

# Impact and Control of Valley Fever: A Workshop

Health and Medicine Division Board on Global Health

Workshop Briefing Book November 17 & 18, 2022



## Contents

### Board on Global Health Reference Documents

About the Board on Global Health	1
Highlights of Recent Publications	2
Convening Activities	3
Board on Global Health Membership and Staff	5

### Workshop Documents

Workshop Background	7
Workshop Statement of Task	8
Sponsors and Planning Committee	9
Workshop Agenda	10
Planning Committee Biographies	16
Speaker Biographies	19

### NASEM Statements

NASEM Statement on Preventing Discrimination, Harassment, and Bullying	29
The National Academies' Statement on Diversity and Inclusion	30

## About the Board on Global Health

### DIRECTOR: JULIE PAVLIN, <u>JPAVLIN@NAS.EDU</u>

The health of the world knows no boundaries, and health events in one area impact far beyond local populations. In light of this, the Board on Global Health (BGH), within the <u>Health and Medicine Division</u>, carries out activities and studies aimed at advancing the health of people worldwide.

### **Board Statement of Task**

The Board on Global Health (BGH) is charged with monitoring the broad field of global health and the pursuit of critical concerns in three major areas:

- 1. U.S. policies and programs in global health;
- 2. Health problems in developing countries; and
- 3. Health issues of mutual concern to the United States and other industrialized and industrializing societies.

The mission of the Board is to provide expert analysis and judgments to the National Academies, the United States government, and to other appropriate audiences, on the meaning to the United States of health developments beyond its borders, and areas of U.S. international health investment that are most likely to benefit the health of the U.S. population and promote global well-being, security, and economic development.

## **Highlights of Recent Publications**

### **CONSENSUS REPORTS**

- <u>Vaccine Research and Development to Advance Pandemic and Seasonal Influenza</u> <u>Preparedness and Response: Lessons from COVID-19</u> (November 17, 2021) (collaboration with NAM)
- <u>Public Health Lessons for Non-Vaccine Influenza Interventions: Looking Past COVID-19</u> (November 17, 2021) (collaboration with NAM)
- <u>Countering the Pandemic Threat Through Global Coordination on Vaccines: The Influenza</u> <u>Imperative (November 17, 2021) (collaboration with NAM)</u>
- <u>Globally Resilient Supply Chains for Seasonal and Pandemic Influenza Vaccines</u> (November 17, 2021) (collaboration with NAM)
- <u>Combating Antimicrobial Resistance and Protecting the Miracle of Modern Medicine</u> (October 20, 2021) (collaboration among BPH, BGH, BANR/DELS)
- <u>Improving the CDC Quarantine Station Network's Response to Emerging Threats</u> (June, 2022) (collaboration among BGH [lead] and BPH)

### WORKSHOP PROCEEDINGS

- <u>Toward a Post-Pandemic World: Lessons from COVID-19 for Now and the Future: Proceedings</u> of a Workshop (July, 2022)
- <u>Innovations for Tackling Tuberculosis in the Time of COVID-19: Proceedings of a Workshop</u> (March 24, 2022)
- Lessons Learned in Health Professions Education from the COVID-19 Pandemic, Part 2: Proceedings of a Workshop (March 1, 2022)
- Systematizing the One Health Approach in Preparedness and Response Efforts for Infectious
   Disease Outbreaks: Proceedings of a Workshop (January 11, 2022)
- Innovations for Tackling Tuberculosis in the Time of COVID-19: Current Tools and Challenges: <u>Proceedings of a Workshop—in Brief (December 13, 2021)</u>
- <u>The Utility, Feasibility, Security, and Ethics of Verifiable COVID-19 Credentials for International</u> <u>Travel: Proceedings of a Workshop—in Brief (December 2, 2021)</u>
- Using Syndemic Theory and the Societal Lens to Inform Resilient Recovery from COVID-19: Toward a Post-Pandemic World: Proceedings of a Workshop in Brief (July 27, 2021)
- Lessons Learned in Health Professions Education During the COVID-19 Pandemic, Part 1: Proceedings of a Workshop (July 13, 2021)
- <u>The Critical Public Health Value of Vaccines: Tackling Issues of Access and Hesitancy:</u> <u>Proceedings of a Workshop</u> (April 29, 2021)



## **Convening Activities**

### **FORUMS/ROUNDTABLES**

#### Forum on Microbial Threats

Chair: Peter Daszak, Vice-Chair: Kent E. Kester; Director: Julie Liao

Workshops and Events:

- <u>Applying Lessons Learned from COVID-19 Research and Development to Future Epidemics: A</u> <u>Workshop</u> (December 7-8, 2022)
- <u>Accelerating the Development of Rapid Diagnostics to Address Antibiotic Resistance A</u> <u>Workshop</u> (collaboration among Forum on Microbial Threats/BGH, Forum on Drug Discovery, Development, and Translation (HSP), and the Forum on Medical and Public Health Preparedness for Disasters and Emergencies (HSP)) (October 13-14, 2022)
- <u>The Role of Agricultural Practices on Development of Antimicrobial Resistant Microbes Affecting</u> <u>Human Health: A Workshop Series</u> (June 6, 13, and 27, 2022)
- <u>Towards a Post-Pandemic World: Lessons from COVID-19 for Now and the Future: A Workshop</u> (March 17 and September 21-24, 2021)
- Innovations for Tackling Tuberculosis in the Time of COVID-19: A Two-Part Workshop Series (July 22, September 14-16, 2021)
- <u>Pivotal Interfaces of Environmental Health and Infectious Disease Research to Inform</u> <u>Responses to Outbreaks, Epidemics, and Pandemics - A Workshop</u> (collaboration among Forum on Microbial Threats/BGH and Standing Committee on Use of Emerging Science for Environmental Health Decisions/DELS) (June 8-9, 2021)
- Integrating Public and Ecosystem Health Systems to Foster Resilience in Social-ecological Systems: A Workshop to Identify Research to Bridge the Knowledge-to-action Gap (collaboration among Forum on Microbial Threats/BGH, Board on Life Sciences/DELS, Board on Atmospheric Sciences and Climate/DELS, Board on Environmental Studies and Toxicology/DELS) (TBD, probably Aug/Sep 2022)
- One Health Action Collaborative

#### **Global Forum on Innovation in Health Professional Education**

Co-Chairs: Patrick DeLeon and Zohray Talib; Director: Patricia Cuff

Workshops and Events:

- <u>Exploring a Culture of Fairness, Respect, and Anti-Racism Through Diversity, Equity, and</u> <u>Inclusion in Health Professions Education: A Workshop Series</u> (February 9, 22, March 23, 2022)
- <u>Exploring the Role of Health Professional Students and Trainees as Members of the Health</u> <u>Workforce: A Workshop Series</u> (September 30 and October 27, 2021)
- Lessons Learned in Health Professions Education from the COVID-19 Pandemic: A Workshop Series
  - <u>Lessons Learned in Health Professions Education from the COVID-19 Pandemic: A</u> <u>Workshop</u> (December 3, 2020)
  - <u>Lessons Learned in Health Professions Education from the COVID-19 Pandemic: Part</u> <u>2 of a Workshop Series: Scenario Planning Session</u> (April 7, 2021)



- <u>Lessons Learned in Health Professions Education from the COVID-19 Pandemic: April</u> <u>22 Public Workshop</u> (April 22, 2021)
- <u>Closing Session: Lessons Learned in Health Professions Education from the COVID-</u> <u>19 Pandemic: A Workshop Series</u> (May 25, 2021)

### **STANDING COMMITTEES:**

 <u>Standing Committee On Emerging Infectious Diseases and 21st Century Health Threats</u> (*collaboration among HSP [lead] and BGH*) Chair: Harvey Fineberg; Director: Lisa Brown

### **PROJECTS UNDER DEVELOPMENT**

- Science-based Approaches for Prioritization of Global Health Security Capabilities (with Board on Life Sciences (BLS)/Division on Earth and Life Studies (DELS))
- Exploration of Critical Issues to Address in Post-COVID-19 Pandemic Research Enterprise (with BLS/DELS and Policy and Global Affairs Division (PGA))
- Exploring NASEM's Role in Supporting Refugee Health, Safety and Security (with Committee on Populations/Division of Behavioral and Social Science and Education (DBASSE) and Committee on Human Rights (CHR)/PGA)
- Preventing Global Violence Against Health Care Providers (with CHR/PGA and National Academy of Medicine)



### Board on Global Health Membership

#### Ann E. Kurth, Ph.D., CNM, M.P.H., FAAN

*(Co-Chair)* Dean and Professor Yale University School of Nursing

#### Lukoye Atwoli, MBChB, MMed Psych, Ph.D.

(Co-Chair) Professor of Psychiatry and Dean Medical College East Africa Aga Khan University

