

109TH CONGRESS
2^D SESSION

H. R. 6214

To increase awareness of and research on autoimmune diseases, which are a major women's health problem, affect as many as 22 million Americans, and encompass more than 100 interrelated diseases, such as lupus, multiple sclerosis, rheumatoid arthritis, Sjögren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, sarcoidosis, and fibromyalgia, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 2006

Mr. KENNEDY of Rhode Island 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 22 million Americans, and encompass more than 100 interrelated diseases, such as lupus, multiple sclerosis, rheumatoid arthritis, Sjögren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, sarcoidosis, and fibromyalgia, 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 Disease Act of 2006”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) The National Institutes of Health estimates
9 that between 14 and 22 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) Frequently used immunosuppressant treat-
11 ments lead to devastating long-term side effects.
12 Those with autoimmune diseases lack effective treat-
13 ments.

14 (7) The Institute of Medicine reports that the
15 United States is behind other countries in research
16 into immune system self-recognition, the process in-
17 volved in autoimmune diseases.

18 (8) Understanding how to modulate immune
19 system activity will benefit transplant recipients,
20 cancer patients, AIDS patients, and infectious dis-
21 ease patients.

22 (9) The National Institutes of Health estimates
23 that annual direct health care costs for autoimmune
24 disease are in the range of \$100,000,000,000.

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

12 (11) Examples of autoimmune diseases include
13 lupus, multiple sclerosis, rheumatoid arthritis,
14 Sjögren's syndrome, polymyositis, pemphigus, myas-
15 thenia gravis, Wegener's granulomatosis, psoriasis,
16 celiac disease, autoimmune platelet disorders,
17 scleroderma, alopecia areata, vitiligo, autoimmune
18 thyroid disease, sarcoidosis, and fibromyalgia.

19 (12) Lupus can affect many parts of the body,
20 including joints, skin, kidneys, heart, lungs, blood
21 vessels, and brain. At least 1,500,000 Americans
22 have a form of lupus, 9 out of 10 of these Americans
23 are women, and 80 percent of all newly diagnosed
24 cases of lupus are among women of childbearing age.
25 According to a Lupus Foundation of America sur-

1 vey, more than half of the people with lupus suffered
2 for 4 or more years and visited 3 or more doctors
3 before obtaining a diagnosis of lupus. About 1 out
4 of 5 lupus sufferers receives disability payments,
5 costing the Government several billion dollars each
6 year for social security disability benefits, lost taxes,
7 and medical care provided through Medicare and
8 Medicaid. The average annual cost of medical treat-
9 ment for an individual with lupus is \$6,000 to
10 \$10,000; for some people, medical costs may exceed
11 several thousand dollars every month. Early diag-
12 nosis of and commencement of treatment for lupus
13 can prevent or reduce serious organ damage, dis-
14 ability, and death.

15 (13) In multiple sclerosis (MS), the immune
16 system attacks the protective coating around the
17 nerves. The damage affects the brain or spinal cord
18 and interferes with the nerve pathways, causing
19 muscular weakness, loss of coordination, and visual
20 and speech problem. Multiple sclerosis is a chronic
21 and often disabling disease of the central nervous
22 system which often first appears in people who are
23 20 to 50 years of age, with lifelong physical and
24 emotional effects. Multiple sclerosis is twice as com-
25 mon in women as in men. An estimated 250,000 to

1 400,000 individuals have multiple sclerosis nation-
2 ally. According to the Multiple Sclerosis Society, the
3 average annual cost of multiple sclerosis to each af-
4 fected individual is approximately \$50,000, and the
5 total cost can exceed \$3,000,000 over an individual's
6 lifetime. The annual cost of treating all people who
7 suffer from multiple sclerosis in the United States is
8 approximately \$20,000,000,000.

