

111TH CONGRESS
1ST SESSION

H. R. 2084

To increase awareness of and research on autoimmune diseases, which are a major women's health problem, affect as many as 23.5 million Americans, and encompass more than 100 interrelated diseases, such as lupus, multiple sclerosis, rheumatoid arthritis, Sjogren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, and sarcoidosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 23, 2009

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

A BILL

To increase awareness of and research on autoimmune diseases, which are a major women's health problem, affect as many as 23.5 million Americans, and encompass more than 100 interrelated diseases, such as lupus, multiple sclerosis, rheumatoid arthritis, Sjogren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, and sarcoidosis, 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 This Act may be cited as the “Prevention, Awareness,
5 and Research of Autoimmune Diseases Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) The National Institutes of Health estimates
9 that between 14 and 23.5 million Americans have an
10 autoimmune disease and the prevalence is rising.
11 Seventy-five percent of those afflicted are women
12 with most cases occurring during the childbearing
13 years.

14 (2) Researchers have identified more than 100
15 autoimmune diseases and suspect at least 40 addi-
16 tional disorders of having an autoimmune basis.

17 (3) Autoimmune diseases are chronic and can
18 be life-threatening, ranking in the top 10 causes of
19 death in children and women in all age groups up
20 to 64 years of age.

21 (4) Early diagnosis of and commencement of
22 treatment for autoimmune diseases can prevent or
23 reduce serious organ damage, disability, and death.
24 According to a study conducted by the American
25 Autoimmune Related Diseases Association, more

1 than half of those with an autoimmune disease suf-
2 fered for 4 years and visited 4 doctors before obtain-
3 ing a diagnosis, and 44.6 percent of women were
4 told they were chronic complainers or too concerned
5 with their health prior to being diagnosed.

6 (5) A close genetic relationship exists among
7 autoimmune diseases, explaining clustering in indi-
8 viduals and families as well as common pathways for
9 disease development.

10 (6) The rapidly evolving field of epigenetics has
11 shown that environmental factors can cause genes to
12 be “turned on” or “turned off”. Differing exposures
13 to environmental factors can result in differing pat-
14 terns of autoimmune expression.

15 (7) Frequently used immunosuppressant treat-
16 ments lead to devastating long-term side effects.
17 Those with autoimmune diseases lack effective treat-
18 ments.

19 (8) The Institute of Medicine reports that the
20 United States is behind other countries in research
21 into immune system self-recognition, the process in-
22 volved in autoimmune diseases.

23 (9) Understanding how to modulate immune
24 system activity will benefit transplant recipients,

1 cancer patients, AIDS patients, and infectious dis-
2 ease patients.

3 (10) The National Institutes of Health esti-
4 mates that annual direct health care costs for auto-
5 immune disease are in the range of
6 \$100,000,000,000.

7 (11) Lack of awareness on the part of the pub-
8 lic and health care professionals contributes to pa-
9 tients' extreme difficulty in obtaining a correct diag-
10 nosis, and lack of effective treatments. Despite the
11 prevalence of autoimmune diseases, public awareness
12 remains low. According to a Roper study, only 5.5
13 percent of Americans can even name an autoimmune
14 disease and 29 percent incorrectly identify AIDS as
15 an autoimmune disease. Awareness is lowest among
16 adults ages 18 to 34, the age group most likely to
17 develop an autoimmune disease.

18 (12) Examples of autoimmune diseases include
19 lupus, multiple sclerosis, rheumatoid arthritis,
20 Sjögren's syndrome, polymyositis, pemphigus, myas-
21 thenia gravis, Wegener's granulomatosis, psoriasis,
22 celiac disease, autoimmune platelet disorders,
23 scleroderma, alopecia areata, vitiligo, autoimmune
24 thyroid disease, and sarcoidosis.