#### Cheryl A. Anderson, Ph.D., M.P.H., M.S.

Professor and Dean Herbert Wertheim School of Public Health and Human Longevity Science University of California, San Diego

#### Ravi Anupindi, M.E., M.S., Ph.D.

Colonel William G. and Ann C. Svetlich Professor of Operations Research and Management Stephen M. Ross School of Business University of Michigan, Ann Arbor

#### Kelly Baker, Ph.D.

Assistant Professor of Occupational and Environmental Health and Epidemiology College of Public Health University of Iowa

#### Michele Barry, M.D.

Senior Associate Dean and Director Center for Innovation in Global Health Stanford University

#### Chris Beyrer, M.D., M.P.H.

Desmond M. Tutu Professor Department of Epidemiology Johns Hopkins Bloomberg School of Public Health

#### Sarah Cleaveland, Ph.D.

Institute of Biodiversity, Animal Health and Comparative Medicine University of Glasgow

#### Malick Diara, M.D., M.B.A., M.P.H.

Public Health Manager Workplace Wellness & Infectious Disease Control Programs Global Medicine and Occupational Health Department ExxonMobil Corporation

#### Isabel Garcia, D.D.S., M.P.H.

Dean University of Florida College of Dentistry

#### Lawrence O. Gostin, J.D.

University Professor and Founding Linda and Timothy O'Neill Professor of Global Health Law Georgetown University Law Center

#### Andrew Kanter, M.D., M.P.H., FACMI

Assistant Professor of Clinical Biomedical Informatics and Clinical Epidemiology Columbia University

#### Karestan C. Koenen, Ph.D.

Professor Department of Epidemiology Harvard T.H. Chan School of Public Health

#### Orin Levine, Ph.D.

Director, Vaccine Delivery Program The Bill & Melinda Gates Foundation

#### Maureen Y. Lichtveld, M.D., M.P.H.

Dean, Graduate School of Public Health Professor, Environmental and Occupational Health Jonas Salk Chair in Population Health University of Pittsburgh

#### Gbenga Ogedegbe, M.D., M.P.H., FACP

Professor of Population Health and Medicine Chief, Division of Health and Behavior Director, Center for Healthful Behavior Change New York University School of Medicine



**Dorothy Peprah, Ph.D., M.P.H.** Senior Global Health Security Agenda Advisor

United States Agency for International Development

#### Scott C. Ratzan, M.D., M.P.A.

Executive Director Business Partners for Sustainable Development U.S. Council for International Business Senior Scholar The City University of New York Graduate School of Public Health and Health Policy

#### Carlos del Rio, M.D.

NAM Foreign Secretary National Academy of Medicine Distinguished Professor of Medicine Division of Infectious Diseases Emory University School of Medicine

**Kathleen H. Sienko, S.M., Ph.D.** Arthur F. Thurnau Professor Department of Mechanical Engineering University of Michigan

#### Sarah Tishkoff, Ph.D., M.Phil.

David and Lyn Silfen University Professor Departments of Genetics and Biology University of Pennsylvania

### Board on Global Health Staff

#### Elizabeth Ashby, M.S.

Associate Program Officer (202) 334-2248 EAshby@nas.edu

#### Claire Biffl

Research Assistant (202) 334-2178 CBiffl@nas.edu

#### Patricia A. Cuff, M.S., M.P.H.

Director, Global Forum on Innovation in Health Professional Education (202) 334-3969 <u>PCuff@nas.edu</u>

Hannah Goodtree Research Associate (202) 334-1471 hgoodtree@nas.edu Justin Hammerberg Senior Program Assistant JHammerberg@nas.edu

Julie Liao, Ph.D. Director, Forum on Microbial Threats (202) 334-2191 JLiao@nas.edu

Julie A. Pavlin, M.D., Ph.D., M.P.H. Senior Board Director (202) 334-2171 JPavlin@nas.edu

Emilie Ryan-Castillo Research Assistant (202) 334-2322 ERyanCastillo@nas.edu

## Workshop Background

Valley fever (coccidioidomycosis), caused by the *Coccidioides immitus* fungus, is prevalent in the southwestern United States, Central America, and South America, and was recently found in south-central Washington. The fungus lives in the soil, and infection occurs after inhaling the fungal spores. Approximately 40% of those who inhale spores will become symptomatic (fever, cough, chills, etc.), and those at highest risk are persons exposed out of doors to fungus-laden soil (farm/construction workers, firefighters, military undergoing training, prison systems), pregnant women, the elderly, and those with compromised immune systems. Certain ethnic groups (Blacks, Latinos, Filipinos) are more likely to experience severe disease. Approximately 5-10% of people who get valley fever will develop serious or long-term pulmonary problems to include pneumonia, pulmonary nodules, pleural effusion and acute respiratory distress syndrome, and approximately 1% will have spread to other parts of the body such as the central nervous system, skin, bones or joints (1). Curative therapy does not exist for this disease. In 2019, there were 18,407 cases of valley fever in the U.S. reported to the CDC, with the understanding that tens of thousands of illnesses probably occur and are misdiagnosed because of lack of testing, and there are approximately 200 deaths from valley fever each year (2).

The region most affected by valley fever in the southwestern United States has 30 million inhabitants and comprises 10% of the entire nation and is projected to increase with climate change (3). In addition, people visiting these areas are at risk of acquiring the disease. The estimated cost of valley fever to California was \$700 million in 2017 (4). A recent economic evaluation estimates that annual medical costs, lost income and economic welfare losses for valley fever were \$400,000 per case with an annual average cost of \$3.9 billion/year. With climate change and population growth, it is estimated that valley fever may increase by up to 164% by 2050 and 380% by 2090 (5). Valley fever's societal toll is magnified by fatigue and pain in chronic cases, and by costly legal settlements arising from failure-to-protect civil suits.

Because infection, for many, results in life-long immunity from future valley fever, the idea of preventing valley fever through vaccination has been considered since the mid-20th century. In the 1990s, a national collaborative Valley Fever Vaccine Project began work towards a vaccine. Recently, the Vaccine Project has invented a new vaccine candidate that is safe and effective in animal models, and is now in commercial development to prevent valley fever in dogs. It is probable a similar vaccine could also prevent valley fever in people (6).

1. Galgiani JN, Ampel NM, Blair JE, Catanzaro A, Johnson RH, Stevens DA, et al. Coccidioidomycosis. Clin Infect Dis 2005;41:1217-23.

2. CDC. Valley fever (coccidioidomycosis) statistics.

www.cdc.gov/fungal/diseases/coccidioidomycosis/statistics.html (accessed February 5, 2022). 3. Pearson D, Ebisu K, Wu X, Basu R. A review of coccidioidomycosis in California: Exploring the intersection of land use, population movement, and climate change. Epidemiologic Reviews 2019;41(1):145-57.

4. Wilson L, Ting J, Lin H, Shah R, MacLean M, Peterson MW, Stockamp N, Libke R, Brown P. The rise of Valley fever: Prevalence and cost burden of Coccidioidomycosis infection in California. Int J Environ Res Public Health 2019;16(7):1113.

5. Gorris ME, Neumann JE, Kinney PL, Sheahan M, Sarofim MC. Economic valuation of coccidioidomycosis (valley fever) projections in the United States in response to climate change. Weather Clim Soc 2021;13(1):107-23.

6. Valley Fever Center for Excellence. Ongoing research. https://vfce.arizona.edu/valley-fever-dogs/research-valley-fever-dogs/ongoing-research (accessed February 5, 2021).



## Workshop Statement of Task

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize a workshop to review the epidemiology of coccidioidomycosis (Valley Fever), its impact on populations, and currently available diagnostic and treatment options. The workshop will explore prospects for control of the disease through vaccination. Specifically, the workshop will feature invited presentations and discussions on the following topics:

- Overview of valley fever in human and animal populations to include current surveillance programs and diagnostic and treatment options;
- Epidemiology of valley fever in the United States and throughout the Americas;
- Impact of climate change on persistence and spread of Coccidioides;
- Risk of disease by occupation, ethnicity, and immunogenetic susceptibility and impact on endemic communities;
- Economic impact of valley fever;
- Immunology of valley fever and potential prevention through vaccination;
- Potential vaccine platforms and current animal models;
- Use of knowledge gained across multiple fungal diseases;
- Regulatory pathways for a fungal disease vaccine;
- Vaccine acceptance and communication.

Speakers and discussants will contribute perspectives from academia, local, national and international public health, pharmaceutical industries, and government regulatory institutions. The planning committee will organize the workshop, select and invite speakers and discussants, and moderate the discussions.



