LUPUS TODAY: RESEARCH INTO ACTION

September 5-6, 2003
Marriott Wardman Park Hotel
Washington, D.C.

Agenda
Executive Summary
Meeting Summary

Sponsored by:
U.S. Department of Health and Human Services

Sponsors
Office of Research on Women's Health, National Institutes of Health (NIH), Department of Health and Human Services (DHHS)
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Alliance for Lupus Research
American Autoimmune Related Diseases Association
Arthritis Foundation
Lupus Clinical Trials Consortium, Inc.
Lupus Foundation of America
Lupus Research Institute
Rheuminations, Inc.
S.L.E. Foundation, Inc.

AGENDA

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Marriott Wardman Park Hotel, Washington, DC

FRIDAY, SEPTEMBER 5, 2003
10:00AM-6:30PM

10:00AM **REGISTRATION**

11:00AM–11:20AM **WELCOMING REMARKS**
Wanda G. Jones, Dr.P.H.
Vivian W. Pinn, M.D.
Steven J. Hausman, Ph.D.

11:20AM–11:45AM **SESSION I: LUPUS PRIMER**
Joan Merrill, M.D.

An introduction to current issues in lupus care and research.

11:45AM-1:00PM **LUNCH BREAK (on your own)**

1:00PM–2:30PM **SESSION II: LUPUS TODAY**

This session will present how lupus affects patients of different ages and populations, current clinical diagnostics, and treatments used today in lupus. Speakers will present cutting edge research on the basic mechanisms of the disease and how the new information may translate into new treatments.

The Reproductive Years, the Pregnant Patient and her Infant
Jill P. Buyon, M.D.
Jane E. Salmon, M.D.

Children and Adolescent Patients
Christy Sandborg, M.D.
Hermine Brunner, M.D.

Race, Ethnicity and the Environment
Patricia A. Fraser, MPH, M.D.
John Reveille, M.D.

2:30PM– 3:00PM **COFFEE BREAK: MEET THE SPEAKERS**

3:00PM-4:30PM **SESSION II: LUPUS TODAY**

The Kidney
Michael P. Madaio, M.D.
Gary S. Gilkeson, M.D.

Cardiovascular Lupus
Michelle Petri, M.D.

Agenda - Continued

Neuropsychiatric Lupus
Betty Diamond, M.D.
Robin L. Brey, M.D.

4:30PM-5:00PM **BREAK: MEET THE SPEAKERS**

5:00PM–7:00PM **SESSION III: DINNER AND PANEL DISCUSSION**

LUPUS TODAY: VIEWPOINTS

Panelists:

Patient and Family:	Barbara Butler
Participating in Clinical Studies:	Debra Lapin (invited)
NIH:	Susana Serrate-Sztein, M.D.
Advocacy Groups:	Alliance for Lupus Research; American Autoimmune Related Diseases Association; Arthritis Foundation; Lupus Clinical Trials Consortium, Inc.; Lupus Foundation of America; Lupus Research Institute; Rheuminations, Inc.; S.L.E. Foundation, Inc.

Discussion topics:

Challenges Patients Face Today and How They Cope
Advocacy groups, and what is their role
Clinical trials: what they are, and what to expect
Issues in patient participation in clinical trials
What are the patients' rights
What is being done to assure protection of clinical study participants

SATURDAY, SEPTEMBER 6, 2003
8:00AM–3:00PM

7:30AM–8:00AM **REGISTRATION AND CONTINENTAL BREAKFAST**

8:00AM–12:00PM **SESSION IV: RESEARCH INTO ACTION**

8:00AM–8:20AM **Novel Diagnostics**
Tim Behrens, M.D.

This session will address emerging technologies and how they are being applied to the development of new diagnostic tools for lupus.

8:20AM–9:45AM **INVESTIGATOR-INITIATED CLINICAL TRIALS**
Introduction
Susana Serrate-Sztein, M.D.

Speakers will describe current clinical trials in lupus. Each will include a basic overview of the disease mechanisms on which the intervention is thought to work and the outcomes to be measured.

