

1 WOMEN NINE TIMES MORE OFTEN THAN MEN AND EIGHTY PERCENT OF NEWLY DIAG-
2 NOSED CASES OF LUPUS DEVELOP AMONG WOMEN OF CHILDBEARING AGE.

3 (C) LUPUS DISPROPORTIONATELY AFFECTS WOMEN OF COLOR - IT IS TWO TO
4 THREE TIMES MORE COMMON AMONG AFRICAN-AMERICANS, HISPANICS, ASIANS AND
5 NATIVE AMERICANS AND IS GENERALLY MORE PREVALENT IN MINORITY POPULATIONS
6 - A HEALTH DISPARITY THAT REMAINS UNEXPLAINED. ACCORDING TO THE CENTERS
7 FOR DISEASE CONTROL AND PREVENTION THE RATE OF LUPUS MORTALITY HAS
8 INCREASED SINCE THE LATE NINETEEN SEVENTIES AND IS HIGHER AMONG OLDER
9 AFRICAN-AMERICAN WOMEN.

10 (D) NO NEW DRUGS HAVE BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINIS-
11 TRATION SPECIFICALLY FOR LUPUS IN NEARLY FORTY YEARS, AND WHILE CURRENT
12 TREATMENTS FOR THE DISEASE CAN BE EFFECTIVE, THEY CAN LEAD TO DAMAGING
13 SIDE EFFECTS.

14 (E) THE PAIN AND FATIGUE ASSOCIATED WITH LUPUS CAN THREATEN PEOPLE'S
15 ABILITY TO LIVE INDEPENDENTLY, MAKE IT DIFFICULT TO MAINTAIN EMPLOYMENT
16 AND LEAD NORMAL LIVES, AND ONE IN FIVE PEOPLE WITH LUPUS IS DISABLED BY
17 THE DISEASE, AND CONSEQUENTLY RECEIVES SUPPORT FROM GOVERNMENT PROGRAMS,
18 INCLUDING MEDICARE, MEDICAID, SOCIAL SECURITY DISABILITY, AND SOCIAL
19 SECURITY SUPPLEMENTAL INCOME.

20 (F) THE ESTIMATED AVERAGE ANNUAL COST OF MEDICAL TREATMENT FOR AN
21 INDIVIDUAL WITH LUPUS CAN RANGE BETWEEN TEN THOUSAND DOLLARS AND THIRTY
22 THOUSAND DOLLARS; FOR PEOPLE WHO HAVE THE MOST SERIOUS FORM OF LUPUS,
23 MEDICAL COSTS CAN GREATLY EXCEED THIS AMOUNT, CAUSING A SIGNIFICANT
24 ECONOMIC, EMOTIONAL AND SOCIAL BURDEN TO THE ENTIRE FAMILY AND SOCIETY.

25 (G) MORE THAN HALF OF THE PEOPLE WITH LUPUS SUFFER FOUR OR MORE YEARS
26 AND VISIT THREE OR MORE PHYSICIANS BEFORE OBTAINING A DIAGNOSIS OF
27 LUPUS; EARLY DIAGNOSIS OF AND COMMENCEMENT OF TREATMENT FOR LUPUS CAN
28 PREVENT OR REDUCE SERIOUS ORGAN DAMAGE, DISABILITY, AND DEATH.

29 (H) DESPITE THE MAGNITUDE OF LUPUS AND ITS IMPACT ON INDIVIDUALS AND
30 FAMILIES, HEALTH PROFESSIONAL AND PUBLIC UNDERSTANDING OF LUPUS REMAINS
31 LOW; ONLY ONE OF FIVE AMERICANS CAN PROVIDE EVEN BASIC INFORMATION ABOUT
32 LUPUS, AND AWARENESS OF LUPUS IS LOWEST AMONG ADULTS AGES EIGHTEEN TO
33 THIRTY-FOUR - THE AGE GROUP MOST LIKELY TO DEVELOP SYMPTOMS OF LUPUS.

34 (I) LUPUS IS A SIGNIFICANT NATIONAL HEALTH ISSUE THAT DESERVES A
35 COMPREHENSIVE AND COORDINATED RESPONSE BY STATE AND FEDERAL GOVERNMENTS
36 WITH INVOLVEMENT OF THE HEALTH CARE PROVIDER, PATIENT, AND PUBLIC HEALTH
37 COMMUNITIES.

