resolution of any conflicts or
15 redundancies between the 2 agencies, including
16 under section 401;

17 (3) a means by which to decrease the burden
18 associated with the initial and subsequent submis-
19 sion of any required regulatory documents by clinical
20 laboratories; and

21 (4) an evaluation of any current Federal reg-
22 istries for products used for personalized medicine
23 (including those for genetic and genomic tests) to
24 determine the appropriateness of establishing a man-
25 datory registry for such products (including specific

1 recommendations pertaining to the purpose, imple-
2 mentation, maintenance, and use of the registry).

3 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
4 out this section, there are authorized to be appropriated
5 \$5,000,000 for fiscal year 2011, and such sums as may
6 be necessary for each of fiscal years 2012 through 2016.

7 **TITLE II—EXPANSION AND AC-**
8 **CELERATION OF RESEARCH**
9 **FOR GENOMICS AND PERSON-**
10 **ALIZED MEDICINE**

11 **Subtitle A—Acceleration of**
12 **Genomics and Personalized**
13 **Medicine Research**

14 **SEC. 201. GRANTS FOR RESEARCH IN GENOMICS AND PER-**
15 **SONALIZED MEDICINE.**

16 (a) IN GENERAL.—The Secretary, acting through the
17 Directors of the Centers for Disease Control and Preven-
18 tion and other relevant agencies (as determined by the
19 Secretary), shall increase and accelerate research and pro-
20 grams to collect, evaluate, and disseminate genetic and
21 genomic data that will advance the field of genomics and
22 personalized medicine, which may include—

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

1 (2) population-based studies of genotype preva-
2 lence, gene-disease association, gene-drug response
3 association, and interactions between genes and the
4 environment;

5 (3) systematic review and synthesis of the re-
6 sults of population-based studies using methods of
7 human genome epidemiology;

8 (4) translation of genomic information into mo-
9 lecular genetic and genomic screening tools,
10 diagnostics, and therapeutics by supporting proc-
11 esses and studies that lead to effective and safe ap-
12 plications in clinical and public health practice;

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

16 (6) comprehensive studies of clinical utility, in-
17 cluding cost-effectiveness and cost-benefit analyses,
18 of molecular genetic and genomic tests and thera-
19 peutics;

20 (7) implementation and postimplementation re-
21 search to facilitate studies for evaluating effective-
22 ness and utility in clinical and policy decision-
23 making;

24 (8) comprehensive studies of clinical and labora-
25 tory practices necessary to ensure effective imple-

1 mentation of high-quality standards of practice
2 using evidence-based clinical and public health
3 guidelines for genetic and genomic tests;

4 (9) systematic review of data on analytic valid-
5 ity, clinical validity, and clinical utility of products
6 used for personalized medicine, and data on imple-
7 mentation and dissemination of evidence-based prac-
8 tices;

9 (10) studies to assess the awareness, knowl-
10 edge, and use of products used for personalized med-
11 icine and their impact on population health and
12 health disparities;

13 (11) bioinformatics research designed to inte-
14 grate genomics and personalized medicine into clin-
15 ical practice; and

16 (12) research to fill gaps in clinical knowledge
17 as determined by the CEGAPP.

18 (b) GRANTS.—

19 (1) IN GENERAL.—The Secretary may award
20 grants to eligible entities to carry out the activities
21 described in subsection (a).

22 (2) PRIORITY.—In awarding grants under this
23 subsection, the Secretary shall give priority to eligi-
24 ble entities that—

1 (A) enter into collaborative research with
2 public and private entities; or

3 (B) propose to address priorities identified
4 by the CEGAPP under subtitle B.

5 (3) DEFINITION.—In this subsection, the term
6 “eligible entity” includes any nonprofit organization
7 with expertise in genomics and personalized medi-
8 cine.