1 (13) Lupus can affect many parts of the body,
2 including joints, skin, kidneys, heart, lungs, blood
3 vessels, and brain. At least 1,500,000 Americans
4 have a form of lupus, 9 out of 10 of these Americans
5 are women, and 80 percent of all newly diagnosed
6 cases of lupus are among women of childbearing age.
7 According to a Lupus Foundation of America sur-
8 vey, more than half of the people with lupus suffered
9 for 4 or more years and visited 3 or more doctors
10 before obtaining a diagnosis of lupus. About 1 out
11 of 5 lupus sufferers receives disability payments,
12 costing the Government several billion dollars each
13 year for Social Security disability benefits, lost
14 taxes, and medical care provided through Medicare
15 and Medicaid. The average annual cost of medical
16 treatment for an individual with lupus is \$6,000 to
17 \$10,000; for some people, medical costs may exceed
18 several thousand dollars every month. Early diag-
19 nosis of and commencement of treatment for lupus
20 can prevent or reduce serious organ damage, dis-
21 ability, and death.

22 (14) In multiple sclerosis (MS), the immune
23 system attacks the protective coating around the
24 nerves. The damage affects the brain or spinal cord
25 and interferes with the nerve pathways, causing

1 muscular weakness, loss of coordination, and visual
2 and speech problem. Multiple sclerosis is a chronic
3 and often disabling disease of the central nervous
4 system which often first appears in people who are
5 20 to 50 years of age, with lifelong physical and
6 emotional effects. Multiple sclerosis is twice as com-
7 mon in women as in men. An estimated 400,000 in-
8 dividuals have multiple sclerosis nationally. Accord-
9 ing to the Multiple Sclerosis Society, the average an-
10 nual cost of multiple sclerosis to each affected indi-
11 vidual is approximately \$57,000, and the total cost
12 can exceed \$3,000,000 over an individual's lifetime.
13 The annual cost of treating all people who suffer
14 from multiple sclerosis in the United States is ap-
15 proximately \$20,000,000,000.

16 (15) Four million Americans suffer from
17 Sjögren's syndrome, a serious autoimmune disease.
18 Ninety percent of those with Sjögren's syndrome are
19 women. Sjögren's affects all races and ethnic groups.
20 Hallmark symptoms of Sjögren's include dry eyes
21 and dry mouth, which can lead to corneal abrasions
22 and blindness and loss of teeth if not recognized and
23 treated and affect a persons' ability to eat, swallow,
24 and digest food. Sjögren's syndrome is a systemic
25 disease that can affect any body organ or system,

1 cause extreme fatigue and pain, and lead to develop-
2 ment of non-Hodgkin's B-cell lymphoma and heart
3 block in babies born to mothers with Sjögren's syn-
4 drome. Sjögren's syndrome is frequently
5 misdiagnosed because of lack of recognition and phy-
6 sician education. According to the Sjögren's Syn-
7 drome Foundation, the average time for those who
8 do obtain a correct diagnosis is 6.3 years after the
9 onset of symptoms and active attempt to obtain a di-
10 agnosis.

11 (16) In rheumatoid arthritis, the immune sys-
12 tem attacks the linings of the joints resulting in
13 joint pain, stiffness, swelling, and destruction.
14 Among the 2,100,000 people with rheumatoid arthri-
15 tis in the United States, women outnumber men 3
16 to 1. According to the Arthritis Foundation, total di-
17 rect costs of rheumatoid arthritis, including money
18 spent on treatments, hospitalizations, medications,
19 transportation, and specialist aids, are approxi-
20 mately \$1,200,000,000 each year. The average med-
21 ical care expenditures over the course of a rheu-
22 matoid arthritis patient's lifetime is \$225,000 to
23 \$370,000.

24 (17) Systemic sclerosis affects approximately
25 240 individuals per million, and an estimated

1 300,000 are affected by all forms of scleroderma in
2 the United States. Scleroderma strikes more women
3 than men, with an overall ratio of approximately 4
4 to 1. Scleroderma is a chronic, often progressive
5 autoimmune disease. The disease, which literally
6 means “hard skin”, can cause thickening and tight-
7 ening of the skin, as well as fibrosis of the internal
8 organs, including the lungs, heart, kidneys, and gas-
9 trointestinal tract. Scleroderma can be life threat-
10 ening. The Scleroderma Foundation estimates the
11 direct and indirect costs of systematic sclerosis in
12 the United States to be \$1,500,000,000, the value of
13 lifetime earnings lost to be \$300,000 per systemic
14 sclerosis death, and direct costs at \$4,731 per pa-
15 tient annually.

