Mary McGowan
CEO, Foundation for Sarcoidosis Research

FDA's Patient Engagement Advisory Committee

Center for Devices and Radiological Health (CDRH)

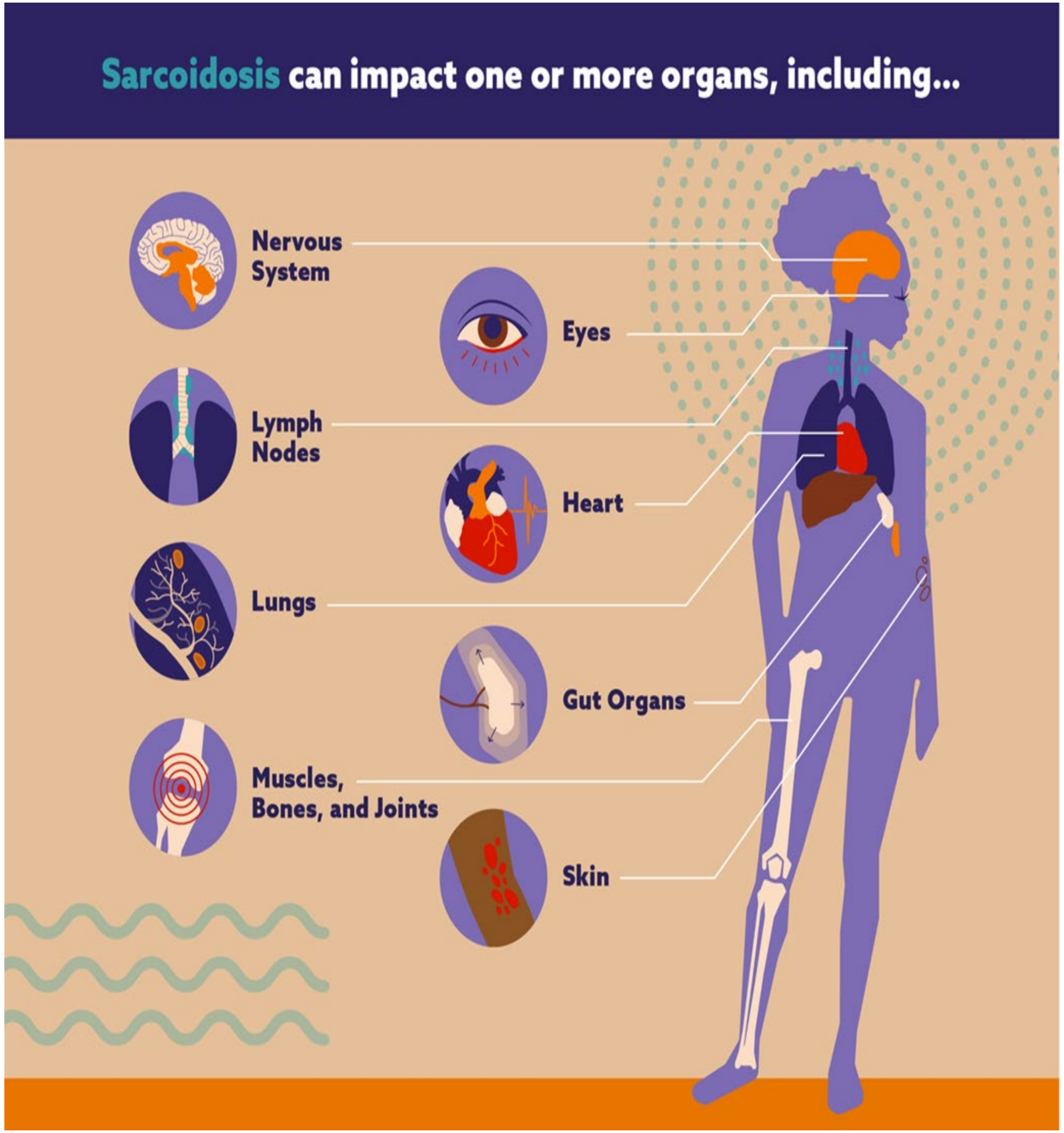
Open Public Hearing: "Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products."

October 30, 2024

FSR

About FSR

- **Founded in 2000,** FSR is the leading international nonprofit dedicated to sarcoidosis patients and research
- **Mission** to find a cure for sarcoidosis and to improve care for patients with sarcoidosis
- **Driven** by a cooperative, communicative, cyclical relationship between patients and research



Sarcoidosis is an inflammatory disease characterized by the formation of granulomas in one or more organs of the body.

90% of patients have lung disease.

5-25% of patients have cardiac sarc requiring a defibulator or pacemaker

Black Americans 2x more likely to have sarcoidosis
12x more likely to die of sarcoidosis
More likely to die at a younger age

Approximately 175,000 in US

Baughman et al. *AJRCCM* 2001

Common Treatment and Diagnosis Types of Devices

- X-Rays
- MRI
- CT
- Endoscope
- FDG-PET Scans
- Broncholavage
- Biopsy
- Echocardiogram
- PFT
- Holter Monitors
- Pacemakers, implantable defibrillators

How we learn from sarcoidosis patients

FSR Patient Registry

-6,702 participants

-68 countries represented

Patient Surveys

- On clinical trials
- Black Patients and Clinical Trials
- FDA Listening Session and an upcoming

Collaborations

-Coalition for Clinical Trial Equity

-FSR Global Sarcoidosis Clinic Alliance

Patient Advisory Panels

-For clinical trials

-For patient experience

Patients want to understand the technology used for tests or therapy

Patient Concerns and Desires for Informed Consent

For implanted devices – let the patient hold/feel device

Early Discussion Matters

Create information they can take home and share with their community

Access to data after

"I think that part of trust is transparency, and doctors who are willing to tell you what they know and what they don't know and then work with you as a member of the team.

Doctors who are willing to say, let's work together. Let's find out. Let's investigate together. I think that that is the most helpful."

-Sarcoidosis Patient

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