9 **SEC. 202. NATIONAL BIOBANK.**

10 (a) IN GENERAL.—The Director of the National In-
11 stitutes of Health, in consultation with the Director of
12 Centers for Disease Control and Prevention, shall estab-
13 lish and maintain a national biobank to advance the field
14 of genomics and personalized medicine. The Director shall
15 coordinate activities under this section with the activities
16 of other public or private biobank or genomic database ini-
17 tiatives, including initiatives funded under section 203.
18 The national biobank shall be designed to collect and inte-
19 grate human biological specimens and biobank data for
20 research purposes associated with genomics and personal-
21 ized medicine.

22 (b) REQUIREMENTS.—In carrying out subsection (a),
23 the Director of the National Institutes of Health shall—

1 (1) establish, directly or by contract, a single
2 point of authority to manage operations of the na-
3 tional biobank;

4 (2) establish and disseminate quality standards
5 and guidelines for the collection, processing,
6 archiving, storage, and dissemination of human bio-
7 logical specimens and biobank data for research and
8 clinical purposes;

9 (3) develop and promulgate guidelines regard-
10 ing procedures, protocols, and policies for the safe-
11 guarding of the privacy of human biological speci-
12 mens and biobank data, in accordance with applica-
13 ble Federal and State regulations, guidelines, and
14 policies, as appropriate;

15 (4) review and make recommendations to ad-
16 dress ownership, patient access issues, and analyses
17 with respect to human biological specimens and
18 biobank data;

19 (5) develop and promulgate guidelines regard-
20 ing procedures, protocols, and policies for access to
21 human biological specimens and biobank data by
22 nongovernmental entities for research purposes;

23 (6) develop and disseminate guidelines for
24 structuring informed consent forms that address—

- 1 (A) privacy and confidentiality of human
2 biological specimens and biobank data;
- 3 (B) understanding of research procedures,
4 benefits, risks, rights, and responsibilities;
- 5 (C) continuous voluntary participation;
- 6 (D) the development of informed consent
7 agreements that allow for future research in ad-
8 vance of clear research objectives; and
- 9 (E) the right of an individual to opt out of
10 research at any time;
- 11 (7) develop mechanisms for informing the pub-
12 lic about the national biobank;
- 13 (8) ensure the inclusion of underrepresented
14 populations with health disparities in the activities
15 of the national biobank, pursuant to the goals of
16 Healthy People 2010;
- 17 (9) incorporate human biological specimens and
18 biobank data from federally conducted or supported
19 genomics initiatives, as feasible;
- 20 (10) encourage voluntary submission of human
21 biological specimens and biobank data obtained or
22 analyzed with private or non-Federal funds;
- 23 (11) facilitate submission of biobank data, in-
24 cluding secure and efficient electronic submission;

1 (12) allow public use of human biological speci-
2 mens and biobank data only—

3 (A) with appropriate privacy safeguards in
4 place; and

5 (B) for research purposes;

6 (13) determine appropriate procedures for ac-
7 cess by nongovernmental entities to human biological
8 specimens and biobank data for research and devel-
9 opment of new or improved tests and treatments,
10 and submission of data generated from research and
11 development to the Food and Drug Administration
12 or appropriate agencies as part of the approval proc-
13 ess for products used for personalized medicine;

14 (14) conduct, directly or by contract, analytical
15 research, including clinical, epidemiological, and so-
16 cial-science, using human biological specimens and
17 biobank data including the development of a long-
18 term population cohort for investigating genetic and
19 environmental health impacts; and

20 (15) make aggregate research findings from
21 biobank initiatives supported by Federal funding
22 publicly available within an appropriate timeframe
23 (as determined by the Secretary).

1 **SEC. 203. BIOBANK INITIATIVE GRANTS.**

2 (a) IN GENERAL.—The Secretary shall establish a
3 program of awarding grants to eligible entities for the de-
4 velopment or expansion of a biobank initiative for the pur-
5 poses of—

6 (1) increasing understanding of how genomics
7 interacts with lifestyle factors and the environment
8 to cause disease;

9 (2) examining the effectiveness of using
10 genomic information in health management and
11 medical decisionmaking;

12 (3) discovering genomic variations that affect
13 drug toxicity and efficacy; and

14 (4) accelerating the development of products
15 used for personalized medicine.