38 2. THE PURPOSES OF THIS TITLE ARE:

39 (A) TO PROMOTE BASIC AND CLINICAL RESEARCH PROGRAMS DESIGNED TO REDUCE
40 OR PREVENT SUFFERING FROM LUPUS, BY PROVIDING ADDITIONAL FUNDING TO
41 STATE ACADEMIC MEDICAL INSTITUTIONS WITHIN THE STATE CURRENTLY CONDUCT-
42 ING OR HAVING AN INTEREST IN CONDUCTING BASIC AND CLINICAL, SOCIAL,
43 TRANSLATIONAL, TECHNOLOGICAL, EPIDEMIOLOGICAL, AND BEHAVIORAL RESEARCH
44 ON LUPUS. SUCH ACTIVITIES MAY INCLUDE:

- 45 (I) INVESTIGATING THE PATHOGENESIS AND PHYSIOLOGY OF LUPUS;
- 46 (II) IDENTIFYING AND VALIDATING LUPUS BIOMARKERS;
- 47 (III) ENHANCING THE STATEWIDE INFRASTRUCTURE TO CONDUCT CLINICAL
48 TRIALS OF POTENTIAL NEW LUPUS THERAPIES;
- 49 (IV) DEVELOPING OR IMPROVING DIAGNOSTIC TESTS FOR EARLY DETECTION OF
50 LUPUS; AND
- 51 (V) DEVELOPING NOVEL THERAPIES TO TREAT LUPUS.

52 (B) TO ESTABLISH A MULTIDISCIPLINARY LUPUS RESEARCH ADVISORY COUNCIL
53 TO MONITOR PROGRESS AND MAKE GRANTING RECOMMENDATIONS TO THE DEPARTMENT.

54 S 256-B. DEFINITION. AS USED IN THIS TITLE, "PROGRAM" SHALL MEAN THE
55 LUPUS RESEARCH ENHANCEMENT PROGRAM CREATED PURSUANT TO SECTION TWO
56 HUNDRED FIFTY-SIX-C OF THIS TITLE.

1 S 256-C. LUPUS RESEARCH ENHANCEMENT PROGRAM. 1. THE COMMISSIONER SHALL
2 ESTABLISH WITHIN THE DEPARTMENT A LUPUS RESEARCH ENHANCEMENT PROGRAM
3 THROUGH WHICH THE DEPARTMENT SHALL MAKE GRANTS TO STATE ACADEMIC MEDICAL
4 INSTITUTIONS WITHIN THE STATE CURRENTLY CONDUCTING OR HAVING AN INTEREST
5 IN CONDUCTING BASIC AND CLINICAL, SOCIAL, TRANSLATIONAL, TECHNOLOGICAL,
6 EPIDEMIOLOGICAL, AND BEHAVIORAL RESEARCH ON LUPUS.

7 2. ALL RESEARCH FUNDS SHALL BE AWARDED ON THE BASIS OF THE RESEARCH
8 PRIORITIES ESTABLISHED FOR THE PROGRAM AND THE SCIENTIFIC MERIT OF THE
9 PROPOSED RESEARCH, AS DETERMINED BY AN OPEN, COMPETITIVE PEER REVIEW
10 PROCESS THAT ENSURES OBJECTIVITY, CONSISTENCY, AND HIGH QUALITY. ALL
11 INVESTIGATORS, REGARDLESS OF AFFILIATION, SHALL HAVE EQUAL ACCESS AND
12 OPPORTUNITY TO COMPETE FOR PROGRAM FUNDS.

13 3. THE PEER REVIEW PROCESS FOR THE SELECTION OF RESEARCH GRANTS
14 AWARDED UNDER THIS PROGRAM SHALL BE MODELED GENERALLY ON THAT USED BY
15 THE NATIONAL INSTITUTES OF HEALTH IN ITS GRANT MAKING PROCESS.

16 4. AN AWARDEE SHALL BE AWARDED GRANTS FOR THE FULL COST, BOTH DIRECT
17 AND INDIRECT, OF CONDUCTING THE SPONSORED RESEARCH CONSISTENT WITH THOSE
18 FEDERAL GUIDELINES GOVERNING ALL FEDERAL RESEARCH GRANTS AND CONTRACTS.
19 ALL INTELLECTUAL PROPERTY ASSETS DEVELOPED UNDER THIS PROGRAM SHALL BE
20 TREATED IN ACCORDANCE WITH STATE AND FEDERAL LAW.