16 (18) Myasthenia gravis is an autoimmune neu-
17 romuscular disease which affects the skeletal mus-
18 cles and is characterized by muscular weakness
19 which is the result of a disturbance of the neuro-
20 muscular transmission. Certain muscles are more
21 frequently involved, and these include the muscles
22 that control eye movement, eyelids, chewing, swal-
23 lowing, coughing, and facial expression. Muscles that
24 control breathing and movement of the arms and
25 legs may also be affected. Approximately 40 to 50

1 percent of individuals with myasthenia gravis experi-
2 ence vision problems at the time of diagnosis, and
3 up to 90 percent experience such problems in the
4 disease's lifetime. About 40 to 50 percent of patients
5 experience generalized myasthenia gravis affecting
6 the muscles of the trunk or limbs, which may result
7 in impaired breathing. The prevalence of myasthenia
8 gravis in the United States is estimated at approxi-
9 mately 36,000 cases. However, myasthenia gravis is
10 probably underdiagnosed, and the prevalence is
11 probably higher. Previous studies have shown that
12 women are more often affected than men; however,
13 now it seems that males over 50 are more often af-
14 fected. The most common age at onset is before age
15 40 in women and after age 50 in men. Treatment
16 for myasthenia gravis can cost up to \$524 per
17 month per prescription. Various surgeries can cost
18 up to \$6,000.

19 (19) Wegener's granulomatosis (WG) strikes 1
20 in every 20,000 to 30,000 people. The disease can
21 occur at any age, although peak occurrence is in the
22 4th or 5th decade of life. Males and females are af-
23 fected equally. Wegener's granulomatosis is a rare
24 form of vasculitis, a disease characterized by inflam-
25 mation of blood vessel walls which can damage vital

1 organs by restricting blood flow. Wegener’s granu-
2 lomatosi s primarily affects the respiratory tract
3 (sinus, nose, trachea, and lungs) and the kidneys
4 and may involve the joints, eyes, and skin. According
5 to the Wegener’s Granulomatosis Association, pa-
6 tients experience a 26 percent reduction in income
7 within the first year of diagnosis, or \$9,700,000 per
8 year in lost income total for all Wegener’s patients.
9 A 1998 survey of Wegener’s patients showed costs
10 of \$33,517 per patient per year.

11 (20) In immune thrombocytopenic purpura
12 (ITP), the body mounts an autoimmune attack
13 against platelets, particles in the blood essential for
14 clotting. People with immune thrombocytopenic pur-
15 pura are prone to spontaneous hemorrhages, poten-
16 tially in the brain and other vital organs. According
17 to the Platelet Disorders Support Association, treat-
18 ing immune thrombocytopenic purpura costs from
19 several thousand to hundreds of thousands of dollars
20 per year, depending on the severity of the case and
21 response to treatments. Immune thrombocytopenic
22 purpura is a diagnosis of exclusion. Many other dis-
23 eases and conditions present with low platelets and
24 can be confused with immune thrombocytopenic pur-
25 pura.

1 (21) According to the National Alopecia Areata
2 Foundation, over 4,500,000 Americans have alopecia
3 areata, alopecia totalis, or alopecia universalis, or
4 1.7 percent of any given population. While children
5 are affected most frequently, alopecia areata occurs
6 in all ages and ethnicities and in males and females.
7 Alopecia areata results in hair loss, with many peo-
8 ple losing all hair over their entire body, including
9 eyebrows and eyelashes and the hair on their head.
10 This leads to loss of self-esteem and filtering protec-
11 tion from the elements and cold. Denting and strip-
12 ping of nails can also occur along with complete nail
13 loss. Since no approved treatments exist for alopecia
14 areata, insurance companies fail to recognize its se-
15 riousness and do not cover treatments that could af-
16 fect the disease's course. Treatments are often paid
17 for by patients or not administered. Diagnosis is dif-
18 ficult because of lack of knowledge, especially among
19 pediatricians and general practitioners who would
20 refer patients to specialists. The International
21 Pemphigus Foundation estimates the incidence of
22 pemphigus and pemphigoid as between 1 and 5 peo-
23 ple per hundred thousand. These diseases affect all
24 races and ethnic groups. Pemphigus and pemphigoid
25 are a group of chronic, rare autoimmune blistering