16 (b) USE OF FUNDS.—As a condition on receipt of
17 a grant under subsection (a), an eligible entity shall agree
18 to use the grant, consistent with the purposes described
19 in such subsection, to develop or expand a biobank initia-
20 tive. Such development or expansion may include any of
21 the following activities:

22 (1) Support for the scientific community and
23 medical advisory committees.

24 (2) Recruitment and education of diverse par-
25 ticipants, especially underrepresented races,

1 ethnicities, and genders pursuant to the goals of
2 Healthy People 2010.

3 (3) Development of consent protocols.

4 (4) Provision of genetic counseling services to
5 participants, as appropriate.

6 (5) Obtaining human biological specimens and
7 biobank data.

8 (6) Obtaining necessary equipment for data col-
9 lection, analysis, and storage.

10 (7) Establishment and maintenance of secure
11 storage for human biological specimens and biobank
12 data.

13 (8) Conducting data analyses and evidence-
14 based systematic reviews that allow for the following:

15 (A) Identification of biomarkers and other
16 surrogate markers to improve predictions of
17 onset of disease, response to therapy, and clin-
18 ical outcomes.

19 (B) Increased understanding of gene and
20 environment interactions.

21 (C) Development of personalized medicine
22 screening, diagnostic, and therapeutic interven-
23 tions.

24 (D) Genotypic characterization of human
25 biological specimens and biobank data.

1 (9) Development of protocols for providing to
2 health care providers and patients, by means of elec-
3 tronic health records in accordance with title XXX
4 of the Public Health Service Act (42 U.S.C. 300jj
5 et seq.), genomic information obtained during the
6 course of research or treatment, for the purpose of
7 improving patient care and outcomes.

8 (10) Development of interactive, Web-based
9 portals to provide participants access to their per-
10 sonal genetic profile.

11 (11) Any other related activities deemed appro-
12 priate by the Secretary.

13 (c) BIOBANK REQUIREMENTS.—The Secretary shall
14 ensure that any biobank supported under this section—

15 (1) supports genomics and personalized medi-
16 cine research;

17 (2) adheres to standards, guidelines, and rec-
18 ommendations developed under section 202(b);

19 (3) is established to complement activities re-
20 lated to the implementation of current public
21 biobank research initiatives, as feasible;

22 (4) is based on well-defined populations, includ-
23 ing population-based registries of disease and family-
24 based registries;

1 (5) collects data from participants with diverse
2 genomic profiles, demographics, environmental expo-
3 sures, and presence or absence of diverse health con-
4 ditions and diseases, as appropriate;

5 (6) has practical experience and demonstrated
6 expertise in genomics and its clinical and public
7 health applications;

8 (7) establishes mechanisms to ensure patient
9 privacy and protection of information from non-
10 health applications and, as feasible, patient access to
11 human biological specimens and biobank data for
12 clinical testing purposes; and

13 (8) contributes biobank data to the national
14 biobank established under section 202.

15 (d) PRIORITY.—In awarding grants under this sec-
16 tion, the Secretary shall give priority to eligible entities
17 with experience in conducting population-based genetic re-
18 search studies (such as focused whole genome, and
19 epigenetics studies) or genomic research on heritable or
20 somatic mutations.

21 (e) QUALITY ASSURANCE.—The Secretary may enter
22 into a contract with an external entity to evaluate grantees
23 under this section to ensure that quality standards estab-
24 lished under section 202(b) are met.

1 (f) APPLICATION OF PRIVACY RULES.—Nothing in
2 this section shall be construed to supersede the require-
3 ments for the protection of patient privacy under—

4 (1) HIPAA privacy and security law (as defined
5 in section 3009(a) of the Public Health Service Act
6 (42 U.S.C. 300jj–19(a));

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

9 (3) the Genetic Information Nondiscrimination
10 Act of 2008 (Public Law 110–233);

11 (4) part 46 of title 45, Code of Federal Regula-
12 tions (or any successor regulations); or

13 (5) part 50 of title 21, Code of Federal Regula-
14 tions (or any successor regulations).