21 5. IN ESTABLISHING ITS RESEARCH PRIORITIES, THE STATE SHALL CONSULT
22 WITH THE LUPUS RESEARCH ADVISORY COUNCIL AND CONSIDER A BROAD RANGE OF
23 CROSS-DISCIPLINARY LUPUS RESEARCH, INCLUDING, BUT NOT LIMITED TO,
24 RESEARCH INTO THE CAUSE, CURE, AND DIAGNOSIS OF LUPUS; TRANSLATIONAL AND
25 TECHNOLOGICAL RESEARCH, INCLUDING RESEARCH TO DEVELOP IMPROVED DIAGNOS-
26 TIC TESTS; RESEARCH REGARDING THE CULTURAL, ECONOMIC, AND LEGAL BARRIERS
27 TO ACCESSING THE HEALTH CARE SYSTEM FOR EARLY DETECTION AND TREATMENT OF
28 LUPUS; AND RESEARCH EXAMINING THE HEALTH DISPARITIES SEEN IN THE INCI-
29 DENCE AND PREVALENCE OF LUPUS.

30 S 256-D. LUPUS RESEARCH ADVISORY COUNCIL. 1. OPERATIONS. (A) THE COUN-
31 CIL SHALL BE COMPRISED OF FIFTEEN MEMBERS REPRESENTING A BROAD RANGE OF
32 EXPERTISE AND EXPERIENCE.

33 (B) INDIVIDUALS AND ORGANIZATIONS MAY SUBMIT NOMINATIONS TO THE
34 COMMISSIONER THROUGH THE COUNCIL.

35 (C) EACH APPOINTED COUNCIL MEMBER SHOULD HAVE FAMILIARITY WITH LUPUS
36 AND ISSUES THAT SURROUND LUPUS AND BE ONE OF THE FOLLOWING: HEALTH AND
37 MEDICAL PROFESSIONAL WITH EXPERTISE IN LUPUS; AN INDIVIDUAL WITH LUPUS;
38 A REPRESENTATIVE FROM A LOCAL OR COUNTY HEALTH DEPARTMENT; OR A RECOG-
39 NIZED EXPERT IN THE PROVISION OF HEALTH SERVICES TO WOMEN, LUPUS
40 RESEARCH OR HEALTH DISPARITIES.

41 (D) THE COUNCIL SHALL BE COMPRISED AS FOLLOWS:

42 (I) AT LEAST THREE INDIVIDUALS WITH LUPUS;

43 (II) NO MORE THAN TWO REPRESENTATIVES FROM THE DEPARTMENT;

44 (III) AT LEAST FIVE INDIVIDUALS FROM LUPUS NONPROFIT HEALTH ORGANIZA-
45 TIONS; AND

46 (IV) AT LEAST FIVE SCIENTISTS OR CLINICIANS WITH EXPERIENCE IN LUPUS
47 AND WHO PARTICIPATE IN VARIOUS FIELDS OF SCIENTIFIC ENDEAVOR, INCLUDING,
48 BUT NOT LIMITED TO, THE FIELDS OF BIOMEDICAL RESEARCH, SOCIAL, TRANSLA-
49 TIONAL, BEHAVIORAL AND EPIDEMIOLOGICAL RESEARCH, AND PUBLIC HEALTH.

50 (E) ALL MEMBERS OF THE COUNCIL SHALL BE APPOINTED BY THE COMMISSIONER
51 AND THE COMMISSIONER SHALL CHOOSE FROM AMONG THE FIFTEEN COUNCIL MEMBERS
52 ONE MEMBER TO SERVE AS CHAIR.

53 (F) ALL MEMBERS OF THE COUNCIL SHALL SERVE TERMS OF TWO YEARS EACH.
54 MEMBERS CAN BE NAMED TO SERVE A TOTAL OF TWO TERMS AND TERMS CAN BE
55 CONSECUTIVE.

(G) MEMBERS SHALL SERVE WITHOUT COMPENSATION, BUT SHALL BE ENTITLED TO ACTUAL, NECESSARY EXPENSES INCURRED IN THE PERFORMANCE OF THEIR BUSINESS AS MEMBERS OF THE COUNCIL.

