

110TH CONGRESS
2D SESSION

S. 2988

To amend the Public Health Service Act to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases.

IN THE SENATE OF THE UNITED STATES

MAY 7, 2008

Mr. LIEBERMAN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases.

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 “Accelerating Cures Act
5 of 2008”.

6 **SEC. 2. TABLE OF CONTENTS.**

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“SUBPART 7—TRANSLATIONAL RESEARCH FUND

“Sec. 449G. Translational Research Fund.

“Sec. 404I. Application of research requirement.”.

1 SEC. 3. FINDINGS; PURPOSE.

2 (a) FINDINGS.—Congress finds the following:

3 (1) The National Institutes of Health (referred
4 to in this section as the “NIH”) is the United
5 States premier biomedical research investment with
6 annual appropriations exceeding \$29,200,000,000.

7 (2) The goals of the NIH are to—

8 (A) foster fundamental creative discoveries,
9 innovative research strategies, and their appli-
10 cations as a basis to significantly advance the
11 Nation’s capacity to protect and improve
12 health;

1 (B) develop, maintain, and renew scientific
2 human and physical resources that will ensure
3 the Nation's capacity to prevent disease;

4 (C) expand the knowledge base in medical
5 and associated sciences in order to enhance the
6 Nation's economic well-being and ensure a con-
7 tinued high return on the public investment in
8 research; and

9 (D) exemplify and promote the highest
10 level of scientific integrity, public accountability,
11 and social responsibility in the conduct of
12 science.

13 (3) Thus, the NIH is tasked with applying
14 basic science discoveries to protect and improve
15 health. This includes, translational research, which
16 is the scientific work necessary to develop a clinical
17 application from a basic science discovery.

18 (4) The United States translational research in-
19 vestment will be key to the Nation responding effec-
20 tively—

21 (A) to public and population health
22 threats;

23 (B) to the complex nature of chronic dis-
24 eases, which are responsible for 7 out of 10
25 deaths in the United States, for 75 percent of

1 the \$2,300,000,000,000 spent annually on
2 healthcare in the United States, and for 16 per-
3 cent of gross domestic product;

4 (C) to research and development vacuums
5 in the private for-profit market, such as in the
6 fields of vaccine and antibiotic production,
7 drugs for Third World diseases, orphan drugs,
8 and medical tools for pediatric populations; and

9 (D) to facilitate the process of converting
10 medical innovations into commercial products.

11 (5) Key components of the translational re-
12 search process include research prioritization, a
13 strengthening and maintenance of an expert work-
14 force, multidisciplinary collaborative work, strategic
15 risk taking, support of small innovative businesses
16 caught along common pathways in the research and
17 development Valley of Death, simplification and pro-
18 motion of the clinical research endeavor, and early
19 involvement of private entities that are skilled in the
20 manufacturing and marketing process in the
21 translational research endeavor.

22 (6) A National Academy of Sciences/Institute of
23 Medicine report made recommendations for reorga-
24 nizing NIH to meet new challenges facing the bio-
25 medical research endeavor. The committee report

1 contained specific recommendations aimed at
2 strengthening clinical and translational research in-
3 cluding: increasing trans-NIH research, promoting
4 innovation and risk taking in intramural research,
5 creating a “special projects” program, and increas-
6 ing funding for research management and support.

7 (7) The Government Accountability Office re-
8 ported that although the pharmaceutical industry
9 has increased its research and development invest-
10 ment by 147 percent from 1993 to 2004, new drug
11 applications to the Food and Drug Administration
12 have only increased by 39 percent; thus, the produc-
13 tivity of the industry’s research and development ex-
14 penditures is declining. The report cited that a lim-
15 ited scientific understanding of how to translate re-
16 search discoveries into safe and effective drugs is
17 contributing to the problem and recommended that
18 training researchers who can translate drug discov-
19 eries into effective medicines is necessary.

20 (8) It is estimated to take 17 years for a
21 science discovery to be translated from the point of
22 proof of concept to clinical application. The percent
23 of physicians engaged in research has declined stead-
24 ily from a peak of 4.6 percent in 1985 to 1.8 per-
25 cent in 2003.

1 (9) A report by the Infectious Disease Society
2 of America cited concerns with the lack of new anti-
3 biotics to treat infectious diseases. The report com-
4 mended the NIH Roadmap, but also recommended
5 that NIH aggressively expand the translational re-
6 search components of the Roadmap, increase grants
7 to small businesses, universities, and nonprofits
8 working in antibiotics research and development,
9 and seek more opportunities to partner with phar-
10 maceutical and biotech companies.

11 (10) Clinical effectiveness results provide pa-
12 tients, payers, and clinicians with tools to evaluate
13 the benefits versus risks of the ever evolving number
14 of prevention, diagnosis, and treatment strategies
15 available.

16 (11) The Common Fund is an annual set aside
17 account created from an agreed upon percentage of
18 the annual budget that supports innovative and
19 trans-NIH initiatives to improve and accelerate re-
20 search to impact health.

21 (12) The “Valley of Death” is a stage in bio-
22 medical development between research and commer-
23 cialization where the success of a product is depend-
24 ent on its profitability.

1 (b) PURPOSE.—The purpose of this Act is to create
2 a new pathway to curing disease by enhancing public and
3 private research to translate new discoveries from bench
4 to bedside.

5 **SEC. 4. ACCELERATING CURES ACT OF 2008.**

6 Title IV of the Public Health Service Act (42 U.S.C.
7 281 et seq.) is amended by adding at the end the fol-
8 lowing:

9 **“PART J—ACCELERATING CURES**

10 **“Subpart 1—Pathways to Cures Subcommittee**

11 **“SEC. 499A. PATHWAYS TO CURES SUBCOMMITTEE.**

12 “(a) DEFINITION OF TRANSLATIONAL RESEARCH.—
13 In this section, the term ‘translational research’ means re-
14 search that transforms scientific discoveries arising from
15 laboratory, clinical, or population studies into clinical ap-
16 plication to reduce disease incidence, morbidity, and mor-
17 tality.