### **Sponsors**

- U.S. Centers for Disease Control and Prevention
- Anivive Lifesciences
- California Health Care Foundation
- Cure Drug Repurposing Collaboratory
- F2G
- Fortress Biotech
- MiraVista Diagnostics
- Mycovia Pharmaceuticals
- Nielsen BioSciences
- Valley Fever Americas Foundation

### **Planning Committee**

#### George Thompson (chair)

UC Davis Health Medical Center

Bridget Barker Northern Arizona University

#### Karen Ehnert

Los Angeles County Department of Public Health

#### John Galgini

University of Arizona College of Medicine— Tucson Valley Fever Center for Excellence **Steve Holland** National Institute of Allergy and Infectious Diseases

Meritxell Riquelme Centro de Investigación Científica y de Educación Superior de Ensenada (CICESE)

#### Leonard Sacks

Food and Drug Administration Center for Drug Evaluation and Research

#### Gail Sondermeyer Cooksey California Department of Public Health



## Workshop Agenda

THURSDAY, NOVEMBER 17, 2022

Arnold and Mabel Beckman Center | 100 Academy Way, Irvine, CA Beckman Auditorium 8:30 AM – 6:00 PM PT

	Valley Fever: Status and Impacts
8:30-8:45	Welcome Remarks, Workshop Overview, and Goals Committee Remarks George Thompson, UC Davis Medical Center Workshop chair
8:45-10:15	Session 1: Introduction to Valley Fever         George Thompson, UC Davis Medical Center         Moderator         Overview of Valley Fever: Why Now?         Joshua Nosanchuk, Albert Einstein College of Medicine         Overview of the Disease in Humans         Neil Ampel, University of Arizona, Mayo Clinic in Arizona Care System         Valley Fever as a Veterinary Disease         Jane Sykes, University of California, Davis School of Veterinary Medicine         Valley Fever Fungus in the Environment         John Taylor, University of California, Berkeley         Patient Perspective         Monk Yun Rou
10:15-10:30	BREAK
10:30-12:45	Session 2: Current Status of Valley Fever Surveillance and Trends

NATIONAL ACADEMIES

[	
	<b>Bridget Barker,</b> Northern Arizona University <i>Moderator</i>
	Incidence of Human Disease <b>Mitsuru Toda,</b> U.S. Centers for Disease Control and Prevention
	Gail Sondermeyer Cooksey, California Department of Public Health
	Epidemiology of Valley Fever in Arizona <b>Shane Brady</b> , Arizona Department of Health Services
	The Future of Cocci
	Soil Mapping Jennifer Head-Zhutenegger, University of California, Berkeley School of Public Health
	Climate Change <b>Morgan Gorris,</b> Los Alamos National Laboratory
	Temporal and Spatial Drivers of <i>Coccidioides</i> in the Air <b>Dave Engelthaler,</b> TGen
12:45-1:45	LUNCH
1:45-3:00	Session 3: Disease Impact
	<b>John Galgiani,</b> University of Arizona College of Medicine-Tucson; Valley Fever Center for Excellence <i>Moderator</i>
	Cocci and Indigenous Populations <b>Shawnell Damon</b> , Indian Health Services
	Valley Fever Among California State Prison Residents: Epidemiology, Prevention, and Challenges <b>Kim Lucas,</b> California Correctional Health Care Services
	Occupational Valley Fever <b>Marie de Perio,</b> National Institute for Occupational Safety and Health. U.S. Centers for Disease Control and Prevention
	Economic Costs of Cocci George Rutherford, University of California San Francisco

NATIONAL ACADEMIES

3:00-4:30	Session 4: Coccidioides: The Organism and Hosts
	Marc Orbach, University of Arizona Moderator
	Ecology and Environment <b>Bridget Barker,</b> Northern Arizona University
	Host Genomics <b>Steve Holland,</b> National Institute of Allergy and Infectious Diseases. National Institutes of Health
	Genomics of <i>Coccidioides</i> Jason Stajich, University of California, Riverside
	Virulence of <i>Coccidioides</i> Anita Sil, University of California San Francisco
4:30-4:45	BREAK
4:45-6:00	Session 5: Current Status of Patient Management
	<b>Neil Ampel,</b> University of Arizona, Mayo Clinic in Arizona Care System <i>Moderator</i>
	Diagnostics – Current Methods and Challenges <b>Fariba Donovan</b> , University of Arizona College of Medicine
	Current Therapy: Past and Present Treatment Options George Thompson, UC Davis Medical Center
	Developing New Therapies for Coccidioidomycosis: A Developer's Perspective <b>John Rex</b> , F2G
	Summary and Adjourn
	END OF DAY 1

### FRIDAY, NOVEMBER 18, 2022

Arnold and Mabel Beckman Center | 100 Academy Way, Irvine, CA

#### Beckman Auditorium

8:30 AM - 4:00 PM PT

	Valley Fever: Solutions	
8:30-8:40	Welcome Remarks, Review of Day 1 George Thompson, UC Davis Medical Center Workshop chair	
8:40-10:25	Session 6: Improved Surveillance Strategies <u>Ecological Surveillance</u> Gail Sondermeyer Cooksey, California Department of Public Health <i>Moderator</i>	
	Soil and Air Monitoring Dan Kollath, Northern Arizona University Development of Air-Sampling and Molecular Detection Methods for <i>Coccidioides</i> Ana Litvintseva, U.S. Centers for Disease Control and Prevention Wildlife Surveillance Paris Salazar-Hamm, University of New Mexico	
	<ul> <li><u>Enhanced Diagnostics</u></li> <li>Technology to Increase Sensitivity of Diagnostics</li> <li><u>Amanda Burnham-Marusich</u>, Dx Discovery; University of Nevada, Reno School of Medicine</li> <li>Future of Diagnostics: Metabolomics</li> <li><u>Ian McHardy</u>, Scripps Health</li> </ul>	
	Breath Tests to Diagnose Valley Fever and Measure Disease Burden Heather Bean, Arizona State University Discussion	
10:25-10:35	BREAK	

NATIONAL ACADEMIES

to Humans Lisa Shubitz, University of Arizona College of Medicine Chiung-Yu Hung, University of Texas at San Antonio Prospects for the development of nucleic acid vaccines and a preclinical nonhum primate model for Valley Fever Deb Fuller, University of Washington School of Medicine Development Pathway of a Live, Attenuated Vaccine against Cocci: From Dogs to People Tom Monath, Crozet BioPharma Update on the NIAID Strategic Plan for Research to Develop a Valley Fever	10:35-11:45	<ul> <li>Session 7: Medical Countermeasures</li> <li>George Thompson, UC Davis Medical Center Moderator</li> <li>One Health Perspective: Medications for Humans and Animals Marcus Teixeira, Northern Arizona University; University of Brasilia</li> <li>Challenges of Clinical Trial Designs for Therapeutics and Vaccines John Galgiani, University of Arizona College of Medicine-Tucson; Valley Fever Center for Excellence</li> </ul>
12:45-2:45       Session 8: Vaccines         Panel Discussion - Current Approaches to Developing Valley Fever Vaccines         George Rutherford, University of California San Francisco         Moderator         Coccidioidal Immunization: Past, Present & Future         Royce Johnson, Kern Medical         Δcps1 Vaccine to Prevent Valley Fever in Dogs: A One Health Journey from Planto Humans         Lisa Shubitz, University of Arizona College of Medicine         Chiung-Yu Hung, University of Texas at San Antonio         Prospects for the development of nucleic acid vaccines and a preclinical nonhum primate model for Valley Fever         Deb Fuller, University of Washington School of Medicine         Development Pathway of a Live, Attenuated Vaccine against Cocci: From Dogs to People         Tom Monath, Crozet BioPharma         Update on the NIAID Strategic Plan for Research to Develop a Valley Fever		
<ul> <li>Panel Discussion - Current Approaches to Developing Valley Fever Vaccines</li> <li>George Rutherford, University of California San Francisco <i>Moderator</i></li> <li>Coccidioidal Immunization: Past, Present &amp; Future Royce Johnson, Kern Medical</li> <li><i>Acps1</i> Vaccine to Prevent Valley Fever in Dogs: A One Health Journey from Plan to Humans</li> <li>Lisa Shubitz, University of Arizona College of Medicine</li> <li>Chiung-Yu Hung, University of Texas at San Antonio</li> <li>Prospects for the development of nucleic acid vaccines and a preclinical nonhum primate model for Valley Fever</li> <li>Deb Fuller, University of Washington School of Medicine</li> <li>Development Pathway of a Live, Attenuated Vaccine against Cocci: From Dogs to People</li> <li>Tom Monath, Crozet BioPharma</li> <li>Update on the NIAID Strategic Plan for Research to Develop a Valley Fever</li> </ul>	11:45-12:45	LUNCH
	12:45-2:45	<ul> <li>Panel Discussion - Current Approaches to Developing Valley Fever Vaccines</li> <li>George Rutherford, University of California San Francisco <i>Moderator</i></li> <li>Coccidioidal Immunization: Past, Present &amp; Future Royce Johnson, Kern Medical</li> <li><i>Acps1</i> Vaccine to Prevent Valley Fever in Dogs: A One Health Journey from Plants to Humans</li> <li>Lisa Shubitz, University of Arizona College of Medicine</li> <li>Chiung-Yu Hung, University of Texas at San Antonio</li> <li>Prospects for the development of nucleic acid vaccines and a preclinical nonhuman primate model for Valley Fever</li> <li>Deb Fuller, University of Washington School of Medicine</li> <li>Development Pathway of a Live, Attenuated Vaccine against Cocci: From Dogs to People</li> <li>Tom Monath, Crozet BioPharma</li> <li>Update on the NIAID Strategic Plan for Research to Develop a Valley Fever Vaccine</li> <li>Dona Love, National Institute of Allergy and Infectious Diseases, National Institutes</li> </ul>



