ONSITE GUIDE

Patient & Health Advocacy Summit

October 30-31, 2019
Park Hyatt, Washington, DC

Dear Patient Advocacy Community,

Albert Einstein once said, "We learn from yesterday, live for today, and hope for tomorrow. The important thing is to never stop questioning."

I think that quote is a terrific embodiment of the optimism and tenacity represented here at the eighth-annual BIO Patient and Health Advocacy Summit.

It's the spirit captured by a community of tireless patient advocates who refused to be an afterthought in the U.S. Food and Drug Administration drug development process, demanding that the patient voice be put front and center in agency decisions. BIO is proud to have helped bring your voices to the highest level of the FDA. Working together, we got patients a seat at the table.

Because you have never stopped questioning, patients are now working side by side with federal regulators to make sure the opinions and experiences of those most impacted by drug development are given far greater weight in FDA regulatory decision-making.

Because you have never stopped questioning, patient-led partnerships are now driving therapeutic development in areas of great unmet need across the biopharmaceutical industry.

And because you have never stopped questioning, we've made progress in changing the dialogue in Washington, so policymakers focus on the drug prices that matter most: what patients pay out of their own pockets.

These are challenging times for our country and for our industry in the court of public opinion. That's why it's more important than ever for BIO – and the thousand companies we represent – to clearly state our ethical obligation to the patients who depend on us.

BIO's advocacy strategy hinges on two interlocking moral imperatives: patients should never go without the medicine they need, and we must expand access to drugs in ways that don't kill innovation for patients still waiting for cures to come.

The way forward is to reaffirm and live by our social contract with patients, making sure we are their most zealous defenders in every policy discussion and pricing decision.

Thank you for your passion, leadership and persistence. Working together, we'll strive to make sure our politicians ask the right questions, so our scientists can deliver answers to the most vexing medical challenges of our time. I hope you all have a productive, collaborative and inspiring experience at this year's summit.

Sincerely,

Jim Greenwood
President & CEO
Biotechnology Innovation Organization (BIO)

About the BIO Patient & Health Advocacy Summit

The BIO Patient and Health Advocacy Summit, hosted annually by the Biotechnology Innovation Organization (BIO), brings together patient advocacy and voluntary health organizations, academia, regulators, and the biotechnology industry for two days of programming to discuss current policy issues, share best practices, and exchange ideas. The Summit also provides invaluable opportunities to advance partnership among stakeholders in the healthcare ecosystem.

Schedule of Events

WEDNESDAY, OCTOBER 30

8:00 AM – 4:30 PM	**Registration Open** Location: Salon Foyer
8:00 AM – 3:00 PM	**Networking Lounge Open** Location: Salon Rooms
8:00 AM – 9:00 AM	**Continental Breakfast** Location: Salon Foyer
9:00 AM – 5:00 PM	**BIO One-on-One Partnering™** Location: Gallery Lounge
9:15 AM – 9:30 AM	**Opening Remarks** Location: Gallery Ballroom
9:30 AM – 10:30 AM	**Practices and Principles: Navigating the FDA** Location: Gallery Ballroom
10:30 AM – 11:30 AM	**Closing the Gap: Partnering to Invest in Areas of Unmet Need** Location: Gallery Ballroom
11:30 AM – 1:15 PM	**Lunch and Keynote Session** Location: Salon Foyer and Gallery Ballroom
1:15 PM – 1:45 PM	**Networking Break** Location: Gallery Foyer
1:45 PM – 3:00 PM	**International Reference Pricing and the Impact on Patient Access and Future Innovation** Location: Gallery Ballroom
3:00 PM – 3:30 PM	**Congressional Keynote** Location: Gallery Ballroom
3:30 PM – 4:00 PM	**An Overview of Drug Pricing Proposals in Congress and the Administration** Location: Gallery Ballroom

4:00 PM – 5:00 PM	**Where Do We Go From Here?** Location: Gallery Ballroom
5:00 PM – 7:00 PM	**Networking Reception** Location: Salon Rooms and Salon Foyer

