

STATE OF NEW YORK

6721

2019-2020 Regular Sessions

IN ASSEMBLY

March 15, 2019

Introduced by M. of A. PEOPLES-STOKES, THIELE -- Multi-Sponsored by --
M. of A. ENGLEBRIGHT -- read once and referred to the Committee on
Health

AN ACT to amend the public health law, in relation to creating the lupus
research enhancement program; and to amend the state finance law, in
relation to creating the lupus research enhancement fund

The People of the State of New York, represented in Senate and Assem-
bly, do enact as follows:

Section 1. Article 2 of the public health law is amended by adding a
new title 4-A to read as follows:

TITLE IV-A

LUPUS RESEARCH ENHANCEMENT ACT

Section 256. Short title.

256-a. Legislative intent.

256-b. Definition.

256-c. Lupus research enhancement program.

256-d. Lupus research advisory council.

256-e. Lupus research enhancement fund.

§ 256. Short title. This title shall be known and may be cited as the
"lupus research enhancement act".

§ 256-a. Legislative intent. 1. The legislature hereby finds the
following:

(a) Lupus is a serious, complex, debilitating autoimmune disease that
can cause inflammation and tissue damage to virtually any organ system
in the body, including the skin, joints, other connective tissue, blood
and blood vessels, heart, lungs, kidney, and brain.

(b) The Lupus Foundation of America, Inc. estimates that approximately
1.5 to two million Americans live with some form of lupus; lupus affects
women nine times more often than men and eighty percent of newly diag-
nosed cases of lupus develop among women of childbearing age.

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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(c) Lupus disproportionately affects women of color - it is two to three times more common among African-Americans, Hispanics, Asians and Native Americans and is generally more prevalent in minority populations - a health disparity that remains unexplained. According to the Centers for Disease Control and Prevention the rate of lupus mortality has increased since the late nineteen seventies and is higher among older African-American women.

(d) No new drugs have been approved by the U.S. Food and Drug Administration specifically for lupus in nearly forty years, and while current treatments for the disease can be effective, they can lead to damaging side effects.

(e) The pain and fatigue associated with lupus can threaten people's ability to live independently, make it difficult to maintain employment and lead normal lives, and one in five people with lupus is disabled by the disease, and consequently receives support from government programs, including medicare, medicaid, social security disability, and social security supplemental income.

(f) The estimated average annual cost of medical treatment for an individual with lupus can range between ten thousand dollars and thirty thousand dollars; for people who have the most serious form of lupus, medical costs can greatly exceed this amount, causing a significant economic, emotional and social burden to the entire family and society.

(g) More than half of the people with lupus suffer four or more years and visit three or more physicians before obtaining a diagnosis of lupus; early diagnosis of and commencement of treatment for lupus can prevent or reduce serious organ damage, disability, and death.

(h) Despite the magnitude of lupus and its impact on individuals and families, health professional and public understanding of lupus remains low; only one of five Americans can provide even basic information about lupus, and awareness of lupus is lowest among adults ages eighteen to thirty-four - the age group most likely to develop symptoms of lupus.

(i) Lupus is a significant national health issue that deserves a comprehensive and coordinated response by state and federal governments with involvement of the health care provider, patient, and public health communities.

2. The purposes of this title are:

(a) To promote basic and clinical research programs designed to reduce or prevent suffering from lupus, by providing additional funding to state academic medical institutions within the state currently conducting or having an interest in conducting basic and clinical, social, translational, technological, epidemiological, and behavioral research on lupus. Such activities may include:

- (i) investigating the pathogenesis and physiology of lupus;
- (ii) identifying and validating lupus biomarkers;
- (iii) enhancing the statewide infrastructure to conduct clinical trials of potential new lupus therapies;
- (iv) developing or improving diagnostic tests for early detection of lupus; and

(v) developing novel therapies to treat lupus.

(b) To establish a multidisciplinary lupus research advisory council to monitor progress and make granting recommendations to the department.

§ 256-b. Definition. As used in this title, "program" shall mean the lupus research enhancement program created pursuant to section two hundred fifty-six-c of this title.

§ 256-c. Lupus research enhancement program. 1. The commissioner shall establish within the department a lupus research enhancement program

1 through which the department shall make grants to state academic medical
2 institutions within the state currently conducting or having an interest
3 in conducting basic and clinical, social, translational, technological,
4 epidemiological, and behavioral research on lupus.

5 2. All research funds shall be awarded on the basis of the research
6 priorities established for the program and the scientific merit of the
7 proposed research, as determined by an open, competitive peer review
8 process that ensures objectivity, consistency, and high quality. All
9 investigators, regardless of affiliation, shall have equal access and
10 opportunity to compete for program funds.

11 3. The peer review process for the selection of research grants
12 awarded under this program shall be modeled generally on that used by
13 the national institutes of health in its grant making process.

14 4. An awardee shall be awarded grants for the full cost, both direct
15 and indirect, of conducting the sponsored research consistent with those
16 federal guidelines governing all federal research grants and contracts.
17 All intellectual property assets developed under this program shall be
18 treated in accordance with state and federal law.

19 5. In establishing its research priorities, the state shall consult
20 with the lupus research advisory council and consider a broad range of
21 cross-disciplinary lupus research, including, but not limited to,
22 research into the cause, cure, and diagnosis of lupus; translational and
23 technological research, including research to develop improved diagnos-
24 tic tests; research regarding the cultural, economic, and legal barriers
25 to accessing the health care system for early detection and treatment of
26 lupus; and research examining the health disparities seen in the inci-
27 dence and prevalence of lupus.