	<i>Discussion</i> <b>Scott Stibitz,</b> Center for Biologics Evaluation and Research, U.S. Food and Drug Administration
2:45-2:55	BREAK
2:55-3:45	Communication and Engagement George Thompson, UC Davis Medical Center Neil Ampel, University of Arizona, Mayo Clinic in Arizona Care System <i>Moderators</i> Overview of FORWARD Act Katherine Phillips, Office of Senator Mark Kelly Open public discussion and comment
3:45-4:00	Summary and Close
	END OF WORKSHOP



## **Planning Committee Biographies**

**George Thompson, M.D.**, *chair,* is a Professor of Medicine at UC Davis Medical Center with a joint appointment in Internal Medicine, Division of Infectious Disease and the Department of Medical Microbiology and Immunology. Dr. Thompson specializes in the care of patients with invasive fungal infections and has research interest in clinical trials, fungal diagnostics, and host immunogenetics. His current research focuses on the development of new antifungal agents, mechanisms of resistance, and molecular causes of adverse side effects. Dr. Thompson has published over 180 papers in peer-reviewed journals, and serves as several national and international committees and advisory boards including the Infectious Diseases Society of America, Coccidioidomycosis Study Group and the Mycoses Study Group where he chairs the education committee. He received his M.D. from the University of Missouri.

**Bridget Barker, Ph.D., M.S.,** received her B.A. in Biology and M.S. in Ecological Genetics from the University of Montana. Dr. Barker started her PhD program as an IGERT Fellow at the University of Arizona in 2004. It was at this time she became interested in working on human fungal pathogens, specifically Coccidioides immitis and C. posadasii, the causative agents of coccidioidomycosis, more commonly known as Valley Fever. In 2009, Dr. Barker completed her Ph.D. in Genetics with co-mentors Dr. Scott Kroken and Dr. Steven Rounsley, and then started her postdoctoral work at Montana State University, where she worked to characterize the sterol regulatory element binding protein in Aspergillus fumigatus, in the lab of Dr. Robert Cramer. In 2013, she joined the faculty at TGEN-North, and returned to working on Coccidioides spp. with the assistance of an National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID) K-22 award. In 2016 she became tenure track faculty at Northern Arizona University (NAU) in the Pathogen and Microbiome Institute (PMI), and a member of the Biology faculty. In 2020, she was promoted to Associate Professor with tenure in the Department of Biological Sciences at NAU.

**Karen Ehnert, D.V.M., M.P.V.M., M.S.,** is the director of the Veterinary Public Health Program at the Los Angeles County Department of Public Health. Dr. Ehnert has over 32 years of experience in the field of public health and is passionate about her work to protect human health through monitoring and controlling animal diseases. After receiving a Master's of Preventive Veterinary Medicine (epidemiology), she completed a residency with the California Department of Public Health. She then became the Monterey County public health epidemiologist and county communicable disease control officer. In 2000, Dr. Ehnert accepted a position as the senior veterinarian with the Los Angeles County Department of Public Health's Veterinary Public Health Program. She was the acting director for three and a half years, before becoming the director in February 2014. In addition to her work at the Veterinary Public Health Program, Dr. Ehnert serves as a clinical professor with the Western University College of Veterinary Medicine, and oversees four-week clinical practicums for senior veterinary students. Dr. Ehnert received her Doctorate in Veterinary Medicine, Masters of Preventative Veterinary Medicine (epidemiology), and Masters of Science (animal science) from the University of California at Davis. She is board certified in veterinary preventive medicine and has been on the American Veterinary Medical Association (AVMA) Council on Public Health for six years.



**John Galgiani, M.D.,** was born in San Francisco, received his B.A. from Stanford University, his M.D. from Northwestern University, and a fellowship in Infectious Diseases from Stanford. In 1978, Dr. Galgiani joined the faculty of the University of Arizona, where he is currently Professor of Medicine. Dr. Galgiani has focused his career primarily on the special problems of coccidioidomycosis (Valley fever) and its impact on the general population and special groups such as organ transplant recipients and patients with AIDS. In 1996, Dr. Galgiani founded the Valley Fever Center for Excellence to disseminate information about Valley Fever, help patients with the severest complications of this disease, and to encourage research into the biology and diseases of its etiologic agent.

Steve Holland, M.D., received his M.D. from the Johns Hopkins University School of Medicine in 1983. He remained at Johns Hopkins for his internal medicine residency, chief residency, and fellowship in infectious diseases. He then came to the NIH, National Institute of Allergy and Infectious Diseases (NIAID), Division of Intramural Research (DIR) as a National Research Council fellow working on transcriptional regulation of HIV. A few years later, Dr. Holland shifted his research to the host side, with a focus on phagocyte defects and their associated infections. His work centered on the pathogenesis and management of chronic granulomatous disease, as well as other congenital immune defects affecting phagocytes, including those predisposing to mycobacterial diseases. He was chief of Laboratory of Clinical Infectious Diseases from 2004 to 2016 until selected as director of the NIAID, DIR in 2016. In NIAID, he continues to lead the Immunopathogenesis Section, a therapeutic and research program taking a fully integrated approach to infectious disease, incorporating the molecular genetics of the host and the pathogen as well as mechanisms of pathogenesis that allow the development and study of novel therapeutics. The integrated bench-to-bedside model is intrinsic to the Immunopathogenesis Section approach and is reflected in the close involvement of trainees (both M.D. and Ph.D.) in laboratory work and in the clinical appreciation of disease, which together add new insights into mechanisms of action and avenues of therapy. New protocols in Coccidioides infections and pathogenesis of mycobacterial infections are in progress.

**Meritxell Riquelme, Ph.D., M.Sc.,** is a Research Professor at the Center for Scientific Research and Higher Education of Ensenada (CICESE), Baja California, Mexico. She completed a B.Sc. in Biology at the University of Barcelona, Spain. She received a M.Sc. degree in Plant Pathology and a Ph.D. in Microbiology from the University of California, Riverside. She was a postdoctoral fellow at the University of Oxford, United Kingdom. Her group studies secretory routes of vesicles involved in hyphal growth of *Neurospora crassa*. Additionally, she studies the ecological distribution of Coccidioides spp. in Baja California and the fungal diversity of deep-sea sediments of the Gulf of Mexico. She is editor of Fungal Genetics and Biology, The Cell Surface, and Communications Biology. She has served in several committees of the Mycological Society of America. She was elected member of the Neurospora Policy Committee (2008-2012), the Fungal Genetics Policy Committee (2013-2019), the International Fungal Biology Conference Steering Committee (since 2014), and the Executive Committee of the International Mycological Association (since 2014). She is a member of the Mexican Academy of Sciences. In 2018 she received the B. O. Dodge award for her contributions on Neurospora research, in 2019 she was elected Fellow of the Mycological Society of America, and in 2020 she was elected Fellow of the American Academy of Microbiology.



Leonard Sacks, MBBCh, received his medical education in South Africa at the University of the Witwatersrand receiving his MBBCH in 1979. He moved to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa and he joined the Food and Drug Administration (FDA) in 1998 as medical reviewer in the Office of New Drugs. Subsequently he served as acting director of the Office of Critical Path Programs and is currently associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research at FDA. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. He holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.

**Gail Sondermeyer Cooksey, M.P.H.**, is an infectious diseases epidemiologist whose primary interests include mycotic diseases, emerging infectious diseases, health equity, and epidemiology and surveillance methodologies. Ms. Sondermeyer Cooksey has a Bachelor of Science in biology and peace and justice studies from Villanova University (2009) and a Master of Public Health degree in infectious disease epidemiology from the University of California, Berkeley (2011). Since 2012, Ms. Sondermeyer Cooksey has worked at the California Department of Public Health (CDPH) focusing on Valley fever, other mycotic diseases, and COVID-19. Her Valley fever work at CDPH has included conducting, improving, and reporting on Valley fever surveillance, investigating occupational outbreaks of Valley fever, and assisting with Valley fever health education for the general public, providers, workers, and employers in California.