Agenda - Continued

	Lupus Nephritis	Mary Anne Dooley, M.D.
	CV	Laura E. Schanberg, M.D.
	Anti-IL-6	Gabor Illei, M.D., MHS
	B cell therapy	John Looney, M.D.
9:45 AM–10:15AM	**BREAK: MEET THE SPEAKERS**	
10:15AM–11:15AM	**INVESTIGATOR-INITIATED CLINICAL TRIALS**	
	Tolerance	Betty Diamond, M.D.
	High Dose Cytoxan	Robert A. Brodsky, M.D.
	Stem Cell Therapy	Kenneth Kalunian, M.D.
	Stem Cell Therapy	Barbara Mittleman, M.D.
11:15AM–12:00PM	**INDUSTRY-INITIATED CLINICAL TRIALS: TBA**	
12:00PM-12:30PM	**BREAK AND MEET THE SPEAKERS**	
12:30PM-3:00PM	**SESSION V: LUNCH AND PANEL DISCUSSION**	
	RESEARCH INTO THE FUTURE	

This session will focus on a panel presentation and discussion of the opportunities for new trials, and discussion of obstacles and possible solutions for expanding current clinical trials in SLE.

Panelists:	Clinical trials - FDA point of view	Lee S. Simon, M.D.
	Clinical trials - the patient view	TBA
	Research Perspectives from industry	Various
	Research Perspectives from Intramural NIH	Gregory Dennis, M.D.
	Research Perspectives from Extramural NIH	Susana Serrate- Sztein, M.D.
	Discussion	
3:00PM	**CLOSING REMARKS; ADJOURN**	

EXECUTIVE SUMMARY

I. Executive Summary

"Lupus Today: Research Into Action," was a scientific conference on the current status and future directions of research and treatment for systemic lupus erythematosus (SLE, or lupus). The primary goals of the conference were to inform, energize, and share the excitement about the future of lupus research with patients and their families, physicians, health care workers, scientists, and organizations that are involved in lupus research and outreach.

The meeting, which was held on September 5-6, 2003, at the Marriott Wardman Park Hotel in Washington, DC, brought together national leaders in lupus research to highlight key research accomplishments and discuss their implications for the current and future management of lupus. The conference also featured panel discussions on the impact of lupus on patients and their families, the role of advocacy groups, patient participation in clinical studies, and the future of lupus clinical trials.

The meeting was organized into five sessions:

- A Lupus Primer – an overview of current knowledge about the disease, recent progress in understanding its underlying causes, and questions and challenges for the future.
- Lupus Today – a series of scientific presentations on how lupus affects patients of different ages and populations; the effects of lupus on the kidneys, cardiovascular system, and the brain and central nervous system; and the latest research aimed at understanding and addressing these aspects of the disease.
- What it Means to Be a Patient with Lupus Today – a panel discussion on the challenges lupus patients face today and how they cope, the role of advocacy groups, and information on patient participation and patient rights and protections in clinical trials.
- Research Into Action – scientific presentations describing emerging technologies being applied to the development of new diagnostic tools for lupus and a variety of ongoing and planned clinical trials for potential new, improved therapies.
- Research Into the Future – a panel presentation and discussion on the opportunities for new clinical trials and discussion of the obstacles and possible solutions for expanding current clinical trials in lupus. The discussion included viewpoints from patients, the Food and Drug Administration, NIH, and industry.

In addition to the scientific sessions and panel discussions, the meeting featured an exhibit room where representatives of voluntary health organizations and other groups distributed information.

The summary below provides a synthesis of the topics discussed at the meeting. A videotape of the entire meeting can be viewed online at http://videocast.nih.gov/PastEvents.asp (Search for Lupus Today: Research Into Action will be listed as "Day 1" and "Day 2" videos).

Sponsors

The meeting was sponsored by the Office of Women's Health, Office of the Secretary, U.S. Department of Health and Human Services (DHHS) and the Office of Research on Women's Health and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, both at the National Institutes of Health

(NIH), DHHS. The meeting was cosponsored by the Office of Minority Health, Office of the Secretary, DHHS; National Center on Minority Health and Health Disparities, NIH, DHHS; National Center for Research Resources, NIH, DHHS; National Heart, Lung, and Blood Institute, NIH, DHHS; National Institute of Diabetes and Digestive and Kidney Diseases, NIH, DHHS; National Institute of Environmental Health Sciences, NIH, DHHS; National Institute of Neurological Disorders and Stroke, NIH, DHHS; Health Resources and Services Administration, DHHS; Office of Women's Health, Centers for Disease Control and Prevention, DHHS; Office of Women's Health, U.S. Food and Drug Administration, DHHS; and the Alliance for Lupus Research, American Autoimmune-Related Diseases Association, Arthritis Foundation, Lupus Clinical Trials Consortium, Inc., Lupus Foundation of America, Lupus Research Institute, Rheuminations, Inc., and S.L.E. Foundation, Inc.