15 (g) DEFINITION.—In this section, the term “eligible
16 entity” includes an academic medical center, a university,
17 a private nonprofit biomedical research institution, and
18 any other entity determined appropriate by the Secretary.

19 **SEC. 204. AUTHORIZATION OF APPROPRIATIONS.**

20 To carry out this subtitle, there are authorized to be
21 appropriated \$150,000,000 for fiscal year 2011, and such
22 sums as may be necessary for each of fiscal years 2012
23 through 2016.

1 **Subtitle B—Committee on the Eval-**
2 **uation of Genomic Applications**
3 **in Practice and Prevention**

4 **SEC. 211. ESTABLISHMENT.**

5 (a) IN GENERAL.—The Secretary, acting through the
6 Director of the Centers for Disease Control and Preven-
7 tion, shall establish (pursuant to section 222 of the Public
8 Health Service Act (42 U.S.C. 217(a)) an advisory com-
9 mittee, composed of members from the public and private
10 sectors, to expand and accelerate knowledge related to the
11 clinical validity and utility of genomics and personalized
12 medicine through the analysis of current literature, and
13 determination of gaps in evidence. Such committee shall
14 be known as the Committee on the Evaluation of Genomic
15 Applications in Practice and Prevention.

16 (b) DUTIES.—The CEGAPP shall expand the
17 breadth of knowledge related to the clinical validity and
18 utility of genomics and personalized medicine by—

19 (1) establishing, testing, and publishing proc-
20 esses and methods for evidence-based reviews and
21 recommendation development that are optimized for
22 genetic and genomic tests and other products used
23 for personalized medicine in transition from research
24 to clinical and public health practice;

1 (2) identifying, prioritizing, and selecting topics
2 for systematic evidence-based review;

3 (3) publishing evidence-based reviews and rec-
4 ommendations for clinical practice and areas for ad-
5 ditional research for such topics;

6 (4) publishing experiences with systematic evi-
7 dence-based review;

8 (5) publishing gaps in knowledge, as deter-
9 mined through reviews and recommendations under
10 paragraph (3), to assist in carrying out section 201;

11 (6) integrating existing recommendations on
12 implementation of genetic and genomic tests and
13 other products used for personalized medicine from
14 professional organizations and advisory committees;

15 (7) integrating knowledge and experience
16 gained from existing processes for evaluation and
17 appraisal, previous public and private initiatives, and
18 the international health technology assessment expe-
19 rience;

20 (8) advising the Centers for Medicare & Med-
21 icaid Services on whether current evidence supports
22 the coverage of specific products used for personal-
23 ized medicine (including genetic and genomic tests
24 used for the screening of diseases in cases where a
25 family history of such disease is present);

1 (9) developing or adapting processes for recog-
2 nizing promising new products used for personalized
3 medicine and supporting their translation to clinical
4 and public health practice; and

5 (10) developing processes for the collection of
6 data reflective of analytic and clinical validity and
7 utility and quality measures indicative of good clin-
8 ical and laboratory practices for tests early in their
9 translation or adoption cycle.

10 (c) AUTHORIZATION OF APPROPRIATIONS.—There
11 are authorized to be appropriated to carry out this section
12 \$5,000,000 for fiscal year 2011, and such sums as may
13 be necessary for each of fiscal years 2012 through 2016.

14 **TITLE III—GENOMICS AND PER-**
15 **SONALIZED MEDICINE IN**
16 **CLINICAL PRACTICE AND**
17 **PUBLIC HEALTH**

18 **SEC. 301. GENOMICS AND PERSONALIZED MEDICINE EDU-**
19 **CATION AND TRAINING.**

20 (a) IN GENERAL.—The Secretary shall make grants,
21 contracts, or cooperative agreements to eligible entities to
22 improve the adequacy of genomics and personalized medi-
23 cine training for specimen collection, diagnosis, treatment,
24 and counseling of adults and children for both rare and
25 common disorders, through support of efforts to—