## **Speaker Biographies**

**Neil Ampel, M.D.**, is currently a Professor Emeritus of Medicine and Immunobiology at the University of Arizona and a Supplemental Clinician in Infectious Diseases at Mayo Clinic in Arizona. He has been clinically involved in the management of patients with coccidioidomycosis for the past 37 years and currently sees patients with coccidioidomycosis two days each week at Mayo Clinic. He also has a research interest in the cellular immune response to coccidioidomycosis and is involved in two NIH-funded research projects regarding this. He is also the President of the Coccidioidomycosis Study Group, which holds an annual meeting presenting recent research on this disease.

**Heather Bean, Ph.D.,** is a bioanalytical chemist who specializes in untargeted metabolomics and biomarker discovery. She received a Ph.D. in Chemistry from Georgia Tech in 2008, then conducted postdoctoral research at the University of Vermont and Dartmouth College as a Postdoctoral Fellow of the Cystic Fibrosis Foundation. In 2015 she joined the School of Life Sciences at Arizona State University as an Assistant Professor, and was promoted to Associate Professor in 2022. Heather and her research team at ASU study the volatile metabolites produced by acute lung infections, polymicrobial communities in chronic lung infections, and microbiomes in other natural and engineered environments. In the context of coccidioidomycosis, the Bean Lab is working on developing a breath test to diagnose Valley fever and differentiate it from bacterial, viral, and non-infectious etiologies of pneumonia.

**Shane Brady, M.P.H.**, is the Deputy State Epidemiologist at the Arizona Department of Health Services (ADHS). He has been an epidemiologist with the department since 2012 and has overseen the Valley fever, vaccine preventable disease, respiratory disease, and infectious disease surveillance programs. His work on Valley fever has been focused on enhancing surveillance to better understand the impact of Valley fever and providing education to the public and providers. Shane received his Bachelor of Science in Biology and Master of Public Health in Epidemiology from Kent State University.

**Amanda Burnham-Marusich, Ph.D., M.S.**, researches improving public health through the creation of accessible diagnostics for infectious diseases. For the last 9 years, her research has focused on i) developing high-quality antibodies for difficult fungal polysaccharides and bacterial proteins, and ii) incorporating these antibodies into rapid, low-cost, point-of-care immunoassay diagnostics. Over the years, she has developed >60 monoclonal antibodies for downstream diagnostic use against the following disease targets: coccidioidomycosis, invasive candidiasis, invasive aspergillosis, mucormycosis, dermatophytosis, and pertussis. Dr. Burnham-Marusich is also the Principal Investigator on several SBIR grants and contracts from NIH to develop immunoassay diagnostic for coccidioidomycosis. Her primary employment (75%) is with DxDiscovery, an early-stage research and development biotechnology company focused on immunoassay diagnostic development. She is also a faculty research scientist (25%) in the Diagnostic Discovery Laboratory of Dr. Thomas Kozel at the University of Nevada, Reno School of Medicine. She received her B.S. and M.S. in Biological Sciences from Stanford University and her Ph.D. in Cell and Molecular Biology from the University of Nevada, Reno.

**Shawnell Damon, M.P.H., M.Sc.,** is the granddaughter of the late Molly Damon, the late Code Talker, Anson Damon, Sr., and the daughter of Lucinda Damon from Old Sawmill, AZ. Shawnell's born for the Ashiihi and her paternal clans are bilaganna, her cheii's are Todichii nii. Shawnell is the mother of two lovely little girls, Avianna Damon- Showalter and Giselle Damon- Showalter. She was born and raised on



the Navajo Nation. Shawnell Damon is the Acting Public Health Director across Navajo Area Indian Health Service. She works to implements and evaluate Public Health programs that include teaching and training through public health activities and events which focuses on self-awareness, health literacy, and cultural competency that may be applied to elevate health status physically, mentally, and spiritually.

**CAPT Marie de Perio, M.D., FIDSA**, is the Senior Medical Advisor in the Office of the Director at the National Institute for Occupational Safety and Health (NIOSH), part of the U.S. Centers for Disease Control and Prevent (CDC). She is a physician board certified in internal medicine and infectious diseases, and she is the NIOSH subject matter expert in occupational infectious diseases. She has led multiple investigations of infectious diseases affecting workers, including valley fever among prison workers, published her findings widely, and contributed to national guidelines. Dr. de Perio has also worked on CDC's past responses to infectious diseases outbreaks including pandemic H1N1 influenza, Ebola, and Zika, COVID-19, and most recently monkeypox.

**Fariba Donovan, M.D., Ph.D.,** researches early pathogen-host interaction in coccidioidomycosis, as well as earlier and improved diagnosis of Valley fever. In her basic research she is studying early coccidioidomycosis events to better understand altered or dysfunctional metabolic pathways as evidence of genetic alterations and a risk factor for severe coccidioidomycosis or disseminated coccidioidomycosis (DCM). In a recently published study, her team found a 2.4 fold increased risk of DCM in autoimmune patients (such as those with rheumatoid arthritis) on biological response modifiers. This work has led to a recent proposal to uncover clinical markers and to identify those at risk for severe coccidioidomycosis. Dr. Donovan's clinical research goals include the development of more rapid, reliable, and cost-effective Valley fever point-of-care testing which will speed and improve diagnostic accuracy and antimicrobial stewardship. She recently completed a prospective study evaluating a rapid lateral flow assay test for Valley fever diagnosis. Her earlier work has demonstrated the human and financial burden of delays in Valley fever diagnosis. Her overall work epitomizes the goal of taking basic research and applying it at the bedside for the benefit of the entire community.

Dave Engelthaler, Ph.D., M.S., is a Professor and the Director of TGen North, the infectious disease division of the non-profit Translational Genomics Research Institute. He is also the Scientific Director of the TGen North Clinical Laboratory, which was stood up in March 2020 to specifically provide COVID-19 testing and has provided tests for tens of thousands of Arizonans and has sequenced over 60,000 strains of SARS-CoV-2. Dave has studied coccidioidomycosis for nearly 30 years, conducting the first ever fungal genomic epi investigation (on a Valley fever transplant-associated outbreak), leading the largest Coccidioides genomic sequencing analysis study, developing and validating new molecular clinical and research tools and developing novel theories on global Coccidoides dispersal. Dave also oversees a number of research groups working on understanding infectious diseases and pathogens such as tuberculosis, Cryptococcus, HAIs, zoonoses and others. His team at TGen also provides genomic services to CDC, state, local and tribal health departments. He has published over 150 scientific papers and chapters on epidemiology, disease ecology, genetics, and microbiology and he has over two dozen patented inventions, including the only diagnostic polymerase chain reaction assay for Valley fever to receive FDA clearance, and multiple small molecules with anti-coccidioidal activity. Dave received his master's degree in microbiology from Colorado State University and his Ph.D. in genomics at Northern Arizona University. Dave was previously the Arizona State Epidemiologist and a biologist for the CDC and the U.S. Forest Service. Dave has worked in federal, state and local government, and has started forprofit and non-profit businesses. Dave sits on a number of local and national Boards and he proudly led the establishment of Flagstaff, Arizona as "America's First STEM City".



**Deborah Fuller, Ph.D.**, is a Professor in the Department of Microbiology at the University of Washington School of Medicine and Associate Director of Research at the Washington National Primate Research Center. Dr. Fuller leads a team that is developing nucleic acid-based vaccines and antivirals including DNA and RNA vaccines for infectious diseases. She led the translation of two vaccines from bench to clinical trials including the first DNA vaccine to induce protective levels of immunity in humans, and in the past year, played a key role in advancing several vaccines and antivirals for the prevention and treatment of COVID-19 including a 2nd generation RNA vaccine for COVID-19 that entered human clinical trials in Spring 2021. She has authored over 100 manuscripts and book chapters and is a co-inventor on over a dozen patents. Dr. Fuller has served as a member of several National Institutes of Health study sections including Vaccines for Microbial Diseases and HIV/AIDS and in 2020-2020 served on the leadership team for NIH's COVID-19 Vaccines and Therapeutics Evaluation Network (COVTEN). She is also the cofounder of Orlance, Inc (www.orlance.com), a biotechnology company that aims to develop a needle-free nucleic acid vaccine platform and serves on the scientific advisory board for several biotechnology companies developing vaccines and therapeutics. Dr. Fuller regularly serves to inform the community and public on the science behind the vaccines, emerging infectious diseases and COVID-19. She has been featured on Bloomberg TV, CNN, NPR, and has contributed to numerous news articles, op-eds, podcasts and instructional videos published by The Washington Post, The Associated Press, The Wall Street Journal, Huffpost, Vox, Conversation.com and others, Her op-ed articles have been translated into multiple languages and read by millions of readers worldwide. Her most recent honors include the University of Washington Latinx Faculty Excellence in Research Awards in 2019, 2020 and 2022 and the Hope College Distinguished Alumni Award in 2021.