MEETING SUMMARY

II. Meeting Summary

Introduction and a Primer on Lupus

On September 5-6, 2003, national leaders in lupus research gathered in Washington, DC, to present the latest discoveries about this complex autoimmune disease and discuss how these findings are opening new avenues for diagnosis and treatment. At the meeting, "Lupus Today: Research Into Action," scientists from universities, the federal government, and industry shared their excitement and optimism about the future of research on systemic lupus erythematosus (SLE, or lupus) with patients and their families, physicians, health care workers, scientific colleagues, and representatives from organizations involved in lupus research and outreach. Other meeting highlights included panel discussions on the impact of lupus on patients and their families as well as patient participation in clinical studies and the future of lupus clinical trials. (Clinical trials are research studies in human volunteers that are designed to test the safety and effectiveness of new treatments or answer specific health questions).

The meeting was a collaborative effort led by the Office of Women's Health at the U.S. Department of Health and Human Services (DHHS) and the Office of Research on Women's Health and the National Institute of Arthritis and Musculoskeletal and Skin Diseases at the National Institutes of Health (NIH), DHHS. Eleven other DHHS components and eight voluntary health organizations cosponsored the meeting, the full agenda of which is available at http://www4.od.nih.gov/orwh/finalupus.pdf.
A videotape of the entire meeting can also be viewed online at http://videocast.nih.gov/PastEvents.asp (Search for Lupus Today: Research Into Action will be listed as "Day 1" and "Day 2" videos).

Researchers have made great strides in understanding the underlying causes of lupus, especially in the last 5 years or so, and they are continuing to piece together the ways that small genetic differences, environmental factors, infection, and hormones interact to trigger the disease. These insights are leading to new approaches for diagnosing, monitoring, and treating lupus. A wide range of clinical trials of potential new therapies are under way or soon to be launched, and pharmaceutical and biotechnology companies are showing increased interest in developing and testing novel lupus therapies. NIH and the U.S. Food and Drug Administration (FDA) as well as private organizations are taking steps to promote and facilitate clinical trials of potential new treatments and help bring new drugs to the market more quickly without compromising patient safety.

Despite the progress being made, many mysteries about lupus remain to be solved. For reasons that are still unclear, the symptoms and severity of the disease vary from person to person and its course is unpredictable, creating special challenges for testing new therapies in humans. And although the outlook today is good even for people who have more serious, organ-threatening manifestations of lupus, many of the drugs used to treat the disease have undesirable side effects and can lead to a host of long-term

complications. Some of these drugs, which work by suppressing the immune response, harm healthy cells in the body as well as the immune cells that contribute to disease. Thus, developing new, more targeted treatments that are less toxic and more effective is a high priority in lupus research.

Lupus is often described as a disease in which the immune system is overactive and produces antibodies that target and attack the body's own tissues and organs, known as autoantibodies. However, recent findings suggest that lupus involves an imbalance in the immune system, rather than just overactivity. The different cell types that make up the immune system normally work together to eliminate sources of potential harm to the body, including viruses, bacteria, and autoantibodies. In lupus, various components of the immune system are either overactive or not active enough. This results in an inappropriate immune response in which autoantibodies are no longer kept in check, leading to inflammation and damage to target organs and tissues.

Lupus Today: The Reproductive Years, Children and Adolescents, Race and Ethnicity

Lupus most often affects women in their childbearing years. Although severe disease activity and some medications used to treat lupus may cause temporary or even permanent infertility, most women with lupus are fertile. However, the potential for complications during pregnancy is significantly higher in women with lupus than in healthy women. Doctors have learned a great deal about managing pregnancy in women with lupus, and many lupus patients have safe pregnancies and deliver healthy babies. But lupus pregnancies are still considered high risk, and some women with lupus are prone to repeated miscarriages (pregnancy loss).

In one promising line of investigation, researchers are studying the causes of lupus pregnancy complications and developing and testing new approaches to prevent these problems. Recent studies in mice with a syndrome that mimics lupus-related pregnancy loss have revealed that inflammation-causing molecules known as complement play a key role in this syndrome, and that blocking the actions of specific complement molecules prevents pregnancy loss in these mice. In the next phase of this work, researchers will explore whether similar mechanisms are involved in pregnancy loss in women with lupus. If the findings from mice translate to humans, drugs that block the effects of complement, which are already available, may provide an effective new treatment for preventing recurrent miscarriage in lupus patients.

