111TH CONGRESS
1ST SESSION

S. 571

To strengthen the Nation's research efforts to identify the causes and cure of psoriasis and psoriatic arthritis, expand psoriasis and psoriatic arthritis data collection, and study access to and quality of care for people with psoriasis and psoriatic arthritis, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 11, 2009

Mr. MENENDEZ (for himself, Mr. WYDEN, Mr. KERRY, Mr. CASEY, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To strengthen the Nation's research efforts to identify the causes and cure of psoriasis and psoriatic arthritis, expand psoriasis and psoriatic arthritis data collection, and study access to and quality of care for people with psoriasis and psoriatic arthritis, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Psoriasis and Psoriatic Arthritis Research, Cure, and Care Act of 2009''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS.

The Congress finds as follows:

(1) Psoriasis and psoriatic arthritis are autoimmune, chronic, inflammatory, painful, disfiguring, and life-altering diseases that require lifelong sophisticated medical intervention and care and have no cure.

(2) Psoriasis and psoriatic arthritis affect as many as 7,500,000 men, women, and children of all ages and have an adverse impact on the quality of life for virtually all affected.

(3) Psoriasis often is overlooked or dismissed because it does not cause death. Psoriasis is commonly and incorrectly considered by insurers, employers, policymakers, and the public as a mere annoyance, a superficial problem, mistakenly thought to be contagious and due to poor hygiene. Treatment for psoriasis often is categorized, wrongly, as ''lifestyle'' and not ''medically necessary.''

(4) Psoriasis goes hand-in-hand with myriad comorbidities such as Crohn's disease, diabetes, meta-

bolic syndrome, obesity, hypertension, heart attack, cardiovascular disease, liver disease, and psoriatic arthritis, which occurs in 10 to 30 percent of people with psoriasis.

(5) The National Institute of Mental Health funded a study that found that psoriasis may cause as much physical and mental disability as other major diseases, including cancer, arthritis, hypertension, heart disease, diabetes, and depression.

(6) Psoriasis is associated with elevated rates of depression and suicidal ideation.

(7) The risk of premature death is 50 percent higher for individuals with severe psoriasis than for individuals without any form of psoriasis.

(8) Total direct and indirect health care costs of psoriasis are calculated at over $11,250,000,000 annually with work loss accounting for 40 percent of the cost burden.

(9) Early diagnosis and treatment of psoriatic arthritis may help prevent irreversible joint damage.

(10) Treating psoriasis and psoriatic arthritis presents a challenge for patients and their health care providers because no one treatment works for everyone, some treatments lose effectiveness over time, many treatments are used in combination with

others, and all treatments may cause a unique set of side effects.

(11) Although new and more effective treatments finally are becoming available, too many people do not yet have access to the types of therapies that may make a significant difference in the quality of their lives.

(12) Psoriasis and psoriatic arthritis constitute a significant national health issue that deserves a comprehensive and coordinated response by Federal and State governments with involvement of the health care provider, patient, and public health communities.

SEC. 4. EXPANSION OF BIOMEDICAL RESEARCH.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this Act referred to as the ''Secretary''), acting through the Director of the National Institutes of Health, shall continue to expand and intensify research and related activities of the Institutes with respect to psoriasis and psoriatic arthritis.

(b) RESEARCH BY NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES.—

(1) IN GENERAL.—The directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Institute of Allergy

and Infectious Diseases shall continue to conduct and support research to expand understanding of the causes of, and to find a cure for, psoriasis and psoriatic arthritis, including the following:

(A) Basic research to discover the pathogenesis and pathophysiology of the disease.

(B) Expansion of molecular biology and immunology studies, including additional animal models.

(C) Global association mapping with single nucleotide polymorphisms.

(D) Identification of environmental triggers and autoantigens in psoriasis.

(E) Elucidation of specific immunologic cells and their products involved.

(F) Pharmacogenetic studies to understand the molecular basis for varying patient response to treatment.

(G) Identification of genetic markers of psoriatic arthritis susceptibility.

(H) Research to increase understanding of joint inflammation and destruction in psoriatic arthritis.

(I) Investigator-initiated clinical research for the development and evaluation of new treatments, including new biological agents.

(J) Research to develop enhanced diagnostic tests that allow for earlier diagnosis of psoriasis and improved outcomes.

(K) Research to increase understanding of the epidemiology and pathophysiology of comorbidities associated with psoriasis, including shared molecular pathways.

(2) COORDINATION WITH OTHER INSTITUTES.—In carrying out paragraph (1), the directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Institute of Allergy and Infectious Diseases shall coordinate the activities of such Institutes with the activities of other national research institutes and other agencies and offices of the National Institutes of Health relating to psoriasis or psoriatic arthritis.

SEC. 5. PSORIASIS AND PSORIATIC ARTHRITIS DATA COLLECTION AND NATIONAL PATIENT REGISTRY.

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with a national organization serving people with psoriasis and psoriatic arthritis, shall undertake psoriasis

and psoriatic arthritis data collection and develop a psoriasis and psoriatic arthritis patient registry.

SEC. 6. NATIONAL SUMMIT.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary is encouraged to convene a summit on the Federal Government's current and future efforts, and the initiatives necessary to fill any gaps, with respect to the conduct or support of psoriasis and psoriatic arthritis research, treatment, education, quality-of-life, and data collection activities. The summit should also address psoriasis and psoriatic arthritis related co-morbidities and should include researchers, public health professionals, representatives of voluntary health agencies and patient advocacy organizations, representatives of academic institutions, representatives from the pharmaceutical and medical research industry, and Federal and State policymakers, including representatives of the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health.

(b) FOCUS.—The summit convened under this section should focus on—

(1) a broad range of research activities relating to biomedical, epidemiological, psychosocial, and rehabilitative issues;

(2) clinical research for the development and evaluation of new treatments, including new biological agents;

(3) translational research;

(4) information and education programs for health care professionals and the public;

(5) priorities among the programs and activities of the various Federal agencies involved in psoriasis and psoriatic arthritis and related co-morbidities; and

(6) challenges, opportunities, and recommendations for scientists, clinicians, patients, and voluntary organizations.

(c) REPORT TO CONGRESS.—Not later than 180 days after the first day of the summit convened under this section, the Secretary shall submit to the Congress and make publicly available a report that includes a description of—

(1) the proceedings at the summit; and

(2) recommendations related to the research, treatment, education, and quality-of-life activities conducted or supported by the Federal Government with respect to psoriasis and psoriatic arthritis, in-

cluding psoriasis and psoriatic arthritis related co-morbidities.

SEC. 7. STUDY AND REPORT BY THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—The Secretary shall enter into an agreement with the Institute of Medicine to conduct a study on the following:

(1) The extent to which public and private insurers cover prescription medications and other treatments for psoriasis and psoriatic arthritis.

(2) The payment structures, such as deductibles and co-payments, and the amounts and duration of coverage under health plans and their adequacy to cover the costs of providing ongoing care to, and ensure access for, patients with psoriasis and psoriatic arthritis.

(3) Health plan and insurer coverage policies and practices, including lifetime caps, and their impact on the access of such patients to the best regimen and most appropriate care for their particular disease state.

(b) REPORT.—The agreement entered into under subsection (a) shall provide for the Institute of Medicine to submit to the Secretary and the Congress, not later

than 18 months after the date of the enactment of this Act, a report containing a description of—

(1) the results of the study conducted under this section; and

(2) the conclusions and recommendations of the Institutes of Medicine regarding each of the issues described in paragraphs (1) through (3) of subsection (a).

SEC. 8. AUTHORIZATION OF APPROPRIATIONS.

To carry out this Act, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

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