THURSDAY, OCTOBER 31

7:30 AM – 11:45 AM	**Registration Open** Location: Salon Foyer
7:30 AM – 11:45 AM	**Networking Lounge Open** Location: Salon Rooms
7:30 AM – 11:30 AM	**BIO One-on-One Partnering™** Location: Gallery Lounge
7:30 AM – 8:30 AM	**Networking Breakfast** Location: Salon Rooms and Salon Foyer
8:30 AM – 10:00 AM	**The Art of Storytelling** Location: Gallery Ballroom
10:00 AM – 10:15 AM	**Networking Break** Location: Gallery Foyer
10:15 AM – 11:30 AM	**Value Assessment Frameworks** Location: Gallery Ballroom

CONNECT TO THE WI-FI:

NETWORK:
HYATT-MEETING

ACCESS CODE:
BIO2019

BIO One-on-One Partnering™

at the BIO Patient & Health Advocacy Summit

For the third year in a row, we are offering the opportunity to schedule meetings with fellow attendees during the 2019 Summit using BIO One-on-One Partnering.

- Post your organization's profile in the system, making it searchable by registered Summit attendees.
- Request and accept meetings with other attending organizations and companies to explore new collaborations during designated partnering hours.

Partnering meetings will be available in 30-minute timeslots from 9:00 AM – 5:00 PM on **Wednesday, October 30** and 7:30 AM – 11:30 AM on **Thursday, October 31**.

About BIO One-on-One Partnering™

BIO One-on-One Partnering is the most efficient way to connect and explore partnerships with patient advocacy organizations, biopharmaceutical companies, and other healthcare stakeholders to advance your public policy and research and development agendas.

Our online partnering system allows you to communicate directly with other 2019 Summit registered attendees. You can request and accept invitations to meet with other organizations and companies. Once your meetings are mutually accepted, BIO does the scheduling for you, so you arrive with a plan and get the most from your 2019 Summit experience!

BIO Patient Advocacy Committee Co-Chairs:

Julie L. Gerberding, MD, MPH

Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy, & Population Health
Merck & Co., Inc.

Julie L. Gerberding, MD, MPH, is Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy, and Population Health at Merck & Co., Inc., where she also has responsibility for the "Merck for Mothers" global program to prevent maternal mortality and the Merck Foundation. She joined Merck in January 2010 as president of Merck Vaccines and led efforts to make the company's vaccines more available and affordable to people in resource-limited countries around the world. She left her tenured faculty position at the University of California, San Francisco in 1998 to lead the U.S. Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion and then served as the CDC Director from 2002 to 2009. As director, she led the CDC through more than 40 emergency responses to public health crises, including anthrax bioterrorism, SARS, and natural disasters. She also advised governments around the world on urgent issues such as pandemic preparedness, AIDS, antimicrobial resistance, tobacco, and cancer.

Dr. Gerberding currently serves on the Boards of CWRU, National Association of City and County Health Officials (NACCHO) Foundation, MSD Wellcome Trust Hilleman Laboratories, and the BIO Executive Committee. She has received more than 50 awards and honors, including the United States Department of Health and Human Services (DHHS) Distinguished Service Award for her leadership in responses to anthrax bioterrorism and the September 11, 2001 attacks. She was named to Forbes Magazine's 100 Most Powerful Women in the World in 2005 through 2008 and to TIME Magazine's 100 Most Influential People in the World in 2004.

Paul Hastings

Chief Executive Officer

Nkarta Therapeutics

Paul Hastings was appointed Chief Executive Officer of Nkarta in February 2018. Mr. Hastings was recently the Chairman and CEO of OncoMed Pharmaceuticals. Prior to joining OncoMed in 2006, Mr. Hastings was President and Chief Executive Officer of QLT, Inc. Previous to that, Mr. Hastings served as President and Chief Executive Officer of Axys Pharmaceuticals, which was acquired by Celera Corporation in 2001. From 1999 to 2001, Mr. Hastings served as the President of Chiron BioPharmaceuticals, a division of Chiron Corporation. Prior to that, he was President and Chief Executive Officer of LXR Biotechnology. Mr. Hastings also held a series of management positions of increasing responsibility at Genzyme Corporation, including serving as President of Genzyme Therapeutics Europe as well as President, Genzyme Therapeutics. Mr. Hastings also served as Vice President, Marketing and Sales and General Manager, Europe for Synergen, Inc., and previously held a series of marketing and sales management positions with Hoffmann-La Roche. Paul is Chair and CEO of Youth Rally Inc, a non-profit patient advocacy organization (www.rally4youth.org) that serves the needs of teens and adults with 53 different diagnoses of the bowel and bladder. Paul was diagnosed with Crohn's disease in 1973, and has been through multiple surgeries and treatments.