18 “(b) ESTABLISHMENT OF PATHWAYS TO CURES
19 SUBCOMMITTEE.—There is established a Pathways to
20 Cures Subcommittee within the Council of Councils of the
21 Office of Portfolio Analysis and Strategic Initiatives of the
22 National Institutes of Health that shall convene not less
23 frequently than twice a year to help advise and direct the
24 translational research priorities of the Office of Portfolio

1 Analysis and Strategic Initiatives (referred to in this part
2 as the ‘OPASI’).

3 “(c) MEMBERSHIP.—

4 “(1) IN GENERAL.—The subcommittee estab-
5 lished under subsection (b) may be composed of the
6 following members:

7 “(A) The Director of NIH and the Direc-
8 tor of OPASI who shall be subcommittee co-
9 chairs.

10 “(B) The heads of the institutes and cen-
11 ters of the National Institutes of Health.

12 “(C) Heads from Federal agencies, includ-
13 ing—

14 “(i) the Administrator for the Sub-
15 stance Abuse and Mental Health Services
16 Administration;

17 “(ii) the Under Secretary for Science
18 and Technology of the Department of
19 Homeland Security;

20 “(iii) the Commanding General for
21 the United States Army Medical Research
22 and Materiel Command;

23 “(iv) the Director of the Centers for
24 Disease Control and Prevention;

1 “(v) the Commissioner of Food and
2 Drugs;

3 “(vi) the Director of the Office of
4 Science of the Department of Energy;

5 “(vii) the President of the Institute of
6 Medicine;

7 “(viii) the Director of the Agency for
8 Healthcare Research and Quality; and

9 “(ix) the Director of the Defense Ad-
10 vanced Research Projects Agency.

11 “(2) OTHER MEMBERS.—The subcommittee es-
12 tablished under subsection (b) shall also include not
13 fewer than 3 leaders from the small business medical
14 research community, 3 leaders from large pharma-
15 ceutical or biotechnology companies, and 3 leaders
16 from academia and patient advocacy organizations,
17 all of whom shall be appointed by the Director of
18 NIH.

19 “(d) RECOMMENDATIONS; COORDINATION; FUND-
20 ING.—

21 “(1) SETTING PRIORITIES.—The subcommittee
22 established under subsection (b) shall make rec-
23 ommendations to assist the Director of OPASI in
24 setting translational research priorities.

1 “(2) RECOMMENDATIONS.—In making rec-
2 ommendations, the subcommittee shall—

3 “(A) consider risk and burden of disease
4 as well as lines of research uniquely poised to
5 deliver effective diagnostics and therapies; and

6 “(B) be mission-driven and identify re-
7 search that shows specific promise for a new
8 treatment or cure for a disease.

9 “(3) COORDINATION.—The subcommittee shall
10 ensure sharing of research agendas among the insti-
11 tutes and centers of the National Institutes of
12 Health for the purpose of coordinating translational
13 research priorities, where appropriate, across such
14 institutes and centers.

15 “(4) FUNDING.—The subcommittee and the Di-
16 rector of OPASI—

17 “(A) shall identify research with applica-
18 tion or commercialization potential; and

19 “(B) may fund such research

20 “(e) REPORT.—The subcommittee established under
21 subsection (b) shall submit an annual report to Congress
22 on progress towards finding new treatments and cures.

1 **“Subpart 2—Clinical Effectiveness; FFRDC**

2 **“SEC. 499B. FEDERALLY FUNDED RESEARCH AND DEVEL-**
3 **OPMENT CENTER.**

4 “(a) ESTABLISHMENT OF CENTER.—

5 “(1) IN GENERAL.—The Director of NIH, in
6 conjunction with the Director of the Agency for
7 Healthcare Research and Quality (referred to in this
8 subpart as the ‘AHRQ’), shall establish a Federally
9 Funded Research and Development Center (referred
10 to in this subpart as the ‘FFRDC’) on clinical effec-
11 tiveness research.

12 “(2) DEFINITION OF CLINICAL EFFECTIVENESS
13 RESEARCH.—In this section, the term ‘clinical effec-
14 tiveness research’ means research that—

15 “(A) provides information for health care
16 decision makers, including patients, providers,
17 and public and private payers, to make evi-
18 dence-based decisions about the delivery of
19 health care; and

20 “(B) considers specific subpopulations.

21 “(3) DIRECTOR OF THE FFRDC.—The Director
22 of NIH, in conjunction with the Director of the
23 AHRQ, shall appoint a Director of the FFRDC.

24 “(b) DUTIES OF THE DIRECTOR OF THE FFRDC.—
25 The Director of the FFRDC shall—

1 “(1) review, synthesize, and disseminate clinical
2 effectiveness research;

3 “(2) set priorities for, and fund, trials, such as
4 randomized controlled trials, adaptive trials, and
5 practical trials, observational studies, secondary data
6 analysis in areas of clinical effectiveness research
7 where evidence is lacking, systematic reviews of ex-
8 isting research, as necessary, and cost-effectiveness
9 studies;

10 “(3) make recommendations regarding the find-
11 ings of paragraphs (1) and (2);

12 “(4) study the differential outcomes of interven-
13 tions on subpopulations within diseases;

14 “(5) use competitive award processes, including,
15 but not solely, competitive peer review, and examine
16 methods of rapid review cycles to reduce delays in
17 funding decisions;

18 “(6) encourage the development and use of elec-
19 tronic health data to conduct clinical effectiveness
20 research for the goal of improving clinical care deliv-
21 ery;

22 “(7) support the development of methodological
23 standards to be used when conducting studies of
24 clinical effectiveness and value in order to help en-

1 sure accurate and effective comparisons and update
2 such standards not less frequently than annually;

3 “(8) include, and collaborate and consult with,
4 as necessary, the Food and Drug Administration,
5 the Centers for Medicare & Medicaid Services, the
6 Centers for Disease Control and Prevention, the De-
7 partment of Defense, the Department of Veterans
8 Affairs, and other Federal agencies, and the Insti-
9 tute of Medicine, as well as private payers, insurers,
10 pharmaceutical and device companies, patient advo-
11 cacy and public interest groups, professional soci-
12 eties, hospitals, academic institutions, and health
13 foundations;

14 “(9) establish a public review or hearing proc-
15 ess, which includes the Food and Drug Administra-
16 tion, to examine findings of studies;

17 “(10) determine the best approach to make
18 available the findings resulting from subparagraphs
19 (A) and (B) to relevant Federal agencies, private
20 and public stakeholders in the health care system,
21 and consumers;

22 “(11) provide a public forum for addressing
23 conflicting guidelines and recommendations; and

24 “(12) submit annual reports to Congress on the
25 research activities and findings of the FFRDC.

