

LUPUS FOUNDATION OF AMERICA, INC

**TESTIMONY PRESENTED TO THE
HOUSE LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION AND RELATED AGENCIES APPROPRIATIONS
SUBCOMMITTEE**

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**FY 2007 FUNDING PRIORITIES FOR LUPUS RESEARCH TO
REDUCE AND TREAT
SUFFERING FROM LUPUS**

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Summary of Testimony:

The Lupus Foundation of America will present testimony on the value and importance of the National Institutes of Health (NIH) in conducting much needed research to find better treatments and a cure for lupus, an often debilitating autoimmune disease that can strike any part of the body. Testimony will also highlight the need for the Labor, Health and Human Services, and Education bill to include funding for a lupus awareness campaign at the HHS Office of Women's to educate the general public and health care professionals about lupus symptoms and treatments with an emphasis on reaching those people at highest risk for lupus – young women of color. Furthermore, the Committee will be informed of the need for a comprehensive lupus epidemiological study to be accomplished through continuation and expansion of the National Lupus Patient Registry (NLPR) at the Centers for Disease Control and Prevention (CDC).

Good morning Chairman Regula, Ranking Member Obey, and Members of the House Labor, Health and Human Services and Education Appropriations Subcommittee. Thank you for inviting the Lupus Foundation of America to testify at this important hearing. I am Sandra C. Raymond, the President and CEO of the Foundation. LFA is the nation's leading non-profit voluntary health organization dedicated to improving the diagnosis and treatment of lupus, supporting individuals and families affected by the disease, increasing awareness of lupus among health professionals and the public, and finding the causes and cure. As you may know, lupus is a debilitating, chronic autoimmune disease that causes inflammation and tissue damage to virtually any organ system; it can cause significant disability or even death. Lupus is the prototypical autoimmune disease; therefore, finding answers to questions about lupus may also provide understanding about other autoimmune diseases that affect 22 million Americans. On behalf of the leaders and members of LFA and people suffering from lupus, I respectfully request the following for FY 2007 to reduce and treat suffering from lupus:

- **\$29.7 billion for the National Institutes of Health (NIH) to support lupus research.** Specifically, we urge Congress to direct NIH to support and bolster lupus research across all relevant institutes, centers, and offices.
- **\$1 million in new funding for The Office of Women's' Health at the Department of Health and Human Services (HHS) to support a sustained national lupus education campaign.** This campaign is directed towards the general public and healthcare professionals who diagnose and treat people with lupus, with emphasis on reaching those individuals at highest risk – women of color – a health disparity that remains unexplained.
- **\$1.5 million for the National Lupus Patient Registry (NLPR)** at the National Center for Chronic Disease Prevention and Health Promotion within the Centers for Disease Control and Prevention (CDC) to sustain current epidemiological efforts, and expand the CDC's work to include all forms of lupus and all affected populations, particularly African Americans, Hispanics, and Asian Americans who are disproportionately at-risk for – and have worse outcomes associated with – lupus.

The purpose of the CDC lupus registry is to collect data and conduct lupus epidemiological studies to better understand and measure the burden of the illness, the social and economic impact of the disease, and stimulate additional private investment by industry in the development of new, safe and effective therapies for lupus. Existing epidemiological data on lupus is decades old and no longer reliable. Population-based epidemiological studies of lupus must be conducted at strategically-located sites throughout the nation that will provide accurate data on all forms of lupus (i.e. systemic lupus, primary discoid lupus, drug-induced lupus,

neonatal lupus, antiphospholipid antibodies) and the disparity among the various racial and ethnic populations.

To ensure that we begin to comprehensively study and understand the dramatic health disparities associated with lupus, the NLPR and associated epidemiological studies must be expanded to include additional sites that constitute a mix of urban and rural areas and contain academic centers with a track record and some existing infrastructure for performing epidemiological studies.

Good morning. I am Dr. Michael Madaio, Professor of Medicine at the University of Pennsylvania School of Medicine, and a lupus researcher. I have been funded for lupus research for over twenty years. I am proud to be affiliated with the Lupus Foundation of America as a member of the Medical Scientific Advisory Board and Chairman of the Medical Advisory Board for the Southeastern Pennsylvania Chapter of the LFA. While I am a nephrologist, since my research and clinical practice is focused on lupus, I really work day-to-day within the realms of nephrology and rheumatology as well as other medical specialties and subspecialty areas. I understand the importance of biomedical research funding and the impact that federal research funding has had, does have, and can have on the lives of the 1.5 million people living with lupus and the 22 million Americans with other autoimmune diseases.