Wednesday, October 30

REGISTRATION OPEN

8:00 AM – 4:30 PM • Salon Foyer

CONTINENTAL BREAKFAST

8:00 AM – 9:00 AM • Salon Foyer

NETWORKING LOUNGE OPEN

8:00 AM – 3:00 PM • Salon Rooms

Stop by the Networking Lounge in between sessions to casually network with other Summit attendees! This designated area is open throughout the day on Wednesday and Thursday morning, so feel free to use it as needed.

BIO ONE-ON-ONE PARTNERING

9:00 AM – 5:00 PM • Gallery Lounge

ONE ON PARTNERING™ Powered by BIO

Request and accept meetings with other attending organizations and companies to explore new collaborations during designated partnering hours. Partnering meetings will be available in 30-minute timeslots during this time.

"[The BIO Patient & Health Advocacy Summit] is the best opportunity for advocates and biotechnology companies to network with each other in a stress-free, dynamic environment."

OPENING REMARKS

9:15 AM – 9:30 AM • Gallery Ballroom

Julie Gerberding, MD, MPH
Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health
Merck & Co., Inc.

PRACTICES AND PRINCIPLES: NAVIGATING THE FDA

9:30 AM – 10:30 AM • Gallery Ballroom

Patients, their caregivers, and patient advocacy organizations engage with the FDA to impact the FDA's thinking and to influence drug development. This session will address the kind of feedback and engagement the FDA and drug developers are looking for. This panel of patients, patient advocacy organizations, the FDA, and drug developers will discuss recent efforts underway, including the patient-focused drug development initiative, Patient Affairs Staff listening sessions, and PDUFA VII. Learn about opportunities for engagement and hear from patients, caregivers, and patient organizations about their experiences impacting the FDA's thinking and drug development.

MODERATOR:

Cartier Esham, PhD
Executive Vice President, Emerging Company Section and Senior Vice President, Science and Regulatory Affairs
Biotechnology Innovation Organization (BIO)

SPEAKERS:

Jeff Allen, PhD
President and CEO
Friends of Cancer Research

Captain Robyn Bent
Director, Patient-Focused Drug Development
Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

Samir Shaikh, MBA
Deputy Director, Patient Affairs Staff, Office of the Commissioner, Office of Clinical Policy and Programs
U.S. Food and Drug Administration (FDA)

Pat Wildman
Vice President, Advocacy and Government Relations
Lupus Foundation of America

"This is a really good time for industry and patient advocacy to come together. There's a lot of innovation and research as well as a lot of genuine, passionate interest in innovation and research on all possible sides. I think BIO is taking a lead in connecting everyone together and can keep this up in a really positive way."

CLOSING THE GAP: PARTNERING TO INVEST IN AREAS OF UNMET NEED

10:30 AM – 11:30 AM • Gallery Ballroom

As the drug development landscape evolves, nonprofit disease foundations are leading the charge to ensure that the patient perspective is integrated throughout the lifecycle of a medical product. This panel will explore the heart of patient advocacy, how patient-led partnerships can drive therapeutic development particularly in areas of unmet need. Speakers will share key learnings and best practices as well as obstacles and solutions from collaborations.