1 “(c) CLINICAL EFFECTIVENESS ADVISORY BOARD.—

2 “(1) ESTABLISHMENT AND FUNCTION.—The
3 Director of the FFRDC shall establish, in conjunc-
4 tion with the Director of NIH and the Director of
5 the AHRQ, an independent Clinical Effectiveness
6 Advisory Board (referred to in this section as the
7 ‘Advisory Board’), to include not more than 20 ap-
8 pointed members, in order to provide expert advice
9 and guidance on the research priorities of the
10 FFRDC.

11 “(2) MEMBERSHIP.—

12 “(A) IN GENERAL.—Membership on the
13 Advisory Board shall be comprised of—

14 “(i) representatives of the National
15 Institutes of Health, the AHRQ, the Food
16 and Drug Administration, the Centers for
17 Medicare & Medicaid Services, the Centers
18 for Disease Control and Prevention, the
19 Department of Defense, the Department of
20 Veterans Affairs, and other Federal agen-
21 cies, and the Institute of Medicine; and

22 “(ii) private payers, insurers, pharma-
23 ceutical and device companies, patient ad-
24 vocacy and public interest groups, profes-

1 sional societies, hospitals, academic institu-
2 tions, and health foundations.

3 “(B) EXPERTS.—Membership on the Advi-
4 sory Board shall consist of leading experts from
5 diverse disciplinary areas, including physicians,
6 social scientists, statisticians, health services re-
7 searchers, economists, and other health care
8 professionals.

9 “(C) TERMS.—Terms for members of the
10 Advisory Board shall be fixed, multiyear, and
11 staggered.

12 “(D) APPOINTMENT.—The members of the
13 Advisory Board who are described in subpara-
14 graph (A)(ii) shall be appointed by the Director
15 of the FFRDC, the Director of NIH, and the
16 Director of the AHRQ.

17 “(E) CHAIR.—The Director of the AHRQ
18 shall be chair of the Advisory Board.

19 “(3) CONFLICTS OF INTEREST.—Members of
20 the Advisory Board shall disclose any financial, po-
21 litical, or organizational conflicts of interest in con-
22 ducting the work of the Advisory Board.

23 “(4) DUTIES.—The Advisory Board shall—

24 “(A) recommend priorities for clinical ef-
25 fectiveness research to be undertaken by the

1 FFRDC, taking into consideration significant
2 gaps in clinical effectiveness research, including
3 research needs for information on subpopula-
4 tions and diverse populations, including women,
5 children, and racial and ethnic minorities, and
6 on individuals with comorbid diseases;

7 “(B) identify existing and novel research
8 designs and methods that may be considered by
9 the FFRDC in conducting clinical effectiveness
10 research;

11 “(C) review clinical effectiveness research
12 methods;

13 “(D) review the FFRDC processes to de-
14 termine whether the research conducted is ob-
15 jective, credible, developed through a trans-
16 parent process that includes consultations with
17 appropriate stakeholders, including consumers,
18 patient organizations, and the public, and is
19 clinically relevant;

20 “(E) make recommendations to the AHRQ
21 and the National Institutes of Health for the
22 effective dissemination of the findings of the
23 FFRDC supported research to clinicians, pay-
24 ers, and consumers, and patient organizations;
25 and

1 “(F) following the first year, review cur-
2 rent and previous research agendas and make
3 recommendations regarding research agendas.

4 “(5) INITIAL MEETING.—The initial meeting of
5 the Advisory Board shall be no later than 6 months
6 after the date of enactment of the Accelerating
7 Cures Act of 2008.

8 “(6) ADVISORY NATURE OF BOARD.—The rec-
9 ommendations of the Advisory Board shall not be
10 binding, but shall be considered by the Director of
11 the FFRDC when developing the clinical effective-
12 ness research agenda.

13 “(d) RESEARCH AGENDA.—The Director of the
14 FFRDC shall establish the research agenda of the
15 FFRDC, based on the priorities established by the Advi-
16 sory Board, and shall update such agenda not less fre-
17 quently than annually, and shall—

18 “(1) focus on—

19 “(A) identifying gaps in clinical effective-
20 ness research relating to medical procedures,
21 medical technologies, pharmaceuticals, health
22 information technologies, and other relevant
23 services and products that significantly con-
24 tribute to health care outcomes and expendi-
25 tures;

1 “(B) funding trials, studies, and reviews,
2 and coordinating these efforts with ongoing re-
3 search efforts in the Federal Government, aca-
4 demic institutions, and private entities to fill
5 gaps identified under subparagraph (A);

6 “(C) synthesizing and reviewing clinical ef-
7 fectiveness research to fill gaps identified under
8 subparagraph (A); and

9 “(D) supporting the development of an evi-
10 dence base for the development of clinical care
11 guidelines based on the results of clinical effec-
12 tiveness research;

13 “(2) convene such working groups on clinical
14 effectiveness research as the Director of the FFRDC
15 determines necessary;

16 “(3) meet with members representing the Na-
17 tional Institutes of Health, the AHRQ, the Food
18 and Drug Administration, the Centers for Medicare
19 & Medicaid Services, the Centers for Disease Control
20 and Prevention, the Department of Defense, the De-
21 partment of Veterans Affairs, and other Federal
22 agencies, and the Institute of Medicine, as well as
23 private payers, insurers, pharmaceutical and device
24 companies, patient advocacy and public interest
25 groups, professional societies, hospitals, academic in-

1 stitutions, practice based research networks health
2 foundations, and the general public to promote com-
3 munication and transparency; and

4 “(4) notify the public well in advance of any
5 public meetings.

6 “(e) REPORTS.—

7 “(1) GUIDANCE OR RECOMMENDATIONS.—The
8 Director of the FFRDC, in conjunction with the Di-
9 rector of NIH and the Director of the AHRQ, shall
10 provide, not less frequently than annually, guidance
11 or recommendations to health care providers, payers,
12 and consumers, and Congressional committees of ju-
13 risdiction on the comparative effectiveness of health
14 care services.

15 “(2) STATUS REPORTS.—The Director of the
16 FFRDC shall provide annual status reports on the
17 work of the FFRDC to Congressional committees of
18 jurisdiction.