1 (1) develop and disseminate model education
2 and training programs across all health profes-
3 sionals, including medical student, graduate medical,
4 and continuing education, that reflect the new
5 knowledge and evolving practice of genetics and
6 genomics including the appropriate use of products
7 used in personalized medicine;

8 (2) assist with the review of board and other
9 certifying examinations by professional societies and
10 accreditation bodies to ensure adequate focus on the
11 fundamental principles of genomics and personalized
12 medicine and applications to clinical decisionmaking;

13 (3) identify, evaluate, and develop options for
14 distance or online learning for degree or continuing
15 education programs;

16 (4) identify gaps and opportunities to strength-
17 en continuing education programs for health care
18 professionals;

19 (5) develop and disseminate model programs to
20 train pathologists on the specialized mechanisms of
21 collection and storage of human biological specimens
22 for biobanks; and

23 (6) develop exchange programs for student,
24 residents, and fellows to learn techniques and prac-

1 tices to augment genomics and personalized medi-
2 cine.

3 (b) INTEGRATION.—The Secretary, in consultation
4 with medical professional societies, accreditation bodies,
5 associations of health professional schools, and other pub-
6 lic and private entities, shall support initiatives to increase
7 the integration of genomics and personalized medicine into
8 all aspects of clinical and public health practice by pro-
9 moting genomics and personalized medicine competency
10 across all clinical, public health, and laboratory disciplines
11 through—

12 (1) the development and dissemination of health
13 professional guidelines which shall—

14 (A) include focus on appropriate tech-
15 niques for collection and storage of genomics
16 samples, administration and interpretation of
17 genetic and genomic tests, and subsequent clin-
18 ical and public health decisionmaking; and

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

22 (2) the development and dissemination of evi-
23 dence-based clinical decision support tools for imple-
24 mentation at the point of care in consultation with

1 the Office the National Coordinator for Health In-
2 formation Technology;

3 (3) the development, cataloging, and dissemina-
4 tion of case studies and practice models relating to
5 the use of products of personalized medicine;

6 (4) the dissemination of both public and private
7 systematic reviews on and technology assessments of
8 the clinical validity and utility of products of person-
9 alized medicine in coordination with the CEGAPP to
10 facilitate the development of clinical practice guide-
11 lines;

12 (5) the facilitation of the development of evi-
13 dence-based clinical practice guidelines and dosing
14 guidelines for product use for personalized medicine
15 by supporting consensus-building efforts, which shall
16 include—

17 (A) development of standards that define
18 the minimal levels of evidence required to sup-
19 port guidelines decisions; and

20 (B) the clinical contexts (such as preven-
21 tion, diagnosis, and treatment) in which genetic
22 and genomic tests may be offered; and

23 (6) the encouragement of public and private
24 sector entities to submit clinical practice guidelines
25 on products of personalized medicine to federally es-

1 established clinical practice guidelines clearinghouses
2 to facilitate dissemination and encourage implemen-
3 tation and use of such guidelines.

4 (c) DEFINITION.—In this section, the term “eligible
5 entity” includes any professional genetics and genomics
6 society, accreditation body, health care professional orga-
7 nization, academic institution, and any other entity as de-
8 termined appropriate by the Secretary.

9 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
10 out this section, there are authorized to be appropriated
11 \$30,000,000 for fiscal year 2011, and such sums as may
12 be necessary for each of fiscal years 2012 through 2016.

13 **TITLE IV—REALIZING THE PO-**
14 **TENTIAL OF PERSONALIZED**
15 **MEDICINE**

16 **SEC. 401. REDUCING THE REDUNDANCY OF CLINICAL LAB-**
17 **ORATORY REQUIREMENTS.**

18 (a) IN GENERAL.—The Secretary, acting through the
19 Administrator of the Centers for Medicare & Medicaid
20 Services and the Commissioner of Food and Drugs, shall
21 establish a committee to carry out a comparative analysis
22 of laboratory review requirements under CLIA to—

23 (1) assess and reduce unnecessary differences
24 in such requirements; and

1 (2) identify opportunities to eliminate
2 redundancies and decrease the burden of review, as
3 practicable, of the Centers for Medicare & Medicaid
4 Services, the Food and Drug Administration, and
5 private laboratory certifying entities.