MODERATOR:

Bernhardt Zeiher, MD, FCCP, FACP
Chief Medical Officer, Medical & Development
Astellas

SPEAKERS:

Alice Bast
Chief Executive Officer
Beyond Celiac

Mark Dant
Founder and Volunteer Executive Director
Ryan Foundation
Chairman
EveryLife Foundation

Emily Kramer-Golinkoff
Co-Founder
Emily's Entourage

LUNCH

11:30 PM – 12:00 PM • Salon Foyer, Gallery Ballroom

KEYNOTE: 2020 ELECTION: IMPACT ON PATIENT ACCESS

12:00 PM – 12:45 PM • Gallery Ballroom

This keynote will provide "insider political baseball" on the 2020 election and the various healthcare policy proposals of presidential candidates including Medicare for All. The Affordable Care Act court case and significant state races will also be covered. Attendees will have the opportunity to ask questions during this session.

Amy Walter
National Editor
The Cook Political Report

"This is a great summit to attend if you are a nonprofit organization looking at ways to expand or develop an advocacy program and make new connections with companies you may not otherwise come in contact with."

MODERATED AND AUDIENCE Q&A WITH AMY WALTER

12:45 PM – 1:15 PM • Gallery Ballroom

SPEAKERS:

James C. Greenwood
President & Chief Executive Officer
Biotechnology Innovation Organization (BIO)

Amy Walter
National Editor
The Cook Political Report

NETWORKING BREAK

1:15 PM – 1:45 PM • Salon Foyer

"The opportunity to learn what is working and not working in other areas and the opportunity to learn the needs of other diseases should provide an additional framework in which to operate. The more informed and trained an advocate can be the better chance of making a difference in someone's life."

INTERNATIONAL REFERENCE PRICING AND THE IMPACT ON PATIENT ACCESS AND FUTURE INNOVATION

1:45 PM – 3:00 PM • Gallery Ballroom

The U.S. is the global leader in ensuring patients have access to the newest therapies. As policymakers in Washington D.C. discuss various drug pricing reforms, one idea attracting greater attention would tie drug prices in the U.S. to prices paid in foreign countries. This approach would replace the current market-based system for determining the value of medicines with an approach determined by foreign governments with single-payer health care systems. Under a proposal (H.R. 3) released by Speaker Nancy Pelosi (D-CA), international reference pricing would be imposed on both government programs and the commercial market. The Trump administration has proposed applying international reference pricing to certain drugs reimbursed by Medicare Part B. This panel will explore the impact international reference pricing will have on patient access and innovation.

MODERATOR:

Kenneth I. Moch
President and Chief Executive Officer
Cognition Therapeutics

SPEAKERS:

Cynthia Bens
Senior Vice President
Personalized Medicine Coalition

Alexander Hardy, MBA
Chief Executive Officer
Genentech

Andrew Spiegel, JD
Executive Director
Global Colon Cancer Association

Erin Trish, PhD
Associate Director
USC Schaeffer Center
Assistant Professor, Department of Pharmaceutical and Health Economics
USC School of Pharmacy

CONGRESSIONAL KEYNOTE

3:00 PM – 3:30 PM • Gallery Ballroom

SPEAKER:

U.S. Senator Bob Menendez (D-NJ)

AN OVERVIEW OF DRUG PRICING PROPOSALS IN CONGRESS AND THE ADMINISTRATION

3:00 PM – 4:00 PM • Gallery Ballroom

This discussion will review the drug pricing proposals currently in Congress including the Prescription Drug Pricing Reduction Act (PDPRA) and the Lower Drug Costs Now Act of 2019, and the ultimate impact these proposals will have on the healthcare system and patients.

MODERATOR:

Mike Mattoon
Vice President, Federal Government Relations
Biotechnology Innovation Organization (BIO)

SPEAKER:

Brett Baker
Senior Health Policy Advisor
Senate Finance Committee (Majority)

WHERE DO WE GO FROM HERE?

4:00 PM – 5:00 PM • Gallery Ballroom

During this session, panelists will provide reactions to the previous panels on the 2020 election, patient access to innovative therapies, and drug pricing proposals in Congress and the administration. Speakers will outline where there is alignment within the patient advocacy community, how to move forward, and calls to action.

