NIH Research and Valley Fever
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Director, National Institutes of Health
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NIH: Steward of Medical and Behavioral Research for the Nation

“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems... and the **application of that knowledge** to extend healthy life and reduce illness and disability.”
NIH: Supporting Biomedical Research

FY 2013 Full-Year CR Level: $29.1 Billion

Spending at NIH

Spending Outside NIH
U.S. Department of Health & Human Services: Agencies Collaborating to Halt Valley Fever (VF)

- Centers for Disease Control and Prevention (CDC)
  - Leads efforts to protect Americans from all disease threats
  - *VF*: studies epidemiology; conducts applied research; provides support to health departments; educates patients, providers

- National Institutes of Health (NIH)
  - Supports, conducts biomedical research to advance understanding of health and disease
  - *VF*: basic biology; drug development; clinical trial implementation

- Food and Drug Administration (FDA)
  - Assures safety, efficacy, of drugs, devices, food supply, etc.
  - *VF*: approves drugs, tests, that are proven safe and effective
Valley Fever (Coccidioidomycosis)

A disease that is

- Hard for patients
- Hard for providers
- Hard for researchers
NIH Commitment to Fungal Disease Research: Coccidioidomycosis Treatment Trials

- 7 clinical treatment trials of Coccidioidomycosis from NIAID Mycoses Study Group (with drugs still available)
  - Forms of disease
    - 4 on chronic pulmonary non meningeal disease
    - 3 on meningitis
  - 3 drugs studied—most as sole therapy
  - 1 comparative, randomized, controlled trial—no significant differences found

- Of these 7 trials:
  - All small
  - None on primary pneumonia
Planned Clinical Trial on Valley Fever: The Study *(as currently conceived)*

**CDC**: finds patients with cocci-related Community Acquired Pneumonia (CAP)—and practices willing to participate

**NIH**: conducts “gold standard” clinical trial with CAP patient-volunteers requiring treatment

- **Group 1**: standard treatment (Azithromycin) + placebo
  - Test blood on Days 0, 14, 28, and 42
  - Trial ends, all seropositive patients offered Fluconazole

- **Group 2**: standard treatment (Azithromycin) + test drug (Fluconazole)
Planned Clinical Trial on Valley Fever: Anticipated Outcomes

- Determine safety/efficacy of fluconazole in endemic area
- Assess impact of early treatment on immune response/outcome
- Identify best available diagnostic approaches
- Recognize and characterize early stages of disease
NIH...
Turning Discovery Into Health