1 diseases of the skin or mucous membranes. They are
2 characterized by painful, burn-like blisters or lesions
3 covering much of the body that do not heal, and
4 they can cause serious infection, difficulty swal-
5 lowing, and, with cicatricial pemphigoid (CP), blind-
6 ness. If untreated, pemphigus is usually fatal.

7 (22) Polymyositis is an autoimmune disease
8 that causes inflammation of the small and medium-
9 sized arteries and leads to problems in the muscles,
10 joints, intestines, nerves, kidney, and skin. Myositis
11 is a neuromuscular autoimmune disease affecting
12 about 50,000 Americans. Because it is rare and not
13 easily detectable, individuals with myositis are often
14 misdiagnosed. It is common for those with myositis
15 to go either undiagnosed or misdiagnosed for several
16 years before getting a correct diagnosis. The efficacy
17 of treatment is diminished by delayed diagnoses and
18 the resulting medications required and costs in-
19 curred are substantially higher.

20 (23) More than 5,000,000 people in the United
21 States have been diagnosed with psoriasis or psori-
22 atic arthritis, including children. Psoriasis is a life-
23 long skin disease that occurs when faulty signals in
24 the immune system cause skin cells to regenerate too
25 quickly. Extra skin cells build up on the skin's sur-

1 face forming red, flaky, scaly lesions that can itch,
2 crack, bleed, and be extremely painful. Psoriasis
3 generally appears on the joints, limbs, and scalp, but
4 it can appear anywhere, covering some people from
5 head to toe. The National Psoriasis Foundation esti-
6 mates the cost of psoriasis care in the United States
7 ranges from \$650,000,000 a year to \$4,300,000,000
8 a year. A recent study estimates that Americans
9 with psoriasis lose about 56 million hours of work
10 and spend \$2 to \$3 billion to treat the disease each
11 year.

12 (24) Sarcoidosis results in small growths of
13 blood vessels, cells, and connective tissue and leads
14 to problems in the skin, lungs, eyes, joints, and mus-
15 cles. Sarcoidosis is a disease due to inflammation
16 that can attack any organ in the body in any loca-
17 tion. The disease is characterized by the presence of
18 granulomas, small areas of inflamed cells. They can
19 be either inside the body or on the body's exterior,
20 appearing as sores on the face or shins. Sarcoidosis
21 is most frequently found in the lungs. There are
22 about 25,000 cases of sarcoidosis in the United
23 States. African-Americans have a higher risk for
24 sarcoidosis than do other Americans. However, the
25 disease occurs in every race in the United States and

1 throughout the world, including in individuals of Eu-
2 ropean ancestry. Sarcoidosis occurs predominantly
3 between the ages of 20 and 40 years of age.

4 (25) Vitiligo affects 1 to 2 percent of the popu-
5 lation, or about 3 to 6 million Americans, and af-
6 fects every nationality, race, and gender equally. Vit-
7 iligo is an autoimmune disease in which the immune
8 system mistakenly attacks the pigment cells in the
9 skin. It appears as milky white patches and can
10 occur anywhere on the body. Usually progressive, it
11 can have a devastating impact on a patient's mental
12 state, especially in those with darker skin. Cost var-
13 ies by treatment. Treatment can cost up to \$150 a
14 month for topical medications, \$2,000 to \$3,000 for
15 a home unit for phototherapy, and up to \$30 per
16 doctor's office visit 2 to 3 times per week. Laser
17 treatments can cost \$100 to \$200 per treatment per
18 area. Diagnosis can be extremely difficult, as loss of
19 pigment occurs in several other conditions, and phy-
20 sician education is lacking. It can take several
21 months or trips to several different dermatologists
22 for a definitive diagnosis.