MODERATOR:

Jeanne Haggerty
Executive Vice President, Government Affairs and External Relations
Biotechnology Innovation Organization (BIO)

SPEAKERS:

Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation

Carl Schmid, MBA
Deputy Executive Director
The AIDS Institute

Andrew Sperling, JD
Director of Legislative and Policy Advocacy
National Alliance on Mental Illness (NAMI)

Pam Traxel
Senior Vice President
American Cancer Society Cancer Action Network (ACS CAN)

NETWORKING RECEPTION

5:00 PM – 7:00 PM • Salon Rooms and Salon Foyer

Please join us after the last session of the day for a networking reception with key stakeholders in the healthcare and patient advocacy communities.

"I highly recommend the BIO Patient and Health Advocacy Summit for thoughtful discussions about key public policy issues as well as networking with leaders from patient advocacy organizations and patient engagement professionals from biopharma companies."

BIO Guiding Principles for Interaction with Patient Advocacy Organizations

BIO member companies are committed to investing in, discovering, and developing innovative medicines to cure or disease and improve the lives of patients. BIO and its members recognize that it is of the utmost importance to understand and consider on an ongoing basis the needs and preferences of the patients we serve.

To ensure BIO and its members understand and can thoughtfully address what is most important to patients, their caregivers, and their families, we meaningfully, ethically, and responsibly engage with patient advocacy organizations. *BIO's Guiding Principles for Interaction with Patient Advocacy Organizations* focus on the following themes:

- **Fostering Partnership and Valuing Independence**
- **Advocating for Policies That Improve Patient Outcomes**
- **Supporting Patient Advocacy Organizations**
- **Valuing the Privacy of the Patient Community**
- **Respecting Standards of Ethical Conduct**

To learn more about BIO's *Principles*, please visit
www.bio.org/bio_patient_engagement_principles

Thursday, October 31

REGISTRATION OPEN

7:30 AM – 11:45 AM • Salon Foyer

NETWORKING LOUNGE OPEN

7:30 AM – 11:45 AM • Salon Rooms

NETWORKING BREAKFAST

7:30 AM – 8:30 AM • Salon Rooms and Foyer

BIO ONE-ON-ONE PARTNERING™

7:00 AM – 11:30 AM • Gallery Lounge

ONE ON PARTNERING™ Powered by BIO

Request and accept meetings with other attending organizations and companies to explore new collaborations during designated partnering hours. Partnering meetings will be available in 30-minute timeslots during this time.

"The BIO Patient & Health Advocacy Summit really demonstrates BIO's commitment to patients."

THE ART OF STORYTELLING

8:30 AM – 10:00 AM • Gallery Ballroom

This session will explore storytelling methods that empower patients to tell the most meaningful and memorable stories possible. Examples of successful engagements that have led to advancements in policy or clinical development will be provided. This will be a discussion of skills and best practices including the science behind why stories can impact when statistics cannot, techniques for preparing patients to meet with legislators and regulators, ways to elevate the use of data among patient advocates, and challenges patients face in speaking publicly and how industry can move beyond asking patients to simply "tell us your story."

MODERATOR:

Gwen Mayes, JD, MMSc
Founder and Chief Concept Officer
Patient Story Coach
GwenCo Health

SPEAKERS:

Dena Battle
Co-founder and President
KCCure

Freda C. Lewis-Hall, MD, DFAPA
Chief Patient Officer and Executive Vice President
Pfizer Inc.

Paul Hastings
Chief Executive Officer
Nkarta Therapeutics

NETWORKING BREAK

10:00 AM – 10:15 AM • Gallery Foyer

VALUE ASSESSMENT FRAMEWORKS

10:15 AM – 11:30 AM • Gallery Ballroom

How does a patient advocacy group develop the skills needed for health economics—where do you start, where do you go? This panel will discuss how value assessments are used in the US and will provide best practices for patient advocates on how to engage with value assessment frameworks.