6 (b) REPRESENTATION.—The membership of the com-
7 mittee established under this section shall include rep-
8 resentatives of the agencies of the Public Health Service,
9 other appropriate Federal departments and agencies, pri-
10 vate laboratories, and private laboratory accreditation or-
11 ganizations.

12 (c) PUBLIC INPUT.—The Secretary shall conduct
13 open public meetings and develop a process to allow for
14 public comment on such comparative analysis.

15 (d) REPORTING.—The Secretary shall require the
16 committee established under this section to submit—

17 (1) a draft report on such comparative analysis,
18 including recommendations on opportunities identi-
19 fied under subsection (a)(1), to the Secretary not
20 later than 12 months after the date of the enact-
21 ment of this Act; and

22 (2) a final such report to the Secretary not
23 later than 24 months after such date.

1 **SEC. 402. COMMITTEE ON PUBLIC ENGAGEMENT.**

2 (a) IN GENERAL.—The Secretary shall establish a
3 committee, to be composed of representatives from the pri-
4 vate sector who are engaged in genomics and personalized
5 medicine, to—

6 (1) examine barriers in research, regulation,
7 and reimbursement to innovation, development, and
8 implementation of medical product development for
9 personalized medicine and the impact of such bar-
10 riers; and

11 (2) make recommendations to address such bar-
12 riers.

13 (b) COLLABORATION WITH OPH.—The Secretary
14 shall ensure that, to the extent possible, such committee
15 carries out this section in collaboration with the OPH.

16 (c) REPORTING.—The Secretary shall require such
17 committee to submit a draft report on the committee’s rec-
18 ommendations under subsection (a)(2) to the Secretary
19 not later than 24 months after the date of the enactment
20 of this Act and annually thereafter.

21 **SEC. 403. STUDY BY THE INSTITUTE OF MEDICINE.**

22 (a) IN GENERAL.—The Secretary shall enter into an
23 agreement with the Institute of Medicine, in consultation
24 with public and private sector entities involved in personal-
25 ized medicine, to provide an independent, external review
26 of the current billing, coverage, and reimbursement meth-

1 odologies for products and services used for personalized
2 medicine (including genetic and genomic tests).

3 (b) REQUIREMENTS.—The agreement under sub-
4 section (a) shall provide for preparation of a report by the
5 Institute of Medicine. Such report shall include—

6 (1) a review of the current billing, coverage,
7 and reimbursement policies for products and services
8 used for personalized medicine (including genetic
9 and genomic tests);

10 (2) specific recommendations for billing, cov-
11 erage, and reimbursement models by public and pri-
12 vate insurers that promote research and development
13 of products used for personalized medicine (includ-
14 ing genetic and genomic tests), taking into account
15 the overall impact of such products on patient out-
16 comes (as demonstrated by evidence from clinical
17 trials and other well-designed empirical studies), the
18 value of such products to the health care system,
19 market-based pricing of such products, and savings
20 accrued from test utilization to the health care sys-
21 tem through disease management and early diag-
22 nosis;

23 (3) recommendations for clinical trial designs to
24 provide evidence sufficient to support coverage of
25 products used for personalized medicine (including

1 genetic and genomic tests) by public and private
2 payors, including reimbursement during the evidence
3 development phase of well-designed studies;

4 (4) recommendations for the reimbursement of
5 health care professionals providing genetic coun-
6 seling services to—

7 (A) define which health professionals, tak-
8 ing into consideration certification, licensure,
9 and training and scope of practice under State
10 law, are qualified to provide genetic counseling
11 services;

12 (B) define which professionals should be
13 able to practice, consistent with their scope of
14 practice under State law, without physician su-
15 pervision, direction, responsibility, or control,
16 and, thereby, bill payers directly for their serv-
17 ices; and

18 (C) assess the adequacy of existing current
19 procedural terminology evaluation and manage-
20 ment codes and their associated relative values
21 with respect to genetic counseling services;