1 **SEC. 3. RESEARCH ON ENVIRONMENTAL TRIGGERS OF**
2 **AUTOIMMUNE DISEASES.**

3 Subpart 12 of part C of title IV of the Public Health
4 Service Act (42 U.S.C. 2851 et seq.) is amended by adding
5 at the end the following:

6 **“SEC. 463C. RESEARCH ON ENVIRONMENTAL TRIGGERS OF**
7 **AUTOIMMUNE DISEASES.**

8 “(a) **AUTHORITY.**—The Secretary, acting through
9 the Director of the Institute and in collaboration with the
10 directors of such other national research institutes as the
11 Secretary deems appropriate, shall award not less than 2
12 grants to eligible entities for the conduct or support of
13 research on environmental triggers, such as heavy metals,
14 fluorescent lighting, phthalates, post traumatic stress,
15 and pharmaceuticals, that can cause the initiation of auto-
16 immune diseases in genetically predisposed individuals.

17 “(b) **GRANT PERIOD.**—Each grant under this section
18 shall be for a period of 5 years.

19 “(c) **DEFINITION.**—In this section, the term ‘eligible
20 entity’ means—

21 “(1) a nonprofit organization;

22 “(2) an institution of higher education (as de-
23 fined in section 101 of the Higher Education Act of
24 1965); or

25 “(3) a Federal, State, or local agency.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated to carry out this section
3 \$10,000,000 for each of fiscal years 2010 and 2011.”.

4 **SEC. 4. GRANTS TO INCREASE AWARENESS OF AUTO-**
5 **IMMUNE DISEASES.**

6 (a) PURPOSE.—The purpose of this section is to in-
7 crease awareness of autoimmune diseases in order to pro-
8 vide to the public a more complete understanding of these
9 diseases, which affect 5 to 10 percent of the people in the
10 United States.

11 (b) AMENDMENTS.—Title III of the Public Health
12 Service Act (42 U.S.C. 241 et seq.) is amended by insert-
13 ing after section 317T the following:

14 **“SEC. 317U. GRANTS TO INCREASE AWARENESS OF AUTO-**
15 **IMMUNE DISEASES.**

16 “(a) GRANTS.—The Secretary, acting through the
17 Director of the Centers for Disease Control and Preven-
18 tion, shall award grants to eligible entities to conduct pub-
19 lic and professional awareness activities regarding auto-
20 immune diseases.

21 “(b) USE OF FUNDS.—In conducting public and pro-
22 fessional awareness activities with a grant under this sec-
23 tion, an eligible entity may do any of the following:

24 “(1) Promote increased awareness of early
25 intervention and treatment so as to significantly im-

1 prove the quality of life for people with autoimmune
2 diseases.

3 “(2) Target minority communities that may be
4 underserved or disproportionately affected by auto-
5 immune diseases.

6 “(3) Target women (who are disproportionately
7 affected by autoimmune diseases) so as to help re-
8 duce the amount of time taken for correct diagnosis
9 of such diseases, which often takes more than 1
10 year.

11 “(c) ELIGIBLE ENTITY.—For purposes of this sec-
12 tion, the term ‘eligible entity’ means a nonprofit organiza-
13 tion, an institution of higher education (as defined in sec-
14 tion 101 of the Higher Education Act of 1965), a Federal,
15 State, or local governmental agency, or a media organiza-
16 tion.

17 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
18 is authorized to be appropriated to carry out this section
19 \$18,000,000 for each of fiscal years 2010 and 2011.”.