19 “(f) AVAILABILITY OF RESEARCH FINDINGS.—The
20 Director of the FFRDC shall develop and identify efficient
21 and effective methods of disseminating the findings of the
22 clinical effectiveness assessments of medical procedures,
23 technologies, and therapeutics, including by making these
24 available on the Internet. Any relevant reports (including
25 interim progress reports, draft final clinical effectiveness

1 reviews, and final progress reports on new research sub-
 2 mitted for publication) on the results of clinical effective-
 3 ness research supported by the FFRDC shall be made
 4 available on the Internet, not later than 90 days after the
 5 report is completed.

6 “(g) EVALUATIONS AND REPORTS OF FFRDC.—The
 7 Director of NIH, in conjunction with the Director of the
 8 AHRQ, shall enter into regular agreements with entities,
 9 such as the Institute of Medicine, to—

10 “(1) evaluate the FFRDC and its functioning;

11 and

12 “(2) produce reports on priority setting for the
 13 FFRDC, and on research methods developed and
 14 employed by the FFRDC, among other purposes.

15 **“Subpart 3—Health Advanced Research Projects**

16 **Program**

17 **“SEC. 499C. HEALTH ADVANCED RESEARCH PROJECTS**

18 **PROGRAM.**

19 “(a) ESTABLISHMENT.—There is established within
 20 the OPASI, a Health Advanced Research Projects Pro-
 21 gram (referred to in this section as the ‘Research Projects
 22 Program’) that shall be headed by a Director of the Re-
 23 search Projects Program who is appointed by the Director
 24 of NIH.

1 “(b) COMPOSITION.—The Research Projects Pro-
2 gram shall be composed of portfolio managers in key
3 health areas, which are determined by the Director of the
4 Research Projects Program in conjunction with the Direc-
5 tor of OPASI, the Director of NIH, and the Pathways
6 to Cures Subcommittee established under section 499A.

7 “(c) GUIDANCE.—The Research Projects Program
8 shall be guided by and shall undertake grand challenges
9 that encourage innovative, multidisciplinary, and collabo-
10 rative research across institutes and centers of the Na-
11 tional Institutes of Health, across Federal agencies, and
12 between public and private partners of the National Insti-
13 tutes of Health.

14 “(d) MANAGEMENT GUIDANCE.—The Research
15 Projects Program shall be guided by the following man-
16 agement and organizing principles in directing the Re-
17 search Projects Program:

18 “(1) Keep the Research Projects Program
19 small, flexible, entrepreneurial, and non-hierarchical,
20 and empower portfolio managers with substantial
21 autonomy to foster research opportunities with free-
22 dom from bureaucratic impediments in admin-
23 istering the manager’s portfolios.

1 “(2) Seek to employ the strongest scientific and
2 technical talent in the Nation in research fields in
3 which the Research Projects Program is working.

4 “(3) Rotate a significant portion of the staff
5 after 3 to 5 years of experience to ensure continuous
6 entry of new talent into the Research Projects Pro-
7 gram.

8 “(4) Use, whenever possible, research and de-
9 velopment investments by the Research Projects
10 Program to leverage comparable matching invest-
11 ment and coordinated research from other institutes
12 and centers of the National Institutes of Health,
13 from other Federal agencies, and from the private
14 and nonprofit research sectors.

15 “(5) Utilize supporting technical, contracting,
16 and administrative personnel from other institutes
17 and centers of the National Institutes of Health in
18 administering and implementing research efforts to
19 encourage participation, collaboration, and cross-fer-
20 tilization of ideas across the National Institutes of
21 Health.

22 “(6) Utilize a challenge model in Research
23 Projects Program research efforts, creating a
24 translational research model that supports funda-
25 mental research breakthroughs, early and late stage

1 applied development, prototyping, knowledge diffu-
2 sion, and technology deployment.

3 “(7) Establish metrics to evaluate research suc-
4 cess and periodically revisit ongoing research efforts
5 to carefully weigh new research opportunities
6 against ongoing research.

7 “(8) Support risk-taking in research pursuits
8 and tolerate productive failure.

9 “(9) Ensure that revolutionary and break-
10 through technology research dominates the Research
11 Projects Program’s research agenda and portfolio.

12 “(e) ACTIVITIES.—Using the funds and authorities
13 provided to the Director of NIH, the Research Projects
14 Program shall carry out the following activities:

15 “(1) The Research Projects Program shall sup-
16 port basic and applied health research to promote
17 revolutionary technology changes that promote
18 health.

19 “(2) The Research Projects Program shall ad-
20 vance the development, testing, evaluation, proto-
21 typing, and deployment of critical health products.

22 “(3) The Research Projects Program, con-
23 sistent with recommendations of the Pathways to
24 Cures Subcommittee established under section 499A,
25 with the priorities of OPASI, and with the grand

1 challenges that encourage innovative, multidisci-
2 plinary, and collaborative research, shall empha-
3 size—

4 “(A) translational research efforts, includ-
5 ing efforts conducted through collaboration with
6 the private sector, that pursue—

7 “(i) innovative health products that
8 could address acute health threats such as
9 a flu pandemic, spread of antibiotic resist-
10 ant hospital acquired infections, or other
11 comparable problems;

12 “(ii) remedies for diseases afflicting
13 lesser developed countries;

14 “(iii) remedies for orphan diseases for
15 which the for-profit sector is not finding
16 new treatments;

17 “(iv) alternative technologies with sig-
18 nificant health promise that are not well-
19 supported in the system of health research,
20 such as adjuvant technology or tech-
21 nologies for vaccines based on the innate
22 immunological response; and

23 “(v) fast track development, including
24 development through accelerated comple-
25 tion of animal and human clinical trials,

1 for emerging remedies for significant pub-
2 lic health problems; and

3 “(B) other appropriate translational re-
4 search efforts for critical health issues.

5 “(4) The Research Projects Program shall uti-
6 lize funds to provide support to outstanding research
7 performers in all sectors and encourage cross-dis-
8 ciplinary research collaborations that will allow sci-
9 entists from fields such as information and computer
10 sciences, nanotechnology, chemistry, physics, and en-
11 gineering to work alongside top researchers with
12 more traditional biomedical backgrounds.

13 “(5) The Research Projects Program shall pro-
14 vide selected research projects with single-year or
15 multiyear funding and require researchers for such
16 projects to provide interim progress reports, includ-
17 ing milestones on progress, to the Research Projects
18 Program on not less frequently than a biannual
19 basis.