(H) A MAJORITY OF THE MEMBERS OF THE COUNCIL SHALL CONSTITUTE A QUORUM. A MAJORITY VOTE OF A QUORUM SHALL BE REQUIRED FOR ANY OFFICIAL ACTION OF THE COUNCIL.

(I) THE COUNCIL SHALL MEET AT THE CALL OF THE CHAIR, BUT NOT LESS THAN FOUR TIMES PER YEAR.

2. FUNCTIONS. THE LUPUS RESEARCH ADVISORY COUNCIL SHALL:

(A) REVIEW SUBMITTED GRANT APPLICATIONS AND MAKE RECOMMENDATIONS TO THE COMMISSIONER, AND THE COMMISSIONER SHALL, AT HIS OR HER DISCRETION, GRANT APPROVAL OF APPLICATIONS FOR GRANTS FROM THOSE APPLICATIONS RECOMMENDED BY THE COUNCIL (IF A COUNCIL MEMBER SUBMITS AN APPLICATION FOR A GRANT FROM THE LUPUS RESEARCH AND EDUCATION FUND, HE OR SHE WILL BE PROHIBITED FROM REVIEWING AND MAKING A RECOMMENDATION ON THE APPLICATION);

(B) CONSULT WITH THE NATIONAL INSTITUTES OF HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, THE NATIONAL ACADEMY OF SCIENCES (INSTITUTE OF MEDICINE), LUPUS ADVOCACY GROUPS, AND OTHER ORGANIZATIONS OR ENTITIES WHICH MAY BE INVOLVED IN LUPUS RESEARCH TO SOLICIT BOTH INFORMATION REGARDING LUPUS RESEARCH PROJECTS THAT ARE CURRENTLY BEING CONDUCTED AND RECOMMENDATIONS FOR FUTURE RESEARCH PROJECTS; AND

(C) SHALL TRANSMIT ANNUALLY ON OR BEFORE DECEMBER THIRTY-FIRST, A REPORT TO THE LEGISLATURE ON GRANTS MADE, GRANTS IN PROGRESS, PROGRAM ACCOMPLISHMENTS, AND FUTURE PROGRAM DIRECTIONS. EACH REPORT SHALL INCLUDE, BUT NOT BE LIMITED TO, THE FOLLOWING INFORMATION:

(I) THE NUMBER AND DOLLAR AMOUNTS OF RESEARCH GRANTS, INCLUDING THE AMOUNT ALLOCATED TO INDIRECT COSTS;

(II) THE SUBJECT OF RESEARCH GRANTS;

(III) THE RELATIONSHIP BETWEEN FEDERAL AND STATE FUNDING FOR LUPUS RESEARCH;

(IV) THE RELATIONSHIP BETWEEN EACH PROJECT AND THE OVERALL STRATEGY OF THE RESEARCH PROGRAM;

(V) A SUMMARY OF RESEARCH FINDINGS INCLUDING DISCUSSION OF PROMISING NEW AREAS;

(VI) THE INSTITUTIONS AND CAMPUSES RECEIVING GRANT AWARDS; AND

(VII) THE FIRST ANNUAL REPORT SHALL INCLUDE AN EVALUATION AND RECOMMENDATIONS CONCERNING THE DESIRABILITY AND FEASIBILITY OF REQUIRING FOR-PROFIT GRANTEEES TO COMPENSATE THE STATE IN THE EVENT THAT A GRANT RESULTS IN THE DEVELOPMENT OF A PROFIT-MAKING PRODUCT. THIS EVALUATION SHALL INCLUDE, BUT NOT BE LIMITED TO, THE COSTS AND BENEFITS OF REQUIRING A FOR-PROFIT GRANTEE TO REPAY THE GRANT, TO PROVIDE THE PRODUCT AT COST TO STATE PROGRAMS SERVING LOW-INCOME LUPUS PATIENTS, AND TO PAY THE STATE A PERCENTAGE OF THE ROYALTIES DERIVED FROM THE PRODUCT.

3. CONTRIBUTIONS. THE SECRETARY OF THE LUPUS RESEARCH ADVISORY COUNCIL MAY ACCEPT GRANTS, SERVICES, AND PROPERTY FROM THE FEDERAL GOVERNMENT, FOUNDATIONS, ORGANIZATIONS, MEDICAL SCHOOLS, AND OTHER ENTITIES AS MAY BE AVAILABLE FOR THE PURPOSES OF FULFILLING THE OBLIGATIONS OF THIS PROGRAM. ANY SUCH FUNDS SHALL SUPPLEMENT AND NOT SUPPLANT APPROPRIATIONS PROVIDED FOR THE IMPLEMENTATION OF THIS ARTICLE.

