TESTIMONY OF:
Mary McGowan, FSR President and CEO

ON BEHALF OF:
Foundation for Sarcoidosis Research (FSR)

REGARDING:
Fiscal Year 2027 appropriations for the U.S Department of Labor and Department of Health and Human Services

SUBMITTED TO:
The House Appropriations Committee, Labor, Health and Human Services, Education, and Related Agencies Subcommittee

SUBMITTED ON: April 15, 2026

FISCAL YEAR (FY) 2027 APPROPRIATIONS RECOMMENDATIONS:

- Please provide $51.3 billion for the National Institutes of Health (NIH) for fiscal year (FY) 2027, in addition to support for the Advanced Research Projects Agency for Health, to ensure sustained growth in the sarcoidosis portfolio and rare disease research activities, and to facilitate new awareness and education efforts around clinical trials. Please provide proportional funding increases for NHLBI, NIAMS, NCATS, and related I/Cs.
- Please provide the Centers for Disease Control and Prevention (CDC) with at least $11.6 billion for FY 2027 to support ongoing and emerging public health activities, particularly for rare and chronic conditions.
- Please include timely recommendations in the Committee Report accompanying the annual Labor-Health and Human Services-Education (LHHS) Appropriations Bill encouraging DOL to take substantive action to promote awareness among employers, H.R. departments and patient communities that clinical trial participation is a permissible use of leave under the Family and Medical Leave Act (FMLA). Additionally, please include a recommendation encouraging the National Library of Medicine to share this information on ClinicalTrials.gov.

Chairman Cole, Ranking Member DeLauro, and distinguished Members of the Subcommittee, thank you for the opportunity to present the views of the Foundation for Sarcoidosis Research (FSR) during the consideration of FY 2027 LHHS appropriations. The challenges and opportunities that I will review today are not unique to FSR and our patient community, but the broader chronic and rare disease patient community, as well as related professional and research communities. My comments are provided in the interest of improving patient care, access and treatment options for sarcoidosis patients, as well as other rare and chronic disease patients with similar challenges. In this regard, please consider the FSR and stakeholder organizations a resource moving forward. Thank you again for this important opportunity.

CLINICAL TRIAL PARTICIPATION COVERED UNDER FMLA

Previously, FSR submitted a Request for Opinion Letter on Clinical Trials and the Family and Medical Leave Act (FMLA) with the U.S. Department of Labor (DOL). Prior to submitting the request for an opinion from the DOL, FSR performed surveys and focus group discussions to

better understand barriers for patients to enroll in clinical trials and research related to sarcoidosis treatment. These efforts revealed that a significant barrier to patients participating in clinical trials relates to concerns about receiving time off from working, including concerns that they are not able to take a leave of absence from work for their participation in clinical trials without risk to pay, job assignments, promotions, training, and access to fringe benefits (such as leave and health insurance).

FMLA provides the primary mechanism under which many employees across the U.S. are entitled to a job-protected leave of absence to address time off to care for an individual's or a family member's serious health condition. In addition to providing 12 weeks of unpaid leave for care related to a serious health condition, the FMLA provides security for those taking time off from work to receive treatment for a condition, in that they are generally permitted to maintain terms of employment, including group health coverage, and be reinstated to the same or substantially similar job following FMLA leave. FSR, in partnership with congressional champions and other stakeholders identified that these barriers stemmed from the lack of clarity on whether the concept of "therapeutic benefit and treatment" extends to clinical access to clinical trials, which would match congressional intent and the plain language of existing law. Fortunately, FSR received a letter of clarification from the DOL that ensures employee access to FMLA benefits when participating in clinical trials. To raise awareness of this, we encourage the Committee to direct the Department of Labor and the National Library of Medicine (through ClinicalTrials.gov) to include this information in their resources shared with HR departments, employers, patients and other relevant stakeholders. Please see recommended report language to be included below:

National Institutes of Health
National Library of Medicine

Clinical Trial Participation as a Permissible Use of Leave Under FMLA.–The Committee notes that the Department of Labor (DOL) has clarified that clinical trial participation is a permissible use of leave under the *Family and Medical Leave Act* (FMLA) for both patients and caregivers. The Committee encourages the National Library of Medicine to include this information on clinicaltrials.gov and to work with stakeholder organizations to ensure patients seeking clinical trial access are fully aware of their rights under FMLA.

U.S. Department of Labor
Wage and Hour Division

Clinical Trial Participation as a Permissible Use of Leave Under FMLA.– The Committee recognizes the Department for clarifying that clinical trial participation is a permissible use of leave under the *Family and Medical Leave Act* (FMLA) as the previous lack of guidance led to confusion among the public and employers. Further, we encourage the Department to more actively promote this through its programs and resources and to work with patient groups and stakeholder communities to spread public and professional awareness among human resources departments, employers and their employees.

ABOUT FSR

The Foundation for Sarcoidosis Research (FSR) is the leading international organization dedicated to finding a cure for sarcoidosis and improving care for sarcoidosis patients through research, education, and support. Since its establishment in 2000, FSR has fostered nearly $10

million in sarcoidosis-specific research efforts. FSR is actively working with the world leaders in sarcoidosis, investing in innovative, patient-centered research efforts and providing educational resources, support, and opportunities to accelerate research to patients worldwide

ABOUT SARCOIDOSIS

Sarcoidosis is an inflammatory disease characterized by the formation of granulomas—tiny clumps of inflammatory cells—in one or more organs of the body. When the immune system goes into overdrive and too many of these clumps form, they can interfere with an organ's structure and function. Despite increasing advances in research, sarcoidosis remains difficult to diagnose with limited treatment options and no known cure. It's estimated that the prevalence of sarcoidosis in the US ranges between 150,000 and 200,000 with an estimated 1.2 million individuals with sarcoidosis worldwide. By continued support for federal agencies, such as NIH, CDC and others, that invest in and perform research focused on sarcoidosis, we can continue on the towards better treatment options and patient outcomes.

CLINICIAN AND RESEARCHER REFLECTIONS

"Sarcoidosis is a chronic inflammatory disease of adult onset that is often life changing and sometimes lethal and for which current treatments are inadequate. Support from NIH has been essential for recent progress towards understanding basic disease mechanisms such that more effective therapies can be developed to address the unmet needs of sarcoidosis patients. Ongoing NIH will be essential for the scientific development of the next generation of sarcoidosis researchers and clinicians aiming to further improve the quality of life and productivity of sarcoidosis patients, who are often afflicted with the disease during the prime of their adult lives." *Elliott D. Crouser, M.D., Professor of Medicine, Director, Comprehensive Sarcoidosis Program Division of Pulmonary, Critical Care and Sleep Medicine, The Ohio State University Medical Center, FSR Scientific Board Chair and FSR Global Sarcoidosis Clinic Alliance Member Columbus, OH, USA*

"As a senior investigator with decades of funding from the National Institutes of Health, via NHLBI and NIEHS, I have been able to help define factors associated with sarcoidosis, a rare and deadly disease, including exposures, clinical features, immune and oxidative stress pathways as well as severe devastating manifestations of this disease. These NIH funded studies have been the predominant source of funding which has led to expanding treatment options to reduce deadly disease, early stages of biomarkers and potentially new approaches to diagnose and prognostic or differentiate more severe pulmonary and cardiac manifestations of sarcoidosis for follow up and treatment. Without ongoing funding, all of these studies and others will stop where they are today, without the ability to move this field forward and help prevent and treat this devastating disease; this would be devastating to these patients, the science and investigators like me who have worked for decades to help move this field forward and at a time when we are just starting to build momentum to help patients with sarcoidosis and provide them more specialized care and treatment." *Lisa A. Maier, MD, MSPH, Chief, Division of Environmental and Occupational Health Sciences, National Jewish Health, Denver Colorado, FSR Scientific Advisory Board Member and FSR Global Sarcoidosis Clinic Alliance Member, Denver, CO, USA*

"Stable funding lines are essential to maintain US superiority in science and technology. The current uncertainty, messaging, and proposed budgets and OMB-related funding freezes have already led to significant numbers of promising young scientists to leave the field, and we are

facing a generational loss of talent and expertise from which it may take decades to recover. Sarcoidosis is a rare disease, but one which disproportionately impacts first responders and members of the military, and we are just at the cusp of transformational breakthroughs in our understanding of the disease and development of targeted therapeutics. Support for science and research is essential, and support for sarcoidosis in particular is critically important at this juncture." *Misha Rosenbach, MD, Dermatology & Rheumatology, FSR Scientific Advisory Board Member and FSR Global Sarcoidosis Clinic Alliance Member, Philadelphia, PA, USA*

"Sarcoidosis is a chronic inflammatory disease that is often life changing and debilitating and for which current treatments are inadequate. I and my colleagues have been privileged to have NIH/NINDS support for the investigation of the basic science underlying the neurological manifestations of sarcoidosis. Patients have been enthusiastic in their support of our NIH-supported research because they appreciate how little is known about the underlying mechanisms of disease and they are desperate for more effective and safer treatments. Support from NIH is essential to better our understanding of basic disease mechanisms such that more effective therapies can be developed to address the unmet needs of sarcoidosis patients. Furthermore, ongoing NIH support will be essential for the scientific development of the next generation of sarcoidosis researchers and clinicians aiming to further improve the quality of life of sarcoidosis patients, who are often afflicted with the disease during the prime of their adult lives." *Barney J. Stern, MD, Professor, Johns Hopkins University Department of Neurology, FSR Scientific Advisory Board Member Baltimore, MD, USA*

PATIENT STORIES

"There is a big intangible cost of missing work to participate in clinical trials. There is a great uncertainty when considering clinical trials because you do not know if you can qualify to take FMLA to participate. Approaching human resources with this type of matter is riddled with anxiety and fear, because you don't really know if this puts your job at risk. And when you are working and trying to navigate Sarcoidosis, your job becomes your lifeline because it provides insurance to get the care you need and money to pay for childcare and out-of-pocket medical expenses. Sometimes, we sarcoidosis patients need medical solutions the most. . . Sometimes clinical trials are solutions that have increased financial commitment from the patient, yet the patient is not receiving additional financial support. This can cause a stressful conundrum for the patient. Since the passing of the FMLA policy, I am now more confident about participating in a clinical trial and being able to keep my job. Before I may have hesitated to the point that I put my own health at risk to save my job because of my financial situation and needing insurance to navigate the disease. Now, I know I can participate without fear of losing my livelihood." *Erica Courtney-Mann, Sarcoidosis Patient and FSR Patient Advocate, Spring, TX, USA*

"Participating in a clinical trial requires significant time, energy, and flexibility. During my own experience, the frequent appointments and pandemic-related extensions were difficult to manage even in retirement. This highlights a critical barrier to trial accessibility: for those still in the workforce, balancing professional demands with trial protocols is nearly impossible without structural support. Policies that support job protected leave are essential, as they often determine whether a patient can remain in a study or is forced to withdraw." *Mary Oldham, Sarcoidosis Patient and FSR Patient Advocate, Montara, CA, USA*