Researchers are also studying various aspects of neonatal lupus, a rare condition that affects approximately 2 percent of newborn babies of women with SLE and other women whose immune systems produce a particular type of autoantibody known as anti-Ro/La. Some babies with neonatal lupus have permanent heart damage resulting from inflammation and scarring of heart tissue that occurs before birth. In most cases, doctors can treat the baby's heart defect by implanting a pacemaker, but about 25 percent of cases are fatal. Researchers are making progress in understanding the processes responsible for heart-tissue scarring in neonatal lupus, which may ultimately lead to ways to prevent this problem. They are also investigating the use of echocardiograms for early detection of heartbeat abnormalities in unborn babies of women at risk for delivering babies with neonatal lupus. As part of these studies, researchers are testing whether treating at-risk women with an anti-inflammatory steroid medication (dexamethasone) can reverse heart damage in the unborn child. In other research efforts related to reproductive issues in lupus, results of a clinical trial on the safety of birth control pills for women with lupus will soon be available.

Approximately 15–20 percent of lupus cases begin before age 18, and the disease tends to be more severe and more chronically active in children and adolescents than in adults. Severe kidney disease is especially common, affecting more than 60 percent of children with lupus. A number of unique issues exist for youngsters with lupus, their families, and their doctors. Lupus and some lupus therapies can interfere with normal physical, emotional, and psychological development in children and adolescents. In

addition, the tendency for young people to live for the present and ignore the future can be problematic when dealing with a disease that requires long-term treatment with medications that have unpleasant and sometimes serious side effects. Doctors have not yet established what the best treatment approach is for young people with lupus, nor do they know the long-term effects of the disease and its treatments on those who develop lupus at an early age.

Physician-researchers who treat young lupus patients are working to learn more about the disease in children and adolescents, including why lupus is more severe in these patients. They are also conducting studies aimed at improving the treatment, quality of life, and long-term outlook for these patients. As part of this effort, researchers are conducting a study to find out how patients diagnosed with lupus during childhood are doing later on in life. As part of this study, researchers are investigating the long-term effects of current therapies used for pediatric lupus patients on reproductive health in males and females. In related efforts, researchers are planning a clinical trial of a medication that may protect the ovaries of adolescent girls with SLE who require treatment with cyclophosphamide, which is known to cause infertility due to premature menopause in adults.

The role of race and ethnicity in lupus is another active area of research. Lupus is three times more common in African-American women than in Caucasian women, and is also more common in women of Hispanic, Asian, and Native American descent. Research shows the disease also tends to be more severe in African-Americans and in some U.S. Hispanic groups. Scientists supported by NIH have been investigating why certain ethnic and racial minorities have a greater risk of developing lupus and why disease manifestations, severity, and prognosis differ among various groups. Minor genetic differences, environmental factors, socioeconomic factors, and behavioral and cultural differences all may play a role, and researchers are making progress in identifying the relative contributions of some of these factors to the disease disparities seen among different racial and ethnic groups. For example, studies indicate that socioeconomic factors such as income, availability of health insurance, and education level may account in large part for the poor outcomes seen among African Americans and some U.S. Hispanics with lupus. In other research, scientists found that different genetic regions are associated with lupus in African Americans, Hispanics, and European Americans (Caucasians), suggesting that the specific genetic factors that contribute to disease susceptibility and severity may differ among ethnic groups.

Lupus Today: Effects on Various Body Systems

Scientists are also gaining new insights on how lupus causes damage in various parts of the body, why some people are more likely to develop such damage, and why damage is more severe in some patients. In the past 25–30 years, research has led to major improvements in the understanding and treatment of lupus kidney disease (nephritis)—one of the more serious and potentially fatal manifestations of lupus. Many insights are being gained through studies of mouse strains that spontaneously develop kidney disease that resembles human lupus nephritis. For example, researchers have found that different types of autoantibodies cause different types of kidney disease, and that not all autoantibodies cause nephritis. They have also identified many other factors, including various immune system molecules, which are involved in causing inflammation and tissue damage in the kidneys. In addition, researchers have developed treatment regimens that delay kidney failure and improve survival in people with lupus nephritis. Despite the progress in understanding and treating lupus nephritis, current treatments can cause serious side effects and long-term complications. Clinical trials of several promising and potentially less toxic therapies for lupus nephritis are in progress, and a number of other possible treatments are in the pipeline.