22 (5) recommendations for appropriate mecha-
23 nisms to promote research and development to ad-
24 vance personalized medicine (which may include tax

1 credits, grant programs, or extensions of patent or
2 exclusivity) to include costs and benefits to society;

3 (6) incentives to encourage development of
4 products used for personalized medicine, including
5 development of genetic and genomic tests for pa-
6 tients with rare disorders;

7 (7) criteria for defining when a family history
8 should be considered a personal history of disease
9 for reimbursement purposes under title XVIII of the
10 Social Security Act; and

11 (8) identification or recommendations regarding
12 such other issues as determined appropriate by the
13 Secretary.

14 (c) STAKEHOLDER INPUT.—The agreement under
15 subsection (a) shall require the Institute of Medicine, in
16 preparing the report under this section, to work in con-
17 sultation with each category of public and private stake-
18 holders involved in personalized medicine, including
19 genomics and personalized medicine consumers, physicians
20 and other health care providers including pathologists, sci-
21 entists and researchers, private payors, representatives
22 from clinical and academic laboratories, and representa-
23 tives from the biotechnology, pharmaceutical, and
24 diagnostics industries.

1 (d) REPORT.—Not later than 12 months after the
2 date of the enactment of this Act, the Secretary shall sub-
3 mit the report prepared under this section to the Com-
4 mittee on Finance and the Committee on Health, Edu-
5 cation, Labor, and Pensions of the Senate and the Com-
6 mittee on Ways and Means and the Committee on Energy
7 and Commerce of the House of Representatives.

8 **SEC. 404. FOOD AND DRUG ADMINISTRATION.**

9 (a) ENCOURAGEMENT OF COMPANION DIAGNOSTIC
10 TESTING.—The Secretary, acting through the Commis-
11 sioner of Food and Drugs, may require the sponsor of a
12 drug or biological product—

13 (1) to develop a companion diagnostic test in
14 connection with the submission of an investigational
15 new drug application or a new drug application
16 under section 505 of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 355) to address significant
18 safety concerns of the drug or biological product;

19 (2) to develop a companion diagnostic test if
20 data from postmarketing clinical trials demonstrate
21 significant safety or effectiveness concerns with use
22 of the drug or biological product and include in the
23 label of the drug or biological product a rec-
24 ommendation to use a companion diagnostic test if
25 data demonstrate—

1 (A) significant safety concerns with the
2 drug or biologic product; and

3 (B) improved outcomes with the adminis-
4 tration of a companion diagnostic test; and

5 (3) to conduct additional postmarket studies to
6 identify genetic and other biological, social, behav-
7 ioral, and environmental factors that may underlie
8 the differential drug effects when drugs are shown
9 to be more or less effective in certain racial and eth-
10 nic subpopulations.

11 (b) CLARIFICATION AND GUIDANCE.—The Secretary,
12 acting through the Commissioner of Food and Drugs,
13 shall clarify and issue guidance regarding—

14 (1) the criteria and procedures for determining
15 when labeling of a product used for personalized
16 medicine will incorporate information on related
17 companion diagnostic tests, as well as establish the
18 circumstances under which such tests will be either
19 recommended or required;

20 (2) the standards of evidence that must be met
21 for information pertaining to pharmacogenomics (as
22 defined in section 2) to be included in the label of
23 a product used for personalized medicine, such as
24 with respect to the analytical validity, clinical valid-
25 ity, clinical utility, dosing, adverse events, and drug

1 selection, for use by clinicians when making treat-
2 ment decisions based on the results of genetic and
3 genomic tests;

4 (3) the regulation of automated clinical decision
5 support systems; and

6 (4) the collection and analysis of genetic and
7 other biological factors that may be better biological
8 predictors of individual differences in drug response
9 than broad categories such as race, ethnicity, and
10 gender.