20 “(6) The Research Projects Program shall
21 award competitive, merit-reviewed grants, coopera-
22 tive agreements, or contracts to public or private en-
23 tities, including businesses, federally funded research
24 and development centers, and universities.

1 “(7) The Research Projects Program shall pro-
2 vide advice to the Director of OPASI concerning
3 funding priorities.

4 “(8) The Research Projects Program may so-
5 licit proposals for competitions to address specific
6 health vulnerabilities identified by the Director of
7 NIH and the Director of OPASI and award prizes
8 for successful outcomes.

9 “(9) The Research Projects Program shall peri-
10 odically hold health research and technology dem-
11 onstrations to improve contact among researchers,
12 technology developers, vendors, and acquisition per-
13 sonnel.

14 “(10) The Research Projects Program shall
15 carry out other activities determined appropriate by
16 the Director of NIH.

17 “(f) EMPLOYEES.—

18 “(1) HIRING.—The Director of the Research
19 Projects Program, in hiring employees for positions
20 with the Research Projects Program, shall have the
21 same hiring and management authorities as de-
22 scribed in section 1101 of the Strom Thurmond Na-
23 tional Defense Authorization Act for Fiscal Year
24 1999 (5 U.S.C. 3104 note).

25 “(2) TERM.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), the term of such appoint-
3 ments for employees of the Research Projects
4 Program may not exceed 5 years.

5 “(B) EXTENSION.—The Director of the
6 Research Projects Program may, in the case of
7 a particular employee of the Research Projects
8 Program, extend the term to which employment
9 is limited under subparagraph (A) by not more
10 than 2 years if the Director of the Research
11 Projects Program determines that such action
12 is necessary to promote the efficiency of the Re-
13 search Projects Program.

14 “(g) FLEXIBILITY.—The Director of the Research
15 Projects Program shall have the authority to flexibly fund
16 projects, including the prompt awarding, releasing, en-
17 hancing, or withdrawal of monies in accordance with the
18 assessment of the Research Projects Program and project
19 manager.

20 **“Subpart 4—Clinical Trials**

21 **“SEC. 499D. GRANTS FOR QUALITY CLINICAL TRIAL DESIGN**

22 **AND EXECUTION.**

23 “The Director of OPASI—

24 “(1) shall award grants for clinical trial design
25 and execution to academic centers and practice-

1 based research networks to fund multidisciplinary
 2 clinical research teams, which clinical research teams
 3 may be composed of members who include project
 4 managers, clinicians, epidemiologists, social sci-
 5 entists, and clinical research coordinators; and

6 “(2) may award grants for clinical trial design
 7 and execution to researchers.

8 **“SEC. 499D-1. STREAMLINING THE REGULATORY PROCESS**
 9 **GOVERNING CLINICAL RESEARCH.**

10 “(a) ESTABLISHMENT OF CENTRALIZED INSTITU-
 11 TIONAL REVIEW BOARDS.—

12 “(1) IN GENERAL.—

13 “(A) ESTABLISHMENT AND OVERSIGHT.—

14 The Director of OPASI shall appoint a Director
 15 of Centralized Institutional Review Boards (re-
 16 ferred to in this part as the ‘Director of
 17 CIRBs’) who shall establish and oversee the
 18 functioning and progress of a series of Central-
 19 ized Institutional Review Boards (referred to in
 20 this part as ‘CIRBs’) to serve as human subject
 21 safety and well-being custodians for multi-insti-
 22 tutional clinical trials that are funded partially
 23 or in full by public research dollars.

24 “(B) WORK WITH FDA.—The Director of
 25 CIRBs shall work with the Commissioner of

1 Food and Drugs to make regulations governing
2 multi-site clinical trials and the regulatory re-
3 quirements of the Food and Drug Administra-
4 tion more consistent in order to reduce barriers
5 to commercialization of new treatments.

6 “(2) EXISTING GUIDELINES AND BEST PRAC-
7 TICES.—CIRBs shall be established in accordance
8 with professional best practices and Good Clinical
9 Practice (GCP) guidelines so that institutions in-
10 volved in multi-institutional studies may—

11 “(A) use joint review;

12 “(B) rely upon the review of another quali-
13 fied institutional review board; or

14 “(C) use similar arrangements to avoid du-
15 plication of effort and to assure a high-quality
16 of expert oversight.

17 “(b) HOUSED.—Each CIRB shall be housed—

18 “(1) at the institute or center of the National
19 Institutes of Health with expertise on the subject of
20 the clinical trial; or

21 “(2) at a public or private institution with com-
22 parable organizational capacity, such as the Depart-
23 ment of Veterans Affairs.

24 “(c) SERVICE.—The use of CIRBs shall be available,
25 as appropriate, at the request of public or private institu-

1 tions and shall be funded through user fees of the CIRBs
2 or the National Institutes of Health's funds.

3 “(d) REVIEW PROCESS.—

4 “(1) IN GENERAL.—Each CIRB shall review re-
5 search protocols and subject informed consent forms
6 to ensure the protection of safety and well-being of
7 research participants enrolled in multi-institutional
8 clinical trials.

9 “(2) PROCESS.—The CIRB review process shall
10 consist of contractual agreements between the CIRB
11 and the study sites of multi-institutional clinical
12 trials. The CIRB shall act on behalf, in whole or in
13 part, of the bodies ordinarily responsible for the
14 safety of research subjects in a locality. In the case
15 in which a locality does not have such a body, the
16 locality shall depend solely on the CIRB to oversee
17 the protection of human subjects and the CIRB
18 shall assume responsibility for ensuring adequate as-
19 sessment of the local research context.

20 “(e) RESEARCH APPLICATIONS.—

21 “(1) IN GENERAL.—Each CIRB shall review
22 and package research applications for facilitated
23 electronic review by local institutional review boards
24 participating in a multi-institutional clinical trial.

1 “(2) CIRB REVIEW.—A local institutional re-
2 view board may accept or reject a CIRB review. In
3 the case in which a local institutional review board
4 accepts a CIRB review, the CIRB shall assume re-
5 sponsibility for annual, amendment, and adverse
6 event reviews. If a local institutional review board
7 elects to decline participation in the CIRB, the local
8 institutional review board shall appoint a liaison to
9 the CIRB.