20 **SEC. 5. GRANTS FOR EDUCATION ON RELATIONSHIP BE-**
21 **TWEEN AUTOIMMUNE DISEASES AND MEN-**
22 **TAL ILLNESSES.**

23 Title III of the Public Health Service Act (42 U.S.C.
24 241 et seq.), as amended by section 4, is amended by in-
25 serting after section 317U the following:

1 **“SEC. 317V. GRANTS FOR EDUCATION ON RELATIONSHIP**
2 **BETWEEN AUTOIMMUNE DISEASES AND MEN-**
3 **TAL ILLNESSES.**

4 “(a) GRANTS.—The Secretary, acting through the
5 Administrator of the Health Resources and Services Ad-
6 ministration, shall award grants to eligible entities for the
7 education of health care providers on potential links be-
8 tween autoimmune diseases and cognitive and mood dis-
9 orders, such as depression.

10 “(b) ELIGIBLE ENTITY.—For purposes of this sec-
11 tion, the term ‘eligible entity’ means a nonprofit organiza-
12 tion, an institution of higher education (as defined in sec-
13 tion 101 of the Higher Education Act of 1965), a Federal,
14 State, or local governmental agency, or a media organiza-
15 tion.

16 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
17 is authorized to be appropriated to carry out this section
18 \$5,000,000 for each of fiscal years 2010 and 2011.”.

19 **SEC. 6. LOAN REPAYMENT PROGRAM REGARDING PHYSI-**
20 **CIAN RESEARCH ON AUTOIMMUNE DISEASES.**

21 Title IV of the Public Health Service Act (42 U.S.C.
22 281 et seq.) is amended—

23 (1) by redesignating the second section 487F as
24 section 487G; and

25 (2) by inserting after section 487G (as so re-
26 designated) the following:

1 **“SEC. 487H. LOAN REPAYMENT PROGRAM REGARDING PHY-**
2 **SICIAN RESEARCH ON AUTOIMMUNE DIS-**
3 **EASES.**

4 “(a) ESTABLISHMENT.—To the extent and in the
5 amounts provided in advance in appropriations Acts, the
6 Secretary, acting through the Administrator of the Health
7 Resources and Services Administration, shall establish a
8 program to enter into contracts with qualified physicians
9 under which such qualified physicians agree to conduct re-
10 search for a period of at least 3 years regarding auto-
11 immune diseases in consideration of the Federal Govern-
12 ment agreeing to repay, for each year of service con-
13 ducting such research, not more than \$35,000 of the prin-
14 cipal and interest of the educational loans of such qualified
15 physicians.

16 “(b) APPLICATION OF PROVISIONS.—Except as in-
17 consistent with this section, the provisions of sections
18 338B, 338C, and 338E shall apply to the program estab-
19 lished under this section to the same extent and in the
20 same manner as such provisions apply to the National
21 Health Service Corps Loan Repayment Program estab-
22 lished in subpart III of part D of title III.

23 “(c) QUALIFIED PHYSICIAN.—For purposes of this
24 section, the term ‘qualified physician’ means an individual
25 who has received, or will have received by the time of the
26 research to be conducted under this section, a degree of

1 doctor of medicine or its equivalent and is licensed to prac-
2 tice medicine in the United States.”.

3 **SEC. 7. RESEARCH AND DATABASE ON BIOMARKERS OF**
4 **AUTOIMMUNE DISEASES.**

5 Subpart 4 of part C of title IV of the Public Health
6 Service Act (42 U.S.C. 285d et seq.) is amended by adding
7 at the end the following:

8 **“SEC. 442B. BIOMARKERS OF AUTOIMMUNE DISEASES.**

9 “(a) RESEARCH.—The Director of the Institute shall
10 conduct or support research on biomarkers of autoimmune
11 diseases for the purpose of—

12 “(1) preventing such diseases; and

13 “(2) making dramatic improvements in the di-
14 agnosis, treatment, and monitoring of such diseases.

15 “(b) DATABASE.—The Director of the Institute shall
16 establish and maintain a database on biomarkers of auto-
17 immune diseases for the purpose of facilitating research
18 on, and understanding of, the relationship between such
19 biomarkers and the development and severity of auto-
20 immune diseases.

21 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
22 is authorized to be appropriated to carry out this section
23 \$10,000,000 for each of fiscal years 2010 and 2011.”.

○