After a tragic 40 year dearth of new treatments to manage this often debilitating and devastating disease, the good news is that we finally are on the brink of major breakthroughs, thanks to research sponsored by the National Institutes of Health. Exciting research and strides in treatments for people with lupus are on the horizon and a sustained investment now in lupus research will speed the day to better treatments and a cure. Specifically, I am conducting extensive research on lupus nephritis, which is kidney involvement in lupus disease. My field is advancing rapidly, due in large part to factors directly dependent on NIH funding:

- the burgeoning growth in the number of new animal models, including a wealth of informative transgenic and gene-targeted mutants;
- increased access to improved powerful technologies such as gene and protein arrays, now available at many institutions and to many investigators through NIH core facilities;
- new technologies that permit successful query of the very small amounts of human tissue typically available from patients and, collaboration across disciplines and across institutions to bring crucial expertise together.
- new insights into underlying biology and pathophysiology in immunity and lupus are constantly emerging;
- technologies to identify biomarkers are improved and accessible; and
- new approaches to therapy are being explored.

These endeavors are bearing fruit but they are highly dependent on NIH funding. If funding for the NIH is cut or level funded, it could cripple or paralyze current lupus research efforts.

As lupus is a systemic disease that can affect any organ or tissue elucidating pathogenesis (or cause) and treatments of lupus will have direct impact on many other autoimmune diseases (e.g. results and treatments translating to other diseases). Providing adequate resources to support lupus research will help the nation turn the corner on finding better treatments or a cure for lupus while also supporting breakthroughs and progress for other disease states. It is important to note that the corollary is true: cuts in lupus research funding also will have an adverse effect on progress for lupus and for progress in related diseases. Cuts in NIH funding could bring to a standstill support of clinical trials and large observational studies, and could curtail research on those at highest risk for lupus, women of color; it also could negatively impact pediatric research at a time when researchers have just begun to undertake studies in important new areas. Furthermore, insufficient federal funding also could slow much-needed genetic research when we are just discovering the critical components that may contribute to lupus and its effects. Therefore, it is critical that biomedical researchers be provided the necessary resources to continue seeking answers to the questions that will lead to better lupus treatments. Increased research funding will help deliver much-needed breakthroughs from the laboratory to patients in need.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the institute most involved in lupus research, is one of the smallest institutes at NIH. In the past two years there has been a decrease in research funding for NIAMS overall, with a ten percent decrease in new research grants. Currently, only 12-15 percent of the grant applications submitted to NIAMS receives funding. Further cuts will cause this rate to drop precipitously to below 10 percent next year. Just two or three years ago, funding levels were at 25-30 percent. Cuts in research funding, coupled with the rate of biomedical research inflation (3-4% per year), further erode NIAMS' ability to fund lupus research grant applications at the rate necessary to begin making real progress. As such, an increase above the rate of biomedical research inflation is necessary to allow NIH to sustain and build on its research progress resulting from the recent budget doubling while avoiding the severe disruption to that progress that would result from a lesser increase or cut.

Furthermore, in the proposed budget for NIAMS for 2007 there will be a loss of 10 training grants; each grant funds training for four physicians, mostly rheumatologists. Young and senior investigators alike are moving into other fields

because of the lost of funding. Exacerbating the situation, medical schools are struggling financially due to public funding cuts thus eliminating any safety net for researchers that may have previously existed. As a result, young investigators are not attracted to lupus research which means there will be not be a future generation of lupus scientists and clinicians to do research. Moreover, after having attracted scientists to translational immunology in the last five to ten years, when funding was increasing, there is now a possibility we could lose both the current and next generation of young investigators. Increased funding is necessary to support an adequate number of training grants. Without research and training funds lupus researchers might be forced to become private practice physicians instead, leading to an imbalance in the health care system: sufficient numbers of physicians to treat lupus patients, but no new treatments with which to care for them, and no researchers to develop the cures of tomorrow.

We recognize and appreciate that Congress and the nation face unprecedented fiscal challenges; however, we cannot afford to lose ground in biomedical research at such a promising time. **LFA looks forward to working with the Subcommittee and others in Congress to reduce and prevent the suffering caused by lupus. We stand ready to serve as a resource for any information you may need in this regard and thank you for this opportunity to testify on FY 2007 lupus research funding.**