4. WAIVERS. THE SECRETARY OF THE LUPUS RESEARCH ADVISORY COUNCIL SHALL SEEK ANY FEDERAL WAIVER OR WAIVERS THAT MAY BE NECESSARY TO MAXIMIZE FUNDS FROM THE FEDERAL GOVERNMENT TO IMPLEMENT THIS PROGRAM.

S 256-E. LUPUS RESEARCH ENHANCEMENT FUND. ALL MONEYS RECEIVED PURSUANT TO SECTION TWO HUNDRED FIFTY-SIX-C OF THIS TITLE SHALL BE CREDITED TO

1 THE FUND, AS ESTABLISHED BY SECTION NINETY-FIVE-H OF THE STATE FINANCE
2 LAW. THE COMMISSIONER SHALL USE THE FUND TO ADMINISTER THE LUPUS
3 RESEARCH ENHANCEMENT PROGRAM AND TO MAKE GRANTS TO AWARDEES PURSUANT TO
4 SECTION TWO HUNDRED FIFTY-SIX-C OF THIS TITLE.

5 S 2. The state finance law is amended by adding a new section 95-h to
6 read as follows:

7 S 95-H. LUPUS RESEARCH ENHANCEMENT FUND. 1. THERE IS HEREBY ESTAB-
8 LISHED IN THE JOINT CUSTODY OF THE COMMISSIONER OF TAXATION AND FINANCE
9 AND THE COMPTROLLER, A SPECIAL FUND TO BE KNOWN AS THE "LUPUS RESEARCH
10 ENHANCEMENT FUND".

11 2. SUCH FUND SHALL CONSIST OF ALL MONIES APPROPRIATED FOR THE PURPOSE
12 OF SUCH FUND AND ANY GRANT, GIFT OR BEQUEST MADE TO THE LUPUS RESEARCH
13 ENHANCEMENT PROGRAM AS ESTABLISHED BY TITLE FOUR-A OF ARTICLE TWO OF THE
14 PUBLIC HEALTH LAW.

15 3. MONEYS OF THE FUND SHALL BE AVAILABLE FOR GRANTS THROUGH THE LUPUS
16 RESEARCH ENHANCEMENT PROGRAM ADVISORY COUNCIL AND FOR THE EXPENSES OF
17 THE LUPUS RESEARCH ENHANCEMENT PROGRAM ADVISORY COUNCIL, AND SHALL BE
18 EXPENDED ONLY FOR THE PURPOSES SPELLED OUT IN SECTIONS TWO HUNDRED
19 FIFTY-SIX-C AND TWO HUNDRED FIFTY-SIX-D OF THE PUBLIC HEALTH LAW.

20 4. MONEYS IN THE LUPUS RESEARCH ENHANCEMENT FUND SHALL BE KEPT SEPA-
21 RATE AND SHALL NOT BE COMMINGLED WITH ANY OTHER MONEYS IN THE CUSTODY OF
22 THE COMMISSIONER OF TAXATION AND FINANCE AND THE COMPTROLLER.

23 5. THE MONEYS OF THE FUND SHALL BE PAID OUT ON THE AUDIT AND WARRANT
24 OF THE COMPTROLLER ON VOUCHERS CERTIFIED OR APPROVED BY THE COMMISSIONER
25 OF HEALTH, OR BY AN OFFICER OR EMPLOYEE OF THE DEPARTMENT OF HEALTH
26 DESIGNATED BY SUCH COMMISSIONER.

27 S 3. The sum of two hundred fifty thousand dollars (\$250,000.00), or
28 so much thereof as may be necessary, is hereby appropriated to the
29 department of health out of any moneys in the state treasury in the
30 general fund to the credit of the state purposes account, not otherwise
31 appropriated, and made immediately available, for the purpose of carry-
32 ing out the provisions of this act. Such moneys shall be payable on the
33 audit and warrant of the comptroller on vouchers certified or approved
34 by the commissioner of health in the manner prescribed by law.

35 S 4. This act shall take effect immediately.