10 “(f) WORK IN CONCERT.—In the case in which a
11 local institutional review board works in concert with a
12 CIRB, the local institutional review board shall be respon-
13 sible for taking into consideration local characteristics (in-
14 cluding ethnicity, educational level, and other demographic
15 characteristics) of the population from which research
16 subjects will be drawn, which influence, among other
17 things, whether there is sound selection of research sub-
18 jects or whether adequate provision is made to minimize
19 risks to vulnerable populations.

20 “(g) COMMUNICATION OF IMPORTANT INFORMA-
21 TION.—Each CIRB shall regularly communicate impor-
22 tant information in electronic form to the local institu-
23 tional review boards or, in cases where a local institutional
24 review board does not exist, to the principal investigator,

1 including regular safety updates or requirements to
2 change a research protocol in order to improve safety.

3 “(h) COORDINATION.—Each CIRB shall fully coordi-
4 nate with the institute or center of the National Institutes
5 of Health that has specialized knowledge of the research
6 area of the clinical trial. Other Federal agencies and pri-
7 vate entities undertaking clinical trials may contract with
8 the National Institutes of Health to use a CIRB.

9 **“SEC. 499D-2. CLINICAL RESEARCH STUDY AND CLINICAL**
10 **TRIAL.**

11 “(a) IN GENERAL.—The Director of NIH shall—

12 “(1) commission the Institute of Medicine to
13 study the rules that protect patient safety and ano-
14 nymity so that in a contemporary clinical research
15 context, a better balance can be achieved between
16 clinical research promotion and regulatory require-
17 ments governing research subject safety and privacy;

18 “(2) examine informed consent processes; and

19 “(3) request that the Institute of Medicine issue
20 a written report not later than 18 months after the
21 date of enactment of the Accelerating Cures Act of
22 2008 that shall—

23 “(A) consider changes to the Health Insur-
24 ance Portability and Accountability Act of 1996
25 (Public Law 104–191) and the amendments

1 made by such Act that further promote the
2 clinical research endeavor; and

3 “(B) include recommendations for changes
4 that shall not be limited to legislation but shall
5 include changes to healthcare systems, includ-
6 ing health information technology, and to re-
7 searcher practice that facilitate the clinical re-
8 search endeavor.

9 **“Subpart 5—Training Clinical and Translational**
10 **Researchers of the Future**

11 **“SEC. 499E. TRAINING TRANSLATIONAL AND CLINICAL RE-**
12 **SEARCHERS OF THE FUTURE.**

13 “(a) IN GENERAL.—

14 “(1) ESTABLISHMENT OF PROGRAM.—The Di-
15 rector of OPASI shall establish training programs to
16 increase the number of, and maintain existing,
17 translational and clinical researchers, including re-
18 searchers trained in community-based research.

19 “(2) PURPOSE.—The purpose of the training
20 programs described in paragraph (1) shall be to
21 train a cadre of researchers in core competencies in
22 the translational and clinical sciences for the ulti-
23 mate goal of improving healthcare delivery,
24 healthcare options to the public, the use of
25 healthcare by patients, and healthcare outcomes.

1 “(b) GRANTS.—

2 “(1) IN GENERAL.—The Director of OPASI
3 shall award grants to, and enter into contracts with,
4 public and nonprofit educational entities to establish,
5 strengthen, or expand training programs for re-
6 searchers to be trained in the translational and clin-
7 ical sciences.

8 “(2) AWARDING OF GRANTS.—The Director of
9 OPASI shall award grants to, and enter into con-
10 tracts with, applicants that—

11 “(A) support multidisciplinary approaches
12 in training;

13 “(B) utilize collaborative strategies for
14 conducting research across various disciplines
15 to translate basic science discoveries; and

16 “(C) train researchers focused on improv-
17 ing care and patient outcomes.

18 “(3) REQUIRED USE OF FUNDS.—The Director
19 of OPASI shall award grants to, and enter into con-
20 tracts with, entities for the following purposes:

21 “(A) To establish training programs for
22 M.D. and Ph.D. researchers in translational or
23 clinical research.

24 “(B) To establish training programs for
25 individuals at predoctoral levels, including those

1 in medical school, and for allied health profes-
2 sionals, in translational or clinical research.

3 “(C) To establish training programs for
4 nurses in translational and clinical research.

5 “(D) To strengthen or expand existing
6 training programs for translational or clinical
7 researchers.

8 “(E) To establish a wide range of training
9 programs, including one-year training pro-
10 grams, summer programs, pre- and postdoctoral
11 clinical or translational research fellowships,
12 and advanced research training programs for
13 mid-career researchers and clinicians.

14 “(F) To provide stipends and allowances,
15 including for travel and subsistence expenses, in
16 amounts the Director of OPASI determines ap-
17 propriate, to support the training of
18 translational or clinical researchers.

19 “(G) To provide financial assistance to
20 public and nonprofit educational entities for the
21 purpose of supporting the training of
22 translational or clinical researchers, through
23 clinical education, curricula, and technological
24 support, and other measures.

1 “(H) To measure the impact of the
2 translational and clinical research training pro-
3 grams on the biomedical sciences and on clinical
4 practice.

5 “(c) FUNDS AVAILABLE.—The Director of OPASI
6 may make funds available to support training programs
7 for translational or clinical researchers at the National In-
8 stitutes of Health for entities awarded grants or contracts
9 under subsection (b).

10 “(d) NOVEL AND BEST PRACTICES.—The Director of
11 OPASI shall convene, on not less frequently than a bian-
12 nual basis, members of training institutions to share novel
13 and best practices in training translational or clinical re-
14 searchers.

15 “(e) TRAINING.—A trainee of a program funded
16 under a grant or contract awarded under this section may
17 conduct part of the trainee’s training at the Health Ad-
18 vanced Research Projects Program.

19 “(f) CONSISTENT DEFINITIONS AND METHODOLO-
20 GIES.—For the purposes of funding training programs for
21 clinical researchers, the Director of NIH shall develop con-
22 sistent definitions and methodologies to classify and report
23 clinical research.

1 **“SEC. 499E-1. TRANSLATIONAL RESEARCH TRAINING PRO-**
2 **GRAM.**

3 “The Director of NIH shall ensure that each institute
4 and center of the National Institutes of Health has estab-
5 lished, or contracted for the establishment of, a
6 translational research training program at the institute or
7 center.