Morgan Gorris, Ph.D., M.S., is an Earth system scientist who studies GeoHealth: the nexus of health, humans, and the Earth system. She focuses on how weather and climate affect environmental infectious disease dynamics, including where diseases are a threat, forecasting the number of disease cases, and projecting how these diseases will respond to climate change. Dr. Gorris began studying Valley fever during her Ph.D. at the University of California, Irvine, under the advisement of Drs. Jim Randerson, Charlie Zender, and Kathleen Treseder. She is now a staff scientist at Los Alamos National Laboratory, where she continues her work on Valley fever and other diseases of interest to national security. Her initial study on Valley fever analyzed how climate and environmental conditions impact the number of Valley fever cases each year, focusing on the highly endemic areas of California and Arizona. She then became interested in updating the then-60 year old Valley fever endemicity map used by the CDC by using contemporary case data and climate conditions. Dr. Gorris and team were able to create a new model for estimating where Valley fever was endemic. They then used this model to estimate where Valley fever would be endemic in the future in response to climate change, and found what is now a disease endemic to the southwestern US may become a disease of the western US by year 2100. Her current work includes creating a forecasting model of Valley fever for the Central Valley of California and exploring how wildfires may affect the number of Valley fever cases.

**Jennifer Head-Zhutenegger, Ph.D., M.P.H.**, is Assistant Researcher and Lecturer in the Division of Environmental Health Sciences at University of California, Berkeley. Her research group examines the role of climate, public health policy, and individual behavior on infectious disease dynamics, with a focus on emerging and zoonotic disease. Dr. Head has led modeling research examining the impact of COVID-19 mitigation policies in schools; epidemiologic studies investigating the effect of climate extremes on emerging infectious diseases; and empirical research on the effect of pediatric vaccination on childhood



infections. Dr. Head received her B.S. in Chemical Engineering from Washington University in St. Louis, her M.P.H. in Global Environmental Health from Emory University, and her Ph.D. in Epidemiology from the University of California, Berkeley.

Chiung-Yu Hung, Ph.D., received her BS in Biology from the National Taiwan Normal University and her Ph.D. in Biological Sciences from the University of Texas at Austin. Dr. Hung's research is focused on development of a vaccine against pulmonary fungal infections and studies of the host-pathogen interactions utilizing multidisciplinary approaches including bioinformatics, molecular biology, genetic methodologies, cellular biology, and immunological techniques. Dr. Hung has over 20 years of experience in studies of protective immunity, characterization of fungal virulence factors and identification of fungal antigens for development of anti-fungal therapies, diagnosis assays and vaccines against Coccidioides infections. These fungi are known to live in the soil in the southwestern United States and parts of Mexico and Central and South America and they cause respiratory and disseminated diseases also known as Valley fever (FV). The most common clinical presentation of VF is pulmonary disease while dissemination of infection to skin, bone, and central nerve system can occur. Patients who present with severe acute pneumonia, chronic pulmonary VF, and disseminated coccidioidomycosis require antifungal therapy, which is potentially life-long with currently available drugs. There is urgent and unmet need to develop a human vaccine and better drugs against coccidioidomycosis. Her research is supported by NIH as well as other funding agencies. In 2020. Dr. Hung received the University of Texas at San Antonio (UTSA) President's Distinguished Achievement Award in Sciences for her research contributions to UTSA and her dedication to working to eradicate coccidioidomycosis. In 2022, her team received an NIH U19 grant to establish a San Antonio-based Coccidioidomycosis Collaborative Research Center that is focused on developing therapeutics and vaccines against coccidioidomycosis. Dr. Hung is also the recipient of The UTSA Inventor of the year award in 2022.

**Royce H. Johnson, M.D., FACP, FIDSA**, is the Chief of the Division of Infectious Disease in the Department of Medicine at Kern Medical as well as the Medical Director at the Valley Fever Institute, dedicated to fighting the battle against Valley Fever in Kern County. Dr. Johnson has been a Professor of Medicine with the David Geffen School of Medicine at UCLA since 1992. He has also served as a Professor of Clinical Sciences at CSUB He currently serves as Director of the Tuberculosis Clinic, Director of the Hansen's Disease Clinic, Hospital Epidemiologist, Hospital Employee Health Physician, and Associate of the Division of Pulmonary and Critical Care Medicine at Kern Medical. Dr. Johnson has been with Kern Medical since 1975, where he served as Chair in the Department of Medicine for 11 years. He also served as Director of Fulmonary Function Laboratory and Respiratory Therapy Service, Chief of the Division of Pulmonary and Critical Care Medicine, Director of Quality in the Department of Medicine, and as the Director of Kern Medical's Cancer Registry/Program. He was a Private Practice physician with Kern Faculty Medical Group for 16 years and held courtesy staff position with Mercy Hospital and with Bakersfield Memorial Hospital. Dr. Johnson has received the Lifetime Achievement Award from the Cocci Study Group and the Infectious Disease Society of California and been recognized as one of the Best Doctors in America on eight separate occasions.

**Daniel Kollath, Ph.D.,** received his Ph.D. In biology from Northern Arizona University where he studied under Dr. Bridget Barker. His dissertation focused on the ecology and epidemiology Valley fever in Arizona. He is interested how climate, microbial competitors in the soil, and vertebrate hosts all influence the pathogen in the environment and in turn effect human infection. He uses molecular ecology techniques, statistical and mathematical modeling to help understand the ecological patterns of



Coccidioides spp. (the causative agent of Valley fever) in order to improve the disease surveillance of this pathogen. He also has broad research interests in the field of disease ecology. He continues to work in the Barker lab at Northern Arizona University with the ecology of the organism as well as runs the murine model center to aid in the understanding of viral coinfections with Valley fever as well as aiding in the testing of a Valley fever vaccine.

**Ana Litvintseva, Ph.D.**, is the senior advisor for research at the Mycotic Diseases Branch (MDB), Centers of Disease Control and Prevention (CDC), She work with the Laboratory, Epidemiology and Data and Quality teams in our Branch on the development and implementation of an applied research program with the goal to prevent infection, injury, and death from fungal diseases. The MDB aims to understand how people get infected, how to prevent exposure and improve diagnostics and outcome of fungal infections. In collaboration with several domestic and international partners, we develop and evaluate novel diagnostic and surveillance methods, investigate molecular epidemiology and environmental reservoirs of pathogenic fungi, and develop tools for outbreak response.

**Dona Love, Ph.D.**, is a Program Officer at the National Institute of Allergy and Infectious Diseases (NIAID) and manages research grants and contracts focused on medical mycology. This portfolio encompasses the genetics, genomics, biochemistry, host-pathogen interactions and preclinical animal studies of the major human fungal pathogens. Before joining the NIAID, she served as a scientific review officer at the National Cancer Institute. Dr. Love received her Ph.D. in microbiology and immunology from Temple University School of Medicine and conducted research in glycobiology and genetics at NIH's National Institute for Diabetes and Digestive and Kidney Diseases. Dr. Love's research has covered a variety of topics including host-pathogen interactions, nutrient sensing, and chromatin remodeling.

**Kimberly Lucas, M.P.H.,** received her M.P.H. from the University of California, Berkeley in 2002 and has been working as an epidemiologist and research scientist with the California Correctional Health Care Services (CCHCS), Public Health Branch since 2010. Ms. Lucas serves as the lead for case surveillance, epidemiology, and prevention program evaluation for coccidioidomycosis (Valley fever) among people incarcerated in California State correctional facilities. In 2018, she designed and implemented a webbased case surveillance system that automates collection of CCHCS patient laboratory results and hospitalization discharge diagnoses to support case finding and reporting to Public Health and local health departments. Ms. Lucas also contributed to epidemiologic studies that helped provide the evidence base for policies that medically restrict individuals with elevated risk of severe disease from being incarcerated in State correctional facilities with the highest rates of coccidioidomycosis.

**Ian McHardy, Ph.D.,** is the Director of the Scripps Health Sorrento Mesa Microbiology, Molecular, and Immunology laboratory. Prior to joining Scripps in May 2019, he was Assistant Professor in-residence at University of California, Davis (UC Davis) where he was Director of the UC Davis Coccidioidomycosis Serology lab, Director the UC Davis Center for Valley Fever, Lecturer at the UC Davis School of Medicine, and led research programs in fungal pathogenesis and diagnostic development. He is author on over 50 peer-reviewed publications, abstracts, and patents. Over the course of his career, his research has focused on numerous microorganisms (including pathogenic viruses, bacteria, and fungi), bioinformatic development, and diagnostic development for infectious diseases. Dr. McHardy trained at UCLA, where he obtained a B.S. in Microbiology, Immunology, and Molecular Genetics, received a Ph.D. in Medical Microbiology, completed four years of postgraduate fellowship, and earned board certification



in Medical and Public Health Microbiology. His overarching interest is in harnessing data and analytics to improve patient outcomes and healthcare metrics.