Cardiovascular disease is another major cause of death in lupus patients. Researchers are investigating why people with lupus have a greatly increased risk of cardiovascular complications such as heart attacks and strokes, and are searching for better ways to prevent, diagnose, and treat cardiovascular disease in these patients. Although cardiovascular complications tend to affect lupus patients later on in the course

of the disease, signs of cardiovascular disease can be detected earlier, especially with newer imaging technologies such as carotid ultrasound and helical CT scans, which are not yet covered by insurance. One particular area of interest among lupus researchers is the role of inflammation of the blood vessels in atherosclerosis and cardiovascular disease in lupus patients, and the possibility that nonsteroidal anti-inflammatory drugs may be useful for treating these complications.

Studies are also ongoing to better characterize the many clinical manifestations of neuropsychiatric lupus (NP-SLE), which affects the brain and other parts of the nervous system. NP-SLE causes increasing damage over time, and can lead to various neurological and psychiatric problems. Indeed, some studies indicate that neuropsychiatric problems occur in more than 80 percent of lupus patients at some point during the course of the disease.

In addition to developing better methods of diagnosing NP-SLE, researchers are working to identify the underlying causes of NP-SLE and develop better ways to treat problems such as cognitive dysfunction (disordered thinking), which is the most common manifestation of NP-SLE. For example, recent studies in mice show that some autoantibodies from lupus patients that bind to DNA (known as anti-DNA antibodies) can also bind to specific receptor proteins on nerve cells and damage or trigger the death of these cells. Additional evidence from mouse studies supports the idea that anti-DNA antibodies that get into the brain may be involved in causing cognitive dysfunction and other problems associated with NP-SLE. Interestingly, experiments in mice also show that certain drugs can protect nerve cells from damage caused by anti-DNA autoantibodies. Although a protective barrier normally prevents antibodies from crossing from the bloodstream into the brain, factors such as stress or infection may lead to breaches in this barrier.

Researchers are now investigating whether processes similar to those discovered in mice are involved in causing central nervous system damage and cognitive problems in people with lupus. If this turns out to be the case, drugs that were shown to protect nerve cells from autoantibody-mediated damage in the mouse model of NP-SLE could turn out to be effective therapies for preventing central nervous system damage in people with lupus. In other work on NP-SLE, researchers are studying the use of brain imaging techniques to detect cognitive impairment in lupus patients and gain a better understanding what is going on in the brain when such impairment occurs.

Lupus Today: Viewpoints

In addition to presentations from researchers, meeting participants heard perspectives on various issues related to lupus from patients, patient advocates, and representatives of voluntary health organizations and other nonprofit organizations dedicated to lupus and autoimmune disease. These groups provide information and services for patients and their families, serve as advocates on issues of concern to lupus patients through lobbying and other efforts, raise public awareness of lupus, and fund innovative research projects that might otherwise not receive funding.

Patients can help in the fight against lupus by raising awareness of the disease, advocating for more research, and participating in clinical trials of new treatments. However, as several speakers in panel discussions at the meeting noted, many issues and concerns are associated with patient participation in clinical trials. Such participation may require personal sacrifices and involve a certain amount of risk. Patient concerns include the safety and potential side effects of experimental treatments, privacy and cost issues, and the trustworthiness of those who conduct clinical trials. Thus, doctors and institutions that are conducting clinical trials must be accountable to patients, keep them informed, and build and maintain a sense of trust. It is also important to follow patients after clinical trials are completed and monitor the effects of new treatments once they are in wider use.

Research Into Action: Clinical Trials

Many challenges, frustrations, and risks also exist for those who conduct clinical trials. Despite the challenges involved, a number of clinical trials of possible new therapies for lupus are under way, and others are in the planning stages. These include both investigator-initiated clinical trials funded by the NIH and FDA, which are planned and conducted by researchers at university medical centers across the U.S. and at the NIH clinical center in Bethesda, Maryland, and clinical trials initiated and conducted by pharmaceutical and biotechnology companies. Meeting participants had a rare opportunity to gain insights on the thinking and planning that goes into lupus clinical trials and to hear about ongoing clinical trials for which results are not yet available, as well as clinical trials that are still in the planning stages.