9 (14) Four million Americans suffer from
10 Sjögren's syndrome, a serious autoimmune disease.
11 Ninety percent of those with Sjögren's syndrome are
12 women. Sjögren's affects all races and ethnic groups.
13 Hallmark symptoms of Sjögren's include dry eyes
14 and dry mouth, which can lead to corneal abrasions
15 and blindness and loss of teeth if not recognized and
16 treated and affect a persons' ability to eat, swallow,
17 and digest food. Sjögren's syndrome is a systemic
18 disease that can affect any body organ or system,
19 cause extreme fatigue and pain, and lead to develop-
20 ment of non-Hodgkin's B-cell lymphoma and heart
21 block in babies born to mothers with Sjögren's syn-
22 drome. Sjögren's syndrome is frequently
23 misdiagnosed because of lack of recognition and phy-
24 sician education. According to the Sjögren's Syn-
25 drome Foundation, the average time for those who

1 do obtain a correct diagnosis is 6.3 years after the
2 onset of symptoms and active attempt to obtain a di-
3 agnosis.

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

17 (16) Systemic sclerosis affects approximately
18 240 individuals per million, and an estimated
19 300,000 are affected by all forms of scleroderma in
20 the United States. Scleroderma strikes more women
21 than men, with an overall ratio of approximately 4
22 to 1. Scleroderma is a chronic, often progressive
23 autoimmune disease. The disease, which literally
24 means "hard skin", can cause thickening and tight-
25 ening of the skin, as well as fibrosis of the internal

1 organs, including the lungs, heart, kidneys, and gas-
2 trointestinal tract. Scleroderma can be life threat-
3 ening. The Scleroderma Foundation estimates the
4 direct and indirect costs of systematic sclerosis in
5 the United States to be \$1,500,000,000, the value of
6 lifetime earnings lost to be \$300,000 per systemic
7 sclerosis death, and direct costs at \$4,731 per pa-
8 tient annually.

9 (17) Fibromyalgia is believed to affect approxi-
10 mately 3,700,000 people (approximately 2 percent of
11 the United States population) and occurs more com-
12 monly in women than men. Current research sup-
13 ports a high correlation of those diagnosed with
14 fibromyalgia also diagnosed with an autoimmune
15 disease. Symptoms usually occur first between the
16 ages of 20 to 40 years old. Fibromyalgia is wide-
17 spread pain and tenderness, fatigue, and exhaustion
18 after minimal effort. Fibromyalgia is a lifelong dis-
19 order, with more than 90 percent of patients re-
20 maining symptomatic. Nearly 30 percent of patients
21 claim they cannot hold steady employment due to
22 their condition. The total yearly drain on the United
23 States economy is estimated to be over
24 \$20,000,000,000. About 16.2 percent of
25 fibromyalgia patients draw Social Security disability

1 payments. The average health care cost per patient
2 per year is close to \$2,300.

3 (18) Myasthenia gravis is an autoimmune neu-
4 romuscular disease which affects the skeletal mus-
5 cles and is characterized by muscular weakness
6 which is the result of a disturbance of the neuro-
7 muscular transmission. Certain muscles are more
8 frequently involved, and these include the muscles
9 that control eye movement, eyelids, chewing, swal-
10 lowing, coughing, and facial expression. Muscles that
11 control breathing and movement of the arms and
12 legs may also be affected. Approximately 40 to 50
13 percent of individuals with myasthenia gravis experi-
14 ence vision problems at the time of diagnosis, and
15 up to 90 percent experience such problems in the
16 disease's lifetime. About 40 to 50 percent of patients
17 experience generalized myasthenia gravis affecting
18 the muscles of the trunk or limbs, which may result
19 in impaired breathing. The prevalence of myasthenia
20 gravis in the United States is estimated at approxi-
21 mately 36,000 cases. However, myasthenia gravis is
22 probably underdiagnosed, and the prevalence is
23 probably higher. Previous studies have shown that
24 women are more often affected than men; however,
25 now it seems that males over 50 are more often af-

1 affected. The most common age at onset is under-
2 before age 40 in women and after age 50 in men.
3 Treatment for myasthenia gravis can cost up to
4 \$524 per month per prescription. Various surgeries
5 can cost up to \$6,000.