MODERATOR:

Elisabeth M. Oehrlein, PhD, MS
Senior Director, Research and Programs
National Health Council

SPEAKERS:

Cat Davis Ahmed, MBA
Vice President, Policy and Outreach
The FH Foundation

Annie Kennedy
Senior Vice President, Legislation & Public Policy
Parent Project Muscular Dystrophy

Ashley Valentine
Co-Founder and President
Sick Cells

CONFERENCE ADJOURNS

11:30 AM

Speaker Biographies

Cat Davis Ahmed, MBA

Vice President, Policy and Outreach
The FH Foundation

Cat Davis Ahmed is Vice President for Policy and Outreach for the FH Foundation, where she works with individuals with Familial Hypercholesterolemia (FH) and the medical professionals who treat them. FH is a common, but underdiagnosed genetic disorder that causes very high cholesterol from birth, leading to early aggressive cardiovascular disease. She is an author on publications in the *Journal of the American College of Cardiology*, *Circulation*, and *Atherosclerosis*. Cat is a member of the American Heart Association's Atherosclerosis, Hypertension, and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young. She speaks at national medical conferences about FH, including the Cardiometabolic Health Congress, ISPOR, and the Global Cardio Vascular Clinical Trialists Forum. As someone who has FH herself, she knows first hand the impact the disorder can have on individuals and families. The FH Foundation is a non-profit, patient-centered, research and advocacy organization dedicated to increasing the rate of early diagnosis and encouraging proactive treatment of FH in order to prevent premature heart disease. Cat holds a BA from Union College and an MBA from the Yale School of Management.

Jeff Allen, PhD

President and CEO
Friends of Cancer Research

Jeff Allen, PhD, serves as the President and CEO of Friends of Cancer Research (*Friends*). During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. As a thought leader on many issues related to Food and Drug Administration, regulatory strategy and healthcare policy, he is regularly published in prestigious medical journals and policy publications, and has contributed his expertise to the legislative process on multiple occasions. Recent *Friends* initiatives include the establishment of the Breakthrough Therapies designation and the development of the Lung Cancer Master Protocol, a unique partnership that will accelerate and optimize clinical trial conduct for new drugs. Dr. Allen received his PhD in cell and molecular biology from Georgetown University, and holds a Bachelors of Science in Biology from Bowling Green State University.

Alice Bast

Chief Executive Officer

Beyond Celiac

Alice Bast's experience with celiac disease began more than twenty years ago, when debilitating physical symptoms, multiple miscarriages, a stillbirth and intense mental and emotional strain began to take over her life. Alice struggled to get a proper diagnosis, and after visiting 22 physicians, the 23rd finally diagnosed her with celiac disease, a serious genetic autoimmune condition that currently has only one treatment—a strict gluten-free diet.

In 2003, Alice was compelled to found the organization that is Beyond Celiac, a patient-centric organization serving 2.5 million Americans established to accelerate research and a cure for celiac disease. She represents the celiac disease patient voice in key government, research and industry venues, including:

- The International Coeliac Disease Symposium
- Digestive Disease Week Conference
- The National Advisory Council for the Agency for Healthcare Research and Quality of (AHRQ), Department of Health and Human Services
- FDA GREAT III Workshop
- Digestive Disease National Coalition
- NIH's National Celiac Awareness Campaign and National Digestive Diseases Information Clearinghouse Coordinating Panel
- NIH co-sponsored Autoimmunity Prevention Summit
- International Society for Pharmacoeconomics and Outcomes Research (ISPOR): Patients as Partners in the Development and Interpretation of Clinical Outcome

Alice has secured grants from the NIH and FDA to raise awareness and to investigate the challenge that the community faces in dealing with potential gluten in medications. During her tenure as Beyond Celiac CEO, celiac disease diagnosis rates have climbed from 3% to an estimated 50%. Beyond Celiac is the leading celiac disease patient advocacy organization directly funding research for treatments and a cure to this serious genetic autoimmune disease.

Alice developed and produced the landmark Beyond Celiac 2015 Research Summit. This inaugural event brought together thought leaders from multiple disciplines beyond the field of celiac disease, leveraging the opportunity for key stakeholders, including patients, clinician scientists, drug developers, patient advocacy leaders and the FDA to identify

necessary tools and information to accelerate research. Beyond Celiac will hold a follow-up Summit in November 2019.