28 § 256-d. Lupus research advisory council. 1. Operations. (a) The coun-
29 cil shall be comprised of fifteen members representing a broad range of
30 expertise and experience.

31 (b) Individuals and organizations may submit nominations to the
32 commissioner through the council.

33 (c) Each appointed council member should have familiarity with lupus
34 and issues that surround lupus and be one of the following: health and
35 medical professional with expertise in lupus; an individual with lupus;
36 a representative from a local or county health department; or a recog-
37 nized expert in the provision of health services to women, lupus
38 research or health disparities.

39 (d) The council shall be comprised as follows:

40 (i) at least three individuals with lupus;

41 (ii) no more than two representatives from the department;

42 (iii) at least five individuals from lupus nonprofit health organiza-
43 tions; and

44 (iv) at least five scientists or clinicians with experience in lupus
45 and who participate in various fields of scientific endeavor, including,
46 but not limited to, the fields of biomedical research, social, transla-
47 tional, behavioral and epidemiological research, and public health.

48 (e) All members of the council shall be appointed by the commissioner
49 and the commissioner shall choose from among the fifteen council members
50 one member to serve as chair.

51 (f) All members of the council shall serve terms of two years each.
52 Members can be named to serve a total of two terms and terms can be
53 consecutive.

54 (g) Members shall serve without compensation, but shall be entitled to
55 actual, necessary expenses incurred in the performance of their business
56 as members of the council.

1 (h) A majority of the members of the council shall constitute a
2 quorum. A majority vote of a quorum shall be required for any official
3 action of the council.

4 (i) The council shall meet at the call of the chair, but not less than
5 four times per year.

6 2. Functions. The lupus research advisory council shall:

7 (a) review submitted grant applications and make recommendations to
8 the commissioner, and the commissioner shall, at his or her discretion,
9 grant approval of applications for grants from those applications recom-
10 mended by the council (if a council member submits an application for a
11 grant from the lupus research and education fund, he or she will be
12 prohibited from reviewing and making a recommendation on the applica-
13 tion);

14 (b) consult with the national institutes of health, centers for
15 disease control and prevention, the agency for healthcare research and
16 quality, the national academy of sciences (institute of medicine), lupus
17 advocacy groups, and other organizations or entities which may be
18 involved in lupus research to solicit both information regarding lupus
19 research projects that are currently being conducted and recommendations
20 for future research projects; and

21 (c) shall transmit annually on or before December thirty-first, a
22 report to the legislature on grants made, grants in progress, program
23 accomplishments, and future program directions. Each report shall
24 include, but not be limited to, the following information:

25 (i) the number and dollar amounts of research grants, including the
26 amount allocated to indirect costs;

27 (ii) the subject of research grants;

28 (iii) the relationship between federal and state funding for lupus
29 research;

30 (iv) the relationship between each project and the overall strategy of
31 the research program;

32 (v) a summary of research findings including discussion of promising
33 new areas;

34 (vi) the institutions and campuses receiving grant awards; and

35 (vii) the first annual report shall include an evaluation and recom-
36 mendations concerning the desirability and feasibility of requiring
37 for-profit grantees to compensate the state in the event that a grant
38 results in the development of a profit-making product. This evaluation
39 shall include, but not be limited to, the costs and benefits of requir-
40 ing a for-profit grantee to repay the grant, to provide the product at
41 cost to state programs serving low-income lupus patients, and to pay the
42 state a percentage of the royalties derived from the product.

43 3. Contributions. The secretary of the lupus research advisory council
44 may accept grants, services, and property from the federal government,
45 foundations, organizations, medical schools, and other entities as may
46 be available for the purposes of fulfilling the obligations of this
47 program. Any such funds shall supplement and not supplant appropriations
48 provided for the implementation of this article.

49 4. Waivers. The secretary of the lupus research advisory council shall
50 seek any federal waiver or waivers that may be necessary to maximize
51 funds from the federal government to implement this program.

52 § 256-e. Lupus research enhancement fund. All moneys received pursuant
53 to section two hundred fifty-six-c of this title shall be credited to
54 the fund, as established by section ninety-five-j of the state finance
55 law. The commissioner shall use the fund to administer the lupus

1 research enhancement program and to make grants to awardees pursuant to
2 section two hundred fifty-six-c of this title.

3 § 2. The state finance law is amended by adding a new section 95-j to
4 read as follows:

5 § 95-j. Lupus research enhancement fund. 1. There is hereby estab-
6 lished in the joint custody of the commissioner of taxation and finance
7 and the comptroller, a special fund to be known as the "lupus research
8 enhancement fund".

9 2. Such fund shall consist of all monies appropriated for the purpose
10 of such fund and any grant, gift or bequest made to the lupus research
11 enhancement program as established by title four-A of article two of the
12 public health law.

13 3. Moneys of the fund shall be available for grants through the lupus
14 research enhancement program advisory council and for the expenses of
15 the lupus research enhancement program advisory council, and shall be
16 expended only for the purposes spelled out in sections two hundred
17 fifty-six-c and two hundred fifty-six-d of the public health law.

18 4. Moneys in the lupus research enhancement fund shall be kept sepa-
19 rate and shall not be commingled with any other moneys in the custody of
20 the commissioner of taxation and finance and the comptroller.

21 5. The moneys of the fund shall be paid out on the audit and warrant
22 of the comptroller on vouchers certified or approved by the commissioner
23 of health, or by an officer or employee of the department of health
24 designated by such commissioner.

25 § 3. This act shall take effect immediately.