While some experimental lupus therapies aim to treat or even cure the entire disease, many are directed against specific manifestations of the disease. For instance, people with lupus often develop premature atherosclerosis (hardening of the arteries), leading to an increased risk of heart attacks and strokes. University researchers are conducting clinical trials on the safety and effectiveness of Atorvastatin—one of a group of drugs called statins—for preventing atherosclerosis in both adults and children with SLE. Statins are commonly used to lower cholesterol levels and reduce the risk of heart disease and stroke in adults, but until now they have not been specifically tested in lupus patients.

A number of clinical trials in academia and industry are also ongoing or planned for new, potentially less toxic therapies for lupus nephritis. These therapies differ from current treatments in that they are more specific in their actions. In other words, instead of suppressing the entire immune response and damaging healthy cells along with harmful ones, most of these experimental therapies target specific components of the immune response that research has shown to be involved in the development of lupus. Some of these more targeted therapies will also be tested or are already being tested in lupus patients who do not have kidney disease.

University and government researchers are also exploring more radical approaches for treating serious cases of lupus that are resistant, or refractory, to standard therapies. The goal is to wipe out disease-causing immune cells, restore a healthy immune system, and achieve long-term remission or cure of the disease. Two approaches that have shown some promise in small, preliminary studies will be tested in larger clinical studies. One approach is stem-cell therapy, in which doctors use high-dose chemotherapy with drugs such as cyclophosphamide (Cytoxan) to destroy the patient's immune system, followed by transplantation of hematopoietic (blood-forming) stem cells that were removed from the patient before chemotherapy. The transplanted stem cells develop into mature blood cells and regenerate the immune system. Researchers are also beginning a clinical trial of high-dose cyclophosphamide chemotherapy without stem-cell transplantation for moderate to severe cases of refractory lupus.

One industry-sponsored clinical trial is testing the ability of a drug called prasterone (a synthetic form of the natural hormone DHEA) to prevent bone loss (which increases the risk of osteoporosis) in women with lupus who are taking prednisone. More than 50 percent of lupus patients have increased bone loss resulting from multiple factors, including treatment with prednisone and other drugs as well as effects of the disease itself.

Research Into Action: Novel Diagnostics

Another active area of lupus research focuses on improving diagnosis of the disease. No single laboratory test can determine whether someone has SLE, and it often takes several years from the time that a person first develops symptoms to the time that doctors can make a definitive diagnosis. Recent advances in the study of human genetics may provide a key to developing more accurate and specific diagnostic tests for lupus. Using a technology known as genetic profiling, which simultaneously analyzes the activity of thousands of genes in a single blood sample, researchers have identified a group of genes whose

activity is much higher in people with lupus than in healthy individuals. Researchers hope that continued investigations in this area will lead to the identification of a specific "genetic signature" that is unique to people with lupus and can be used as the basis for a laboratory test that enables rapid and accurate diagnosis of the disease. Ongoing genetic profiling studies of blood samples from a large group of lupus patients may also provide doctors with better ways to monitor and predict disease activity and tailor treatments to individual patients.

Research Into the Future

Many challenges still remain for lupus researchers—and for people affected by the disease. In the final session of the meeting, which focused on the future of lupus research, patients expressed their wishes for a cure for lupus. Until a cure can be found, they said, an important goal is developing more effective and less toxic therapies, so that SLE becomes a chronic, treatable, and less debilitating illness. Patients also noted the importance of educating the public and the broader medical community about lupus, including the fact that the disease occurs in mild as well as more severe forms. They also expressed concern about safety and privacy issues with regard to participation in clinical trials and emphasized the need to reach out to members of minority communities that are affected by lupus.

Intensified efforts and interest in lupus research on the part of federal agencies, private industry, and nonprofit organizations, together with recent advances in understanding the disease, provide new and realistic hope that better treatments, and, ultimately, a cure for lupus will become a reality. Achieving these goals will require collaboration between laboratory scientists and clinical researchers and between members of the public and private sectors, including the NIH, FDA, industry, and voluntary health organizations. As the number of lupus clinical trials increases, it will also be important to promote a sense of partnership between patients and physicians, to gather as much scientific knowledge as possible about potential therapies before launching new trials, and to design these trials so as to maximize their benefits for science and for people with lupus while maintaining the highest ethical standards.