**Thomas Monath, M.D., FASTMH,** is an internationally known virologist and vaccinologist. He is especially well known for his work on yellow fever and other viral hemorrhagic fevers. He is currently Chief Scientific Officer of Crozet BioPharma LLC working on a vaccines against Nipah Virus Disease and Marburg virus funded by Coalition for Epidemic Preparedness Innovations (CEPI) and Biomedical Advanced Research and Development Authority (BARDA). He has 30 years in senior positions in the biotechnology industry and led the development of five vaccines now licensed against Ebola, dengue, Japanese encephalitis, West Nile, yellow fever and smallpox. Before joining industry, Tom served in the US Army and US Public Health Service for 24 years. He was Director, Division of Vector-Borne Viral Diseases at the CDC and Prevention and Chief of the Virology Division at US Army Medical Research Institute of Infectious Diseases (USAMRIID). Tom received his undergraduate degree and M.D. from Harvard. He has served on numerous government and international committees on infectious diseases, biosecurity, World Health Organization (WHO) expert committees and the National Vaccines Advisory Committee, and is Past-President of the American Society of Tropical Medicine and Hygiene. He is a co-founder of the One Health Initiative website (www.onehealthinitiative.com). He has published 450 scientific papers and 6 books on arboviruses, emerging infections, and vaccine development.

Josh Nosanchuck, M.D., is Professor of Medicine (Infectious Diseases) and Microbiology & Immunology and Senior Associate Dean for Medical Education at Albert Einstein College of Medicine and Montefiore Medical Center. His laboratory focuses on pathogenic fungi, including neglected organisms, and the development of novel therapeutics. He has published over 325 scientific papers and 20 book chapters. He has funding from the US NIH and Department of Defense. Dr. Nosanchuk is an elected fellow of the American Society for Clinical Investigation, American Academy of Microbiology, American College of Physicians, and Infectious Diseases Society of America. He has had wide-ranging experience on the National Board of Medical Examiners (NBME), currently serving as a Member of the NBME Board. He also has extensive service at the Infectious Diseases Society of America (IDSA), including chairing the annual meeting (IDWeek) in 2021. Dr. Nosanchuk serves on the editorial boards of several journals, including the Journal of Infectious Diseases, PLoS Neglected Diseases and Infection and Immunity. For his efforts on developing scientists in under resourced countries, Dr. Nosanchuk received a Doctor of Honoris Causa from the University of Szeged, Hungary in 2022. As the Senior Associate Dean, Dr. Nosanchuk oversees and coordinates the all aspects of Einstein's MD program. He has received numerous educational awards, including Einstein's Samuel M. Rosen Outstanding Preclinical Teacher Award, the Harry Eagle Award for Outstanding Basic Science Teaching, and Alpha Omega Alpha, and he is an honorary Alumnus of Einstein.

**Tom Patterson, M.D., FACP, FIDSA**, focuses on the diagnosis and treatment of fungal diseases in clinical and research settings. He has been involved in developing new antifungal drugs and in clinical trials of new antifungal compounds and is funded by the NIH and industry for grants and contracts on drug and diagnostic development. He has conducted pre-clinical studies and clinical trials for coccidioidomycosis. During the COVID-19 pandemic he has led the UT Health San Antonio (UTHSA) Infectious Diseases efforts in COVID-19 care and clinical research and received the UTHSA Presidential Distinguished Research Scholar award. Dr. Patterson has published and lectured extensively with over 300 peer reviewed publications, chapters, books and reviews. He has served as member of the American Board of Internal Medicine, Subspecialty Committee for Infectious Diseases and is a Fellow of the



American College of Physicians and the Infectious Diseases Society of America, Past-President of the Texas Infectious Disease Society, and past-President, International Immunocompromised Host Society.

John Rex, M.D., FACP, is a physician and drug developer with more than 30 years of development and policy experience focused on antimicrobial agents. He is currently chief medical officer for F2G, Ltd. (an antifungal biotech), is an operating partner with a venture capital group (Advent Life Sciences), is Chair of the Scientific Advisory Board of the \$1 billion AMR Action Fund, and was (2015-2019) a voting member on the US Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB). He also blogs regularly at http://amr.solutions/blog.html. His experience includes moving compounds from preclinical development through all development phases via academic positions (NIH, Bethesda, MD; McGovern Medical School-Houston) and vice president-level roles at a multinational pharmaceutical firm (AstraZeneca). Other past activities include advancing novel regulatory paradigms for antibacterials, publications on novel reimbursement models for antibiotics, co-founding of Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X, a public-private partnership), co-founding the New Drugs for Bad Bugs (ND4BB) program of Europe's Innovative Medicines Initiative (IMI), and a 4-year term as Industry Representative on the FDA Anti-Infective Drugs Advisory Committee (AIDAC, 2007–2011).

**George Rutherford, M.D., M.A.**, is Professor of Epidemiology, Preventive Medicine, Pediatrics and History at the University of California, San Francisco. He heads the Division of Infectious Disease and Global Epidemiology in the Department of Epidemiology and Biostatistics in the School of Medicine and directs the Center for Global Strategic Information and Public Health Practice within the Institute for Global Health Sciences and the residency program in General Preventive Medicine and Public Health. Educated at Stanford University and Duke University School of Medicine, he is board certified in pediatrics and in general preventive medicine and public health. His work focuses on the epidemiology and control of communicable diseases. He has held positions in public health agencies, including serving State Health Officer and State Epidemiologist for California and has a long-standing interest in the epidemiology and prevention of coccidioidomycosis. His current academic interest is HIV and other epidemic-prone diseases in low- and middle-income countries in Africa, Latin America and the Caribbean, Asia and Eastern Europe. He is an advisor to the World Health Organization and has also served on numerous National Academy of Medicine boards and committees. He has been intimately involved in the responses to the COVID-19 pandemic at University of California San Francisco, the city of San Francisco, and the state of California since the earliest days.

**Paris Salazar-Hamm, Ph.D., M.Sc.,** received a B.A. in French, as well as a B.S. and M.Sc. in Biology at Western Illinois University (WIU). There she explored the bat skin microbiome and the fungal pathogen causing white-nose syndrome. Her research interests in ecology and evolution of human and animal fungal pathogens brought her to the University of New Mexico (UNM) to work with Dr. Donald Natvig. Her Ph.D. dissertation research combined disease ecology, molecular genetics, and epidemiology. Her dissertation research included the first molecular characterization of clinical Coccidioides isolates from New Mexico. It also expanded knowledge of the geographic distribution and mammalian hosts of Coccidioides across the American Southwest through community sequencing of lung tissue of small mammals. As Adjunct Assistant Professor at UNM and a Post-doctoral Scholar at Oregon State University, her work on Coccidioides continues through population-genetic and phylogenomic approaches.

**Lisa Shubitz, D.V.M.,** has been involved in Valley Fever research since 1996 at the University of Arizona, Valley Fever Center for Excellence. Dr. Shubitz has been heavily engaged in research on vaccines to



prevent Valley Fever in humans and in dogs. Within the last 10 years, the majority of this research has focused on a live, avirulent vaccine that has been shown to be efficacious to prevent Valley Fever pneumonia in dogs and that is currently in the approval process by US Department of Agriculture (USDA). Dr. Shubitz has also studied epidemiology of Valley Fever in dogs in Tucson and Phoenix, collaborated in studies to isolate it from the soil and map locations relative to sick dog residences, and performed clinical studies of investigational antifungal agents in naturally infected dogs in Arizona. Laboratory studies include mouse models of infection, including the development of a chronic, nonfatal infection model in mice that allows the study of later immune responses and disease reactivation. Dr. Shubitz has high hopes that the canine vaccine will greatly reduce the number of severe Valley Fever cases she sees in clinical consultations for dogs with complicated Valley Fever.

**Anita Sil, M.D., Ph.D.,** received her A.B. degree from Harvard University and her Ph.D. and M.D. from the University of California San Francisco (UCSF). She is currently Professor and Vice Chair of the Department of Microbiology & Immunology at UCSF, as well as co-director of the Integrative Microbiology program and co-director of the Biomedical Sciences Graduate Program. In her laboratory, she uses genetics and functional genomics to analyze the basic biology of thermally dimorphic fungal pathogens, as well as their interaction with cells of the innate immune system. Most recently, she has launched molecular genetic efforts to interrogate Coccidioides biology and the interactions between Coccidioides cells and macrophages. Her efforts to bring genomics and molecular genetic analysis to this field have been internationally recognized, resulting in her role as co-chair or chair of numerous international conferences on fungal pathogenesis or microbial pathogenesis. She has been awarded a Burroughs Wellcome New Investigator Award, an Ellison New Scholar Award, and an Early Career Scientist Award from the Howard Hughes Medical Institute. She was awarded the 2021 Rhoda Benham Lifetime Achievement Award in Medical Mycology from the Medical Mycology Society of America, and she is a Fellow of the American Academy of Microbiology.