11 **SEC. 405. ADVERSE EVENTS.**

12 The Secretary, in consultation with the Commissioner
13 of Food and Drugs and the Administrator of the Centers
14 for Medicare & Medicaid Services, shall—

15 (1) facilitate the use of products used for per-
16 sonalized medicine, as feasible, to assess risk for,
17 and reduce incidence of, adverse drug reactions;

18 (2) develop or expand adverse event reporting
19 systems to encompass reports of adverse events re-
20 sulting from products used for personalized medi-
21 cine, including laboratory developed test; and

22 (3) develop systems to appropriately respond to
23 any adverse events resulting from products used for
24 personalized medicine.

1 **SEC. 406. TERMINATION OF CERTAIN ADVERTISING CAM-**
2 **PAIGNS.**

3 The Commissioner of Food and Drugs shall collabo-
4 rate with the Federal Trade Commission to identify and
5 terminate, pursuant to section 5 of the Federal Trade
6 Commission Act (15 U.S.C. 45), advertising campaigns
7 that make false, misleading, deceptive, or unfair claims
8 about the benefits or risks of products used for personal-
9 ized medicine.

10 **SEC. 407. CENTERS FOR DISEASE CONTROL AND PREVEN-**
11 **TION.**

12 (a) PUBLIC AWARENESS.—The Director of the Cen-
13 ters for Disease Control and Prevention shall expand ef-
14 forts to educate and increase awareness of the general
15 public about genomics and personalized medicine and its
16 applications to improve health, prevent disease, and elimi-
17 nate health disparities. Such efforts shall include—

18 (1) ongoing development and dissemination of
19 evidence-based informational resources and materials
20 on the validity and utility of products used for per-
21 sonalized medicine (including genetic and genomic
22 tests);

23 (2) ongoing collection of data on the awareness,
24 knowledge, and use of genetic and genomic tests
25 through public health surveillance systems, and anal-
26 ysis of the impact of such tests on population health;

1 (3) integration of the use of validated genetic
2 and genomic tests in public health programs, as ap-
3 propriate; and

4 (4) evaluation of laboratory standards and prac-
5 tices for quality laboratory services.

6 (b) **DIRECT-TO-CONSUMER MARKETING.**—Not later
7 than 12 months after the date of the enactment of this
8 Act, the Director of the Centers for Disease Control and
9 Prevention, in conjunction with the Food and Drug Ad-
10 ministration and the Federal Trade Commission, with re-
11 spect to products used for personalized medicine (includ-
12 ing genetic and genomic tests) for which consumers have
13 direct access, shall—

14 (1) conduct an analysis of the public health im-
15 pact of direct-to-consumer marketing to the extent
16 possible from available data sources;

17 (2) analyze the validity of claims made in di-
18 rect-to-consumer marketing to determine whether
19 such claims are substantiated by competent and reli-
20 able scientific evidence; and

21 (3) make recommendations to the Secretary re-
22 garding necessary interventions to protect the public
23 from potential harms of direct-to-consumer mar-
24 keting and access to products used for personalized
25 medicine (including genetic and genomic tests).

1 **SEC. 408. AUTHORIZATION OF APPROPRIATIONS.**

2 (a) IN GENERAL.—To carry out sections 403, 404,
3 405, and 406, there are authorized to be appropriated
4 \$40,000,000 for fiscal year 2011, and such sums as may
5 be necessary for each of fiscal years 2012 through 2016.

6 (b) REDUCING THE REDUNDANCY OF CLINICAL LAB-
7 ORATORIES.—To carry out section 401, there are author-
8 ized to be appropriated \$5,000,000 for fiscal year 2011,
9 and such sums as may be necessary for fiscal year 2012.

10 (c) COMMITTEE ON PUBLIC ENGAGEMENT.—To
11 carry out section 402, there are authorized to be appro-
12 priated \$1,000,000 for fiscal year 2011, and such sums
13 as may be necessary for each of fiscal years 2012 through
14 2016.

15 (d) CDC PUBLIC AWARENESS ACTIVITIES.—To
16 carry out section 407, there are authorized to be appro-
17 priated \$20,000,000 for fiscal year 2011, and such sums
18 as may be necessary for each of fiscal years 2012 through
19 2016.

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