8 **“Subpart 6—The ‘Valley of Death’**

9 **“SEC. 499F. SMALL BUSINESS PARTNERSHIPS.**

10 “(a) IN GENERAL.—An independent advisory board
11 shall be established at the National Academy of Sciences
12 to conduct periodic evaluations of the Small Business In-
13 novation Research program (referred to in this subpart
14 as the ‘SBIR program’) and the Small Business Tech-
15 nology Transfer program (referred to in this subpart as
16 the ‘STTR program’) of the Office of Extramural Re-
17 search in the Office of the Director of the National Insti-
18 tutes of Health for the purpose of improving management
19 of the programs through data-driven assessment. The ad-
20 visory board shall consist of the Director of NIH, the Di-
21 rector of the SBIR program, senior National Institutes of
22 Health agency managers, university and industry experts,
23 and program stakeholders.

24 “(b) SBIR AND STTR GRANTS AND CONTRACTS.—

25 “(1) IN GENERAL.—

1 “(A) PROGRAM MANAGERS WITH SUFFI-
2 CIENT EXPERTISE.—Not less than 25 percent
3 of the grants and contracts awarded by each of
4 the SBIR and STTR programs shall be award-
5 ed on a competitive basis by an SBIR or STTR
6 program manager who has sufficient manage-
7 rial, technical, and translational research exper-
8 tise to expertly assess the quality of a SBIR or
9 STTR proposal.

10 “(B) EXPERIENCE OF PROGRAM MAN-
11 AGERS.—In hiring new SBIR or STTR pro-
12 gram managers, the Director of NIH shall con-
13 sider experience in commercialization or indus-
14 try.

15 “(C) EMPHASIS ON GRANT AND CONTRACT
16 AWARDS.—In awarding grants and contracts
17 under the SBIR program and the STTR pro-
18 gram—

19 “(i) each SBIR and STTR program
20 manager shall place an emphasis on appli-
21 cations that identify from the onset prod-
22 ucts with commercial potential to prevent,
23 diagnose, and treat diseases, as well as
24 promote health and well-being; and

1 “(ii) risk-taking shall be supported
2 and productive failure shall be tolerated.

3 “(2) EXAMINATION OF COMMERCIALIZATION
4 AND OTHER METRICS.—The independent advisory
5 board described in subsection (a) shall evaluate the
6 success of the requirement under paragraph (1)(A)
7 by examining increased commercialization and other
8 metrics, to be determined and collected by SBIR and
9 STTR programs.

10 “(3) SUCCESS.—Each recipient of a SBIR or
11 STTR grant or contract, as a condition of receiving
12 such grant or contract, shall report to the SBIR or
13 STTR program—

14 “(A) whether there was eventual commer-
15 cial success of the product developed with the
16 assistance of the grant or contract; and

17 “(B) on other metrics as determined by
18 the SBIR or STTR program to capture broader
19 measures of success.

20 “(c) POTENTIAL PURCHASERS OR INVESTORS.—The
21 SBIR and STTR programs shall administer nonpeer re-
22 view grants and contracts pursuant to this section through
23 program managers who shall place special emphasis on
24 partnering grantees and entities awarded contracts from
25 the very beginning of the research and development proc-

1 ess with potential purchasers or investors of the product,
2 including large pharmaceutical or biotechnology compa-
3 nies, venture capital firms, and Federal agencies (includ-
4 ing the National Institutes of Health).

5 “(d) PHASE I AND II.—The SBIR and STTR pro-
6 grams shall reduce the time period between Phase I and
7 Phase II funding of grants and contracts under the SBIR
8 and STTR programs to—

9 “(1) 6 months; or

10 “(2) less than 6 months if the grantee or entity
11 awarded a contract demonstrates that the grantee or
12 entity awarded a contract has interest from third
13 parties to buy or fund the product development with
14 the grant or contract.

15 “(e) PHASE III.—A SBIR or STTR program man-
16 ager may petition the Director of NIH for Phase III fund-
17 ing of a grant or contract for a project that requires a
18 boost to finalize procurement of a product. The maximum
19 funding for Phase III funding shall be \$2,000,000 for
20 each of a maximum of 2 years. Such Phase III funding
21 may come from the Common Fund of the NIH.

22 “(f) EVALUATION AND REPORTING REQUIRE-
23 MENTS.—In order to enhance the evidence base guiding
24 SBIR and STTR program decisions and changes, the
25 SBIR and STTR programs shall—

1 “(1) conduct regular internal and external eval-
2 uations of the program;

3 “(2) review current data collection methods for
4 the purpose of identifying gaps and deficiencies, and
5 develop a formal plan for evaluation and assessment
6 of program success, including operational bench-
7 marks for success; and

8 “(3) conduct a review on the number of SBIR
9 and STTR awards made to women and minorities
10 and develop outreach and review strategies to in-
11 crease the number of awards to women and minori-
12 ties.

13 “(g) PILOT PROGRAMS.—

14 “(1) IN GENERAL.—The SBIR and STTR pro-
15 grams may initiate pilot programs, based on the de-
16 velopment of a formal mechanism for designing, im-
17 plementing, and evaluating pilot programs, to spur
18 innovation and to test new strategies that may en-
19 hance the effectiveness of the program.

20 “(2) CONSIDERATIONS.—The SBIR and STTR
21 programs shall consider, among other issues, con-
22 ducting pilot programs on including individuals with
23 commercialization experience in study sections, hir-
24 ing individuals with industry experience for staff po-
25 sitions, separating the commercial and scientific re-

1 view processes, and examining the impact of the
2 trend toward larger awards on the overall program.

3 “(h) ELECTRONIC RECORDS.—

4 “(1) IN GENERAL.—The SBIR and STTR pro-
5 grams shall keep a publicly accessible electronic
6 record of all SBIR or STTR investments in research
7 and development.

8 “(2) CONTENT OF RECORD.—The record de-
9 scribed in paragraph (1) shall include, at a min-
10 imum, the following information:

11 “(A) The grantee or entity awarded a
12 grant or contract.

13 “(B) A description of the research being
14 funded.

15 “(C) The amount of money awarded in
16 each phase of SBIR or STTR funding.

17 “(D) If applicable, the purchaser of the
18 product, current use of the product, and esti-
19 mated annual revenue resulting from the pro-
20 curement.

