

One Hundred Tenth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Thursday,
the third day of January, two thousand and eight*

An Act

To amend the Public Health Service Act to provide for the establishment of an
Amyotrophic Lateral Sclerosis Registry.

*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 “ALS Registry Act”.

SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.

“(a) ESTABLISHMENT.—

“(1) IN GENERAL.—Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

“(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as ‘ALS’) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

“(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

“(2) PURPOSE.—It is the purpose of the registry established under paragraph (1)(B) to—

“(A) better describe the incidence and prevalence of ALS in the United States;

“(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

“(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

“(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

- “(E) other matters as recommended by the Advisory Committee established under subsection (b).
- “(b) ADVISORY COMMITTEE.—
- “(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ‘Advisory Committee’). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—
- “(A) two-thirds of such members shall represent governmental agencies—
- “(i) including at least one member representing—
- “(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;
- “(II) the Department of Veterans Affairs;
- “(III) the Agency for Toxic Substances and Disease Registry; and
- “(IV) the Centers for Disease Control and Prevention; and
- “(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and
- “(B) one-third of such members shall be public members, including at least one member representing—
- “(i) national and voluntary health associations;
- “(ii) patients with ALS or their family members;
- “(iii) clinicians with expertise on ALS and related diseases;
- “(iv) epidemiologists with experience in data registries;
- “(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases and
- “(vi) other individuals with an interest in developing and maintaining the National ALS Registry.
- “(2) DUTIES.—The Advisory Committee may review information and make recommendations to the Secretary concerning—
- “(A) the development and maintenance of the National ALS Registry;
- “(B) the type of information to be collected and stored in the Registry;
- “(C) the manner in which such data is to be collected;
- “(D) the use and availability of such data including guidelines for such use; and
- “(E) the collection of information about diseases and disorders that primarily affect motor neurons that are

considered essential to furthering the study and cure of ALS.

“(3) REPORT.—Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

“(c) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

“(d) COORDINATION WITH STATE, LOCAL, AND FEDERAL REGISTRIES.—

“(1) IN GENERAL.—In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

“(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

“(i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;

“(ii) the Department of Veterans Affairs ALS Registry;

“(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;

“(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

“(v) State-based ALS registries;

“(vi) the National Vital Statistics System; and

“(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

“(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

“(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National

Institutes of Health and the Department of Veterans Affairs.

“(e) DEFINITION.—For the purposes of this section, the term ‘national voluntary health association’ means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.”.

SEC. 3. REPORT ON REGISTRIES.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services may submit to the appropriate committees of Congress a report outlining—

- (1) the registries currently under way;
- (2) future planned registries;
- (3) the criteria involved in determining what registries to conduct, defer, or suspend; and
- (4) the scope of those registries.

The report may also include a description of the activities the Secretary undertakes to establish partnerships with research and patient advocacy communities to expand registries.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*