Alice has appeared on nationally televised programs such as ABC's 'The View', CNN and 'The Doctors'. Winner of the 2010 Philadelphia Award, 2013 SmartCEO Brava Award and the 2017 Philadelphia Magazine Trailblazer Award, Alice serves on the board of the Philadelphia Award and has contributed to the *Huffington Post*, *WebMD* and *Allergic Living Magazine*. She has been published in the *Journal of Practical Gastroenterology*.

Dena Battle

Co-founder and President
KCCure

Dena Battle began her career in Washington, DC, as a congressional aide, and went on to work as a lobbyist for more than 10 years, focusing primarily in tax and healthcare policy.

In 2009, at the age of 40, Dena's late husband Chris was diagnosed with metastatic kidney cancer. Together, they began a quest for the best care possible to combat the disease. Chris was treated at four different comprehensive cancer centers and participated in multiple clinical trials. Following his death in 2013, Dena became active as a kidney cancer patient advocate.

In 2016, she left her job to launch KCCure, a grassroots organization dedicated to representing the patient voice in kidney cancer. In addition to her work with KCCure, she serves on the Advisory Board for the Johns Hopkins Sidney Kimmel Cancer Center, sits on the NCI GU Steering Committee which oversees the Renal Task Force, and serves on the GU Steering Committee for the Alliance Cooperative Group. She has testified before the FDA – Oncological Drug Advisory Board (ODAC) and has authored and co-authored numerous publications on patient perspectives in cancer care.

Dena lives in Alexandria, VA, with her two daughters.

Cynthia Bens

Senior Vice President

Personalized Medicine Coalition (PMC)

Cynthia A. Bens, Senior Vice President, Public Policy at PMC, leads the Coalition's policy development and government relations efforts and serves as its primary liaison with the U.S. Congress and federal regulators. In collaboration with PMC's Senior Vice President, Science Policy, Bens is responsible for implementing research, regulatory and reimbursement policy strategies that promote the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.

Before joining PMC, Bens was the Vice President of Public Policy at the Alliance for Aging Research. Bens guided the Alliance's federal policy work, represented the organization in multiple national coalitions and directed all aspects of coalitions led by the Alliance. She spent more than a decade at the Alliance advancing policies to expedite the development of interventions for neurological diseases and physical frailty; to remove access barriers for cardiovascular disease treatments; and to enhance the quality of care for older adults living with multiple chronic conditions.

Prior to joining the Alliance, Bens was a Senior Manager of Government Affairs with the Loeffler Group. Bens holds a bachelor's degree from New York University with concentrations in political science and women's studies.

Captain Robyn Bent

Director, Patient-Focused Drug Development

Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

Captain Robyn Bent joined the US FDA in August of 2019 as the director of CDER's Patient-Focused Drug Development (PFDD) Initiative, an effort to systematically obtain patient input and facilitate the incorporation of meaningful patient input into drug development and regulatory decision making. The PFDD initiative includes the CDER Standard Core Clinical Outcomes Assessments and Endpoints Pilot Grant Program which was recently launched and will provide avenues to advance the use of patient input as an important part of drug development. Prior to joining FDA, Captain Bent held multiple positions at the National Institutes of Health where she gained extensive experience in clinical trial design, conduct, and oversight. Prior to that she was an officer in the U.S. Navy. Captain Bent earned her Bachelor of Science in Nursing from The Catholic University of America and her Master of Science degree from the George Washington University.

Mark Dant

Founder and Volunteer Executive Director
Ryan Foundation
Chairman
EveryLife Foundation

Mark Dant is the current Chairman of the Board of the Washington, DC based EveryLife Foundation for Rare Diseases, a science-based advocacy organization dedicated to accelerating biotech innovations for rare disease treatments through science-driven public policy. Mark is also the founder and Volunteer Executive Director of the Ryan Foundation and former President and CEO of the National MPS Society.

For the past 25+ years, Mark and the Ryan Foundation have partnered with numerous research scientists and universities to help innovative projects move toward treatment in lysosomal storage disease. Mark and his family have been key advocates speaking to the FDA and in 2009