**Jason Stajich, Ph.D.,** is a Professor in the Department of Microbiology and Plant Pathology at University of California-Riverside. The Stajich research group focuses on genomics of Fungi with emphasis on Aspergillus, Candida, Fusarium, and Coccidioides species. The research also encompasses phylogenomics, functional genomics, and evolution among black yeasts, Mucoromycota, Zoopagomycota and chytrid fungi. The Stajich group develops databases and software tools to aid in the application of sequencing technologies to interrogate fungal biology. Dr Stajich is a CIFAR fellow in the Fungal Kingdom: Threats & Opportunities and a fellow of the Mycological Society of America, American Association for the Advancement of Science, and American Academy of Microbiology.

**Scott Stibitz, Ph.D.**, obtained his Ph.D. in 1983 at the University of Wisconsin, Madison working in the laboratories of Julian Davies and William Reznikoff on antibiotic resistance transposons. He then pursued post-doctoral studies under Stanley Falkow at Stanford University. It was there that he began studying the molecular genetics of virulence gene regulation in *Bordetella pertussis*, which remains an active interest of his laboratory at the FDA, where he has worked since 1987. Current research projects also include those on improving testing of live biotherapeutic products and phage and phage therapy of *Staphylococcus aureus*. He is currently chief of the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI/DBPAP/OVRR/CBER/FDA) and oversees its regulatory activities. These activities are primarily review of the chemistry, manufacturing, and controls portions of regulatory submissions such as pre-investigative new drug (IND) meeting requests, INDs, and biologics license applications (BLA). The regulatory portfolio of LMPCI includes vaccines against bacterial and fungal infections, malaria and



other single-celled parasites, and multicellular parasites, as well as novel therapeutic approaches such as live biotherapeutic products, fecal microbiota for transplantation, and bacteriophage therapy.

Jane Sykes, Ph.D., M.B.A., is a Professor of Small Animal Medicine at the UC Davis School of Veterinary Medicine with interest in small animal infectious diseases. She obtained her veterinary degree and Ph.D. in veterinary microbiology at the University of Melbourne, Australia; residency in small animal internal medicine, University of Minnesota; and M.B.A. at University of Georgia. She is Board-Certified in the American College of Veterinary Internal Medicine. She has coauthored more than 100 scientific publications and is the editor of the textbooks "Canine and Feline Infectious Diseases", "Greene's Infectious Diseases of the Dog and Cat (5e)". She was the founder and first President of the International Society of Companion Animal Infectious Diseases (ISCAID) and is current President of the American College of Veterinary Internal Medicine. Her clinical and research interests currently include infectious diseases of dogs and cats with public health implications, including leptospirosis, coccidioidomycosis, and antibiotic-resistant bacterial infections

**John Taylor, Ph.D.,** is a professor at UC Berkeley who studies fungal evolution and ecology. Development of DNA amplification and sequencing in the late 1980s allowed him to study fungal phylogeny and phylogenomics, as well as fungal population genetics and population genomics. Over the past decade, he has used DNA sequence of environmental samples to investigate fungal community ecology of indoor air, forest soils, desert soils and agriculture. In addition to teaching about and researching fungi, he has served in the leadership of his department at Berkeley, as well as national and international mycological associations. His publications can be found at:

<u>https://scholar.google.com/citations?user=AY-DriwAAAAJ</u>. Taylor's research on Coccidioides began in 1990 and continues through 2022. In terms of phylogeny, he and his colleagues have shown that there are two species of the fungal agent of Valley Fever, *Coccidioides immitis* and *C. posadasii*, that both species have the population structure of an outbreeding, sexual organism, that C. posadasii is the more widespread species and that its South American population is genetically depauperate and emerges from the Texas population, and that there is hybridization and introgression between the two species. In terms of ecology, he and his colleagues have shown that Coccidioides has evolved from the ancestral, fungal state of using plants as a food source to the derived state of using animals, supporting a revision of the Coccidioides in rodent lungs and burrows and absence of detection in cultivated land.

**Marcus Teixeira, Ph.D., M.S.,** obtained his degree in Biology at the University Center of Brasília (2005), and his master's degree in Molecular Pathology (2008) and doctorate in Molecular Biology at the University of Brasília (2012). Marcus is a visiting professor at the School of Medicine, University of Brasilia, and associate researcher at the Pathogen & Microbiome Institute, Northern Arizona University. Has experience in microbial ecology and evolution and his research aims focus on molecular epidemiology, molecular mechanisms of antifungal resistance, genetic diversity, and molecular taxonomy of endemic fungal pathogens.

**Mitsuru Toda, Ph.D., M.S.,** is an epidemiologist and the Lead of the Outbreaks and Endemics Unit in CDC's Mycotic Diseases Branch, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases. Dr. Toda trained as CDC's Epidemic Intelligence Service (EIS) Officer. Dr. Toda completed her Ph.D. in Infectious Disease Research (Epidemiology) at Nagasaki University Graduate School of Biomedical Sciences, and M.S. in Health



Monk Yun Rou, has been called the new Alan Watts for his teachings and the Zen Gabriel Garcia Marquez for his writings. Born Arthur Rosenfeld, he received his academic education at Yale, Cornell, and the University of California. Ordained a monk in an official, government-sanctioned ceremony at the Policy & Management at Harvard T.H. Chan School of Public Health. Chun Yang Daoist Temple in Guangzhou, China, his work has appeared in Vogue, Vanity Fair, Parade, Newsweek, The Wall Street Journal, WebMD, Fox Business News, and numerous other websites and newspapers. Yun Rou's unique and primary calling is the ability make obscure ideas, arcane information, and transformative philosophy compelling and accessible through story. Yun Rou is the author of more than 20 award-winning nonfiction books and novels of magical realism that have done exactly this for some decades, several earning Hollywood and Chinese film industry options. From 2010 – 2013, he hosted the hit (reaching 60MM households) national public television show Longevity Tai Chi with Arthur Rosenfeld. The American Heart Association profiled Yun Rou as an inspirational resource in 2016. Respected by academics, practitioners, and lay readers alike. Monk Yun Rou began his formal martial arts training in 1980 and has studied with some of China's top Chen-style tai chi grandmasters. In 2011 he was named Tai Chi and Media Master of The Year at the World Congress on Qigong and Traditional Chinese Medicine. In July 2014, Yun Rou joined the heads of the five tai chi families on the dais, representing American tai chi at the International Tai Chi Symposium in Louisville, Kentucky. He teaches in Southern Arizona, South Florida, and around the world,

### The National Academies' Statement on Preventing Discrimination, Harassment, And Bullying: Policy For Participants In NASEM Activities (Updated December 2, 2021)

The National Academies of Sciences, Engineering, and Medicine (NASEM) are committed to the principles of diversity, inclusion, integrity, civility, and respect in all of our activities. We look to you to be a partner in this commitment by helping us to maintain a professional and cordial environment. All forms of discrimination, harassment, and bullying are prohibited in any NASEM activity. This policy applies to all participants in all settings and locations in which NASEM work and activities are conducted, including committee meetings, workshops, conferences, and other work and social functions where employees, volunteers, sponsors, vendors, or guests are present.

**Discrimination** is prejudicial treatment of individuals or groups of people based on their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws.

**Sexual harassment** is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

**Other types of harassment** include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

**Bullying** is unwelcome, aggressive behavior involving the use of influence, threat, intimidation, or coercion to dominate others in the professional environment.

#### REPORTING AND RESOLUTION

Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual at the time the incident occurs, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400 or hrservicecenter@nas.edu, or
- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

If an investigation results in a finding that an individual has committed a violation, NASEM will take the actions necessary to protect those involved in its activities from any future discrimination, harassment, or bullying, including in appropriate circumstances the removal of an individual from current NASEM activities and a ban on participation in future activities.

#### CONFIDENTIALITY

Information contained in a complaint is kept confidential, and information is revealed only on a need-toknow basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

## The National Academies' Statement on Diversity and Inclusion

The National Academies of Sciences, Engineering, and Medicine value diversity in our members, volunteers, and staff and strive for a culture of inclusion in our workplace and activities. Convening a diverse community to exchange ideas and perspectives enhances the quality of our work and increases our relevance as advisers to the nation about the most complex issues facing the nation and the world.

To promote diversity and inclusion in the sciences, engineering, and medicine, we are committed to increasing the diversity of the National Academies' staff, members, and volunteers to reflect the populations we serve. We pledge to cultivate an environment and culture that promotes inclusion and values respectful participation of all individuals who help advance the mission of the institution.