S T A T E O F N E W Y O R K

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I N S E N A T E

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Introduced by Sens. SAVINO, ADDABBO, AVELLA, CROCI, GOLDEN, KENNEDY, LATIMER, PERALTA, PERKINS, STAVISKY, VENDITTO -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- reported favorably from said committee and committed to the Committee on Finance -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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 ASSEMBLY, 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.

S 256. SHORT TITLE. THIS TITLE SHALL BE KNOWN AND MAY BE CITED AS THE "LUPUS RESEARCH ENHANCEMENT ACT".

S 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

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

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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 DIAGNOSED CASES OF LUPUS DEVELOP AMONG WOMEN OF CHILDBEARING AGE.

(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.

S 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.

S 256-C. LUPUS RESEARCH ENHANCEMENT PROGRAM. 1. THE COMMISSIONER SHALL ESTABLISH WITHIN THE DEPARTMENT A LUPUS RESEARCH ENHANCEMENT PROGRAM THROUGH WHICH THE DEPARTMENT SHALL MAKE GRANTS 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.

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

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

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

5. IN ESTABLISHING ITS RESEARCH PRIORITIES, THE STATE SHALL CONSULT WITH THE LUPUS RESEARCH ADVISORY COUNCIL AND CONSIDER A BROAD RANGE OF CROSS-DISCIPLINARY LUPUS RESEARCH, INCLUDING, BUT NOT LIMITED TO, RESEARCH INTO THE CAUSE, CURE, AND DIAGNOSIS OF LUPUS; TRANSLATIONAL AND TECHNOLOGICAL RESEARCH, INCLUDING RESEARCH TO DEVELOP IMPROVED DIAGNOSTIC TESTS; RESEARCH REGARDING THE CULTURAL, ECONOMIC, AND LEGAL BARRIERS TO ACCESSING THE HEALTH CARE SYSTEM FOR EARLY DETECTION AND TREATMENT OF LUPUS; AND RESEARCH EXAMINING THE HEALTH DISPARITIES SEEN IN THE INCIDENCE AND PREVALENCE OF LUPUS.

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

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

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

(D) THE COUNCIL SHALL BE COMPRISED AS FOLLOWS:

(I) AT LEAST THREE INDIVIDUALS WITH LUPUS;

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

(III) AT LEAST FIVE INDIVIDUALS FROM LUPUS NONPROFIT HEALTH ORGANIZATIONS; AND

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

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

(F) ALL MEMBERS OF THE COUNCIL SHALL SERVE TERMS OF TWO YEARS EACH. MEMBERS CAN BE NAMED TO SERVE A TOTAL OF TWO TERMS AND TERMS CAN BE 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 GRANTEES 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 THE FUND, AS ESTABLISHED BY SECTION NINETY-FIVE-I OF THE STATE FINANCE LAW. THE COMMISSIONER SHALL USE THE FUND TO ADMINISTER THE LUPUS RESEARCH ENHANCEMENT PROGRAM AND TO MAKE GRANTS TO AWARDEES PURSUANT TO SECTION TWO HUNDRED FIFTY-SIX-C OF THIS TITLE.

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

S 95-I. LUPUS RESEARCH ENHANCEMENT FUND. 1. THERE IS HEREBY ESTABLISHED IN THE JOINT CUSTODY OF THE COMMISSIONER OF TAXATION AND FINANCE AND THE COMPTROLLER, A SPECIAL FUND TO BE KNOWN AS THE "LUPUS RESEARCH ENHANCEMENT FUND".

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

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

4. MONEYS IN THE LUPUS RESEARCH ENHANCEMENT FUND SHALL BE KEPT SEPARATE AND SHALL NOT BE COMMINGLED WITH ANY OTHER MONEYS IN THE CUSTODY OF THE COMMISSIONER OF TAXATION AND FINANCE AND THE COMPTROLLER.

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

S 3. This act shall take effect immediately.