21 “(E) Dates of Phases I, II, and III
22 awards, as applicable.

23 “(F) Other metrics as determined by the
24 SBIR or STTR programs.

1 “(i) MEETING.—The Director of NIH shall convene
2 a meeting, not less frequently than annually, consisting
3 of the National Institutes of Health SBIR/STTR program
4 coordinator or manager and each institute and center of
5 the National Institutes of Health to share best practices,
6 report on program activities, and review existing policies.

7 “(j) REPORT TO CONGRESS.—The Director of NIH
8 shall submit an annual report to Congress and the inde-
9 pendent advisory board described in subsection (a) on the
10 SBIR and STTR programs’ activities.

11 **“SEC. 499F-1. RAPID ACCESS TO INTERVENTION DEVELOP-**
12 **MENT.**

13 “(a) IN GENERAL.—The Director of OPASI shall ex-
14 pand the existing Rapid Access to Intervention Develop-
15 ment Program (referred to in this subpart as the ‘RAID’)
16 that—

17 “(1) is designed to assist the translation of
18 promising, novel, and scientifically meritorious
19 therapeutic interventions to clinical use by helping
20 investigators navigate the product development pipe-
21 line;

22 “(2) shall aim to remove barriers between lab-
23 oratory discoveries and clinical trials of new molec-
24 ular therapies, technologies, and other clinical inter-
25 ventions;

1 “(3) shall aim to progress, augment, and com-
2 plement the innovation and research conducted in
3 private entities to reduce duplicative and redundant
4 work using public funds;

5 “(4) shall coordinate with the offices of the Na-
6 tional Institutes of Health that promote
7 translational research in the pre-clinical phase across
8 the National Institutes of Health;

9 “(5) shall identify, for the OPASI, those re-
10 search projects with promise for clinical application
11 or commercialization; and

12 “(6) shall, in collaboration with the
13 Translational Development Program for New Inno-
14 vations, facilitate the translation of new innovations
15 through the development process.

16 “(b) PROJECTS.—

17 “(1) IN GENERAL.—The RAID, in collaboration
18 with the Director of OPASI, shall carry out a pro-
19 gram that shall select, in accordance with paragraph
20 (2), projects of eligible entities to receive access to
21 laboratories, facilities, and other support resources
22 of the National Institutes of Health for the pre-
23 clinical development of drugs, biologics, diagnostics,
24 and devices.

1 “(2) SELECTION.—Not less than 25 percent of
2 the projects selected under paragraph (1) shall be
3 selected on a competitive basis—

4 “(A) by a program manager with sufficient
5 managerial, technical, and translational re-
6 search expertise to adequately assess the quality
7 of a project proposal; or

8 “(B) from a peer review process.

9 “(3) ELIGIBLE ENTITIES.—In this subsection,
10 the term ‘eligible entity’ means—

11 “(A) a university researcher;

12 “(B) a nonprofit research organization; or

13 “(C) a firm of less than 100 employees in
14 collaboration with 1 or more universities or
15 nonprofit organizations such as a community
16 health center.

17 “(4) DISCONTINUE SUPPORT.—The RAID may
18 discontinue support of a project if the project fails
19 to meet commercialization success criteria estab-
20 lished by the RAID.

21 “(c) DISCOVERIES FROM LAB TO CLINICAL PRAC-
22 TICE.—The program under subsection (b) shall accelerate
23 the process of bringing discoveries in medical technology
24 and drugs from the laboratory to the clinic.

1 “(d) ONGOING REVIEW.—The RAID shall review, on
2 an ongoing basis, potential products and may not support
3 products past the proof-of-principle stage.

4 **“SEC. 499F-2. TRANSLATIONAL DEVELOPMENT PROGRAM**
5 **FOR NEW INNOVATIONS.**

6 “(a) IN GENERAL.—The Director of OPASI shall de-
7 velop a Translational Development Program for New In-
8 novations to guide institutions of higher education, small
9 businesses, for-profits, nonprofits, or other such entities
10 through the translational research development process by
11 facilitating the following:

12 “(1) Triage screening of applications for prom-
13 ising innovations expected to reduce disease inci-
14 dence, morbidity, and mortality.

15 “(2) Outlining the tasks, timelines, and costs
16 required to navigate and complete the development
17 process for such innovations.

18 “(3) Providing project management support for
19 the recommended development tasks.

20 “(4) Interfacing with the Food and Drug Ad-
21 ministration and the entity to devise a plan that
22 safely and rapidly brings new drugs, biologics de-
23 vices, diagnostics, and other interventions to ap-
24 proval.

1 “(b) COORDINATION.—The Translational Develop-
2 ment Program for New Innovations shall—

3 “(1) collaborate with the RAID; and

4 “(2) be comprised of personnel with extensive
5 experience with investigational new drug applications
6 and in commercialization.

7 **“Subpart 7—Translational Research Fund**

8 **“SEC. 449G. TRANSLATIONAL RESEARCH FUND.**

9 “(a) ACCOUNT.—There is established an account to
10 be known as the Translational Research Fund that shall
11 consist of amounts appropriated for translational research
12 priorities as described in subsection (b). Such account
13 shall not be funded from amounts otherwise provided to
14 the National Institutes of Health.

15 “(b) AUTHORIZATION OF APPROPRIATIONS.—For
16 each fiscal year, there is authorized to be appropriated for
17 the Translational Research Fund to carry out the activi-
18 ties under this part an amount equal to the amount set
19 aside for the Common Fund for such fiscal year.

20 “(c) ALLOTMENT TO HEALTH ADVANCED RESEARCH
21 PROJECTS PROGRAM.—Not less than half of the annual
22 amount appropriated for the Translational Research Fund
23 shall be allotted to the Health Advanced Research Projects
24 Program.”.

1 **SEC. 5. APPLICATION OF RESEARCH REQUIREMENT.**

2 Part A of title IV of the Public Health Service Act
3 (42 U.S.C. 281 et seq.) is amended by adding at the end
4 the following:

5 **“SEC. 404I. APPLICATION OF RESEARCH REQUIREMENT.**

6 “Each application for, and summary of, a project,
7 grant, or contract from the National Institutes of Health,
8 shall include a statement on the possible application of the
9 research for detecting, treating, or curing a health condi-
10 tion or disease state.”.

○