6 (19) Wegener's granulomatosis (WG) strikes 1
7 in every 20,000 to 30,000 people. The disease can
8 occur at any age, although peak occurrence is in the
9 4th or 5th decade of life. Males and females are af-
10 fected equally. Wegener's granulomatosis is a rare
11 form of vasculitis, a disease characterized by inflam-
12 mation of blood vessel walls which can damage vital
13 organs by restricting blood flow. Wegener's granu-
14 lomatosis primarily affects the respiratory tract
15 (sinus, nose, trachea, and lungs) and the kidneys
16 and may involve the joints, eyes, and skin. According
17 to the Wegener's Granulomatosis Association, pa-
18 tients experience a 26 percent reduction in income
19 within the first year of diagnosis, or \$9,700,000 per
20 year in lost income total for all Wegener's patients.
21 A 1998 survey of Wegener's patients showed costs
22 of \$33,517 per patient per year.

23 (20) In immune thrombocytopenic purpura
24 (ITP), the body mounts an autoimmune attack
25 against platelets, particles in the blood essential for

1 clotting. People with immune thrombocytopenic pur-
2 pura are prone to spontaneous hemorrhages, poten-
3 tially in the brain and other vital organs. According
4 to the Platelet Disorders Support Association, treat-
5 ing immune thrombocytopenic purpura costs from
6 several thousand to hundreds of thousands of dollars
7 per year, depending on the severity of the case and
8 response to treatments. Immune thrombocytopenic
9 purpura is a diagnosis of exclusion. Many other dis-
10 eases and conditions present with low platelets and
11 can be confused with immune thrombocytopenic pur-
12 pura.

13 (21) According to the National Alopecia Areata
14 Foundation, over 4,500,000 Americans have alopecia
15 areata, alopecia totalis, or alopecia universalis, or
16 1.7 percent of any given population. While children
17 are affected most frequently, alopecia areata occurs
18 in all ages and ethnicities and in males and females.
19 Alopecia areata results in hair loss, with many peo-
20 ple losing all hair over their entire body, including
21 eyebrows and eyelashes and the hair on their head.
22 This leads to loss of self-esteem and filtering protec-
23 tion from the elements and cold. Denting and strip-
24 ping of nails can also occur along with complete nail
25 loss. Since no approved treatments exist for alopecia

1 areata, insurance companies fail to recognize its se-
2 riousness and do not cover treatments that could af-
3 fect the disease's course. Treatments are often paid
4 for by patients or not administered. Diagnosis is dif-
5 ficult because of lack of knowledge, especially among
6 pediatricians and general practitioners who would
7 refer patients to specialists. The International
8 Pemphigus Foundation estimates the incidence of
9 pemphigus and pemphigoid as between 1 and 5 peo-
10 ple per hundred thousand. These diseases affect all
11 races and ethnic groups. Pemphigus and pemphigoid
12 are a group of chronic, rare autoimmune blistering
13 diseases of the skin or mucous membranes. They are
14 characterized by painful, burn-like blisters or lesions
15 covering much of the body that do not heal, and
16 they can cause serious infection, difficulty swal-
17 lowing, and, with cicatricial pemphigoid (CP), blind-
18 ness. If untreated, pemphigus is usually fatal.

19 (22) Polymyositis is an autoimmune disease
20 that causes inflammation of the small and medium-
21 sized arteries and leads to problems in the muscles,
22 joints, intestines, nerves, kidney, and skin. Myositis
23 is a neuromuscular autoimmune disease affecting
24 about 50,000 Americans. Because it is rare and not
25 easily detectable, individuals with myositis are often

1 misdiagnosed. It is common for those with myositis
2 to go either undiagnosed or misdiagnosed for several
3 years before getting a correct diagnosis. The efficacy
4 of treatment is diminished by delayed diagnoses and
5 the resulting medications required and costs in-
6 curred are substantially higher.

7 (23) More than 5,000,000 people in the United
8 States have been diagnosed with psoriasis or psori-
9 atic arthritis, including children. Psoriasis is a life-
10 long skin disease that occurs when faulty signals in
11 the immune system cause skin cells to regenerate too
12 quickly. Extra skin cells build up on the skin's sur-
13 face forming red, flaky, scaly lesions that can itch,
14 crack, bleed, and be extremely painful. Psoriasis
15 generally appears on the joints, limbs, and scalp, but
16 it can appear anywhere, covering some people from
17 head to toe. The National Psoriasis Foundation esti-
18 mates the cost of psoriasis care in the United States
19 ranges from \$650,000,000 a year to \$4,300,000,000
20 a year. A recent study estimates that Americans
21 with psoriasis lose about 56 million hours of work
22 and spend \$2 to \$3 billion to treat the disease each
23 year.

24 (24) Sarcoidosis results in small growths of
25 blood vessels, cells, and connective tissue and leads

1 to problems in the skin, lungs, eyes, joints, and mus-
2 cles. Sarcoidosis is a disease due to inflammation
3 that can attack any organ in the body in any loca-
4 tion. The disease is characterized by the presence of
5 granulomas, small areas of inflamed cells. They can
6 be either inside the body or on the body's exterior,
7 appearing as sores on the face or shins. Sarcoidosis
8 is most frequently found in the lungs. There are
9 about 25,000 cases of sarcoidosis in the United
10 States. African Americans have a higher risk for
11 sarcoidosis than do other Americans. However, the
12 disease occurs in every race in the United States and
13 throughout the world, including in individuals of Eu-
14 ropean ancestry. Sarcoidosis occurs predominantly
15 between the ages of 20 and 40 years of age.

16 (25) Vitiligo affects 1 to 2 percent of the popu-
17 lation, or about 3 to 6 million Americans, and af-
18 fects every nationality, race, and gender equally. Vit-
19 iligo is an autoimmune disease in which the immune
20 system mistakenly attacks the pigment cells in the
21 skin. It appears as milky white patches and can
22 occur anywhere on the body. Usually progressive, it
23 can have a devastating impact on a patient's mental
24 state, especially in those with darker skin. Cost var-
25 ies by treatment. Treatment can cost up to \$150 a

1 month for topical medications, \$2,000 to \$3,000 for
2 a home unit for phototherapy, and up to \$30 per
3 doctor's office visit 2 to 3 times per week. Laser
4 treatments can cost \$100 to \$200 per treatment per
5 area. Diagnosis can be extremely difficult, as loss of
6 pigment occurs in several other conditions, and phy-
7 sician education is lacking. It can take several
8 months or trips to several different dermatologists
9 for a definitive diagnosis.

10 **SEC. 3. GRANTS TO INCREASE AWARENESS OF AUTO-**
11 **IMMUNE DISEASES.**

12 (a) **PURPOSE.**—The purpose of this section is to in-
13 crease awareness of autoimmune diseases, such as lupus,
14 multiple sclerosis, rheumatoid arthritis, and fibromyalgia,
15 in order to provide to the public a more complete under-
16 standing of these diseases, which affect 5 to 10 percent
17 of the people in the United States.

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

21 “**SEC. 317T. (a) GRANTS TO INCREASE AWARENESS**
22 **OF AUTOIMMUNE DISEASES.**—The Secretary, acting
23 through the Director of the Centers for Disease Control
24 and Prevention, shall award grants to eligible entities to
25 conduct public and professional awareness activities re-

1 garding autoimmune diseases, such as lupus, multiple scler-
2 rosis, rheumatoid arthritis, and fibromyalgia.

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

6 “(1) Promote increased awareness of early
7 intervention and treatment so as to significantly im-
8 prove the quality of life for people with autoimmune
9 diseases, such as lupus, multiple sclerosis, rheu-
10 matoid arthritis, and fibromyalgia.

11 “(2) Target minority communities that may be
12 underserved or disproportionately affected by auto-
13 immune diseases, such as lupus, multiple sclerosis,
14 rheumatoid arthritis, and fibromyalgia.

15 “(3) Target women (who are disproportionately
16 affected by autoimmune diseases, such as lupus,
17 multiple sclerosis, rheumatoid arthritis, and
18 fibromyalgia) so as to help reduce the amount of
19 time taken for correct diagnosis of such diseases,
20 which often takes more than 1 year.

21 “(c) ELIGIBLE ENTITY.—For purposes of this sec-
22 tion, the term ‘eligible entity’ means a nonprofit organiza-
23 tion, a consumer group, an institution of higher education
24 (as defined in section 101 of the Higher Education Act

1 of 1965), a Federal, State, or local governmental agency,
2 or a media organization.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
4 is authorized to be appropriated to carry out this section
5 \$18,000,000 for each of fiscal years 2007 and 2008.”.

6 **SEC. 4. GRANTS FOR EDUCATION ON RELATIONSHIP BE-**
7 **TWEEN AUTOIMMUNE DISEASES AND MEN-**
8 **TAL ILLNESSES.**

9 Title III of the Public Health Service Act (42 U.S.C.
10 241 et seq.), as amended by section 3, is amended by in-
11 serting after section 317T the following:

12 “SEC. 317U. (a) GRANTS FOR EDUCATION ON RELA-
13 TIONSHIP BETWEEN AUTOIMMUNE DISEASES AND MEN-
14 TAL ILLNESSES.—The Secretary, acting through the Ad-
15 ministrator of the Health Resources and Services Admin-
16 istration, shall award grants to eligible entities for the
17 education of health care providers on potential links be-
18 tween autoimmune diseases, such as lupus, multiple sele-
19 rosis, rheumatoid arthritis, and fibromyalgia, and cog-
20 nitive and mood disorders, such as depression.

21 “(b) ELIGIBLE ENTITY.—For purposes of this sec-
22 tion, the term ‘eligible entity’ means a nonprofit organiza-
23 tion, a consumer group, an institution of higher education
24 (as defined in section 101 of the Higher Education Act

1 of 1965), a Federal, State, or local governmental agency,
2 or a media organization.

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
4 is authorized to be appropriated to carry out this section
5 \$5,000,000 for each of fiscal years 2007 and 2008.”.

6 **SEC. 5. LOAN REPAYMENT PROGRAM REGARDING PHYSI-**
7 **CIAN RESEARCH ON AUTOIMMUNE DISEASES.**

8 Title IV of the Public Health Service Act (42 U.S.C.
9 281 et seq.) is amended—

10 (1) by redesignating the second section 487F as
11 section 487G; and

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

14 **“SEC. 487H. LOAN REPAYMENT PROGRAM REGARDING PHY-**
15 **SICIAN RESEARCH ON AUTOIMMUNE DIS-**
16 **EASES.**

17 “(a) ESTABLISHMENT.—To the extent and in the
18 amounts provided in advance in appropriations Acts, the
19 Secretary, acting through the Administrator of the Health
20 Resources and Services Administration, shall establish a
21 program to enter into contracts with qualified physicians
22 under which such qualified physicians agree to conduct re-
23 search for a period of at least 3 years regarding auto-
24 immune diseases, such as lupus, multiple sclerosis, rheu-
25 matoid arthritis, and fibromyalgia, in consideration of the

1 Federal Government agreeing to repay, for each year of
2 service conducting such research, not more than \$35,000
3 of the principal and interest of the educational loans of
4 such qualified physicians.

5 “(b) APPLICATION OF PROVISIONS.—Except as in-
6 consistent with this section, the provisions of sections
7 338B, 338C, and 338E shall apply to the program estab-
8 lished under this section to the same extent and in the
9 same manner as such provisions apply to the National
10 Health Service Corps Loan Repayment Program estab-
11 lished in subpart III of part D of title III.

12 “(c) QUALIFIED PHYSICIAN.—For purposes of this
13 section, the term ‘qualified physician’ means any indi-
14 vidual who has received, or will have received by the time
15 of the research to be conducted under this section, a de-
16 gree of doctor of medicine or its equivalent and is licensed
17 to practice medicine in the United States.

18 “(d) FUNDING.—

19 “(1) AUTHORIZATION OF APPROPRIATIONS.—
20 For the purpose of carrying out this section, there
21 are authorized to be appropriated such sums as may
22 be necessary for 2007 and each subsequent fiscal
23 year.

24 “(2) AVAILABILITY.—Amounts appropriated for
25 carrying out this section shall remain available until

1 the expiration of the second fiscal year beginning
2 after the fiscal year for which the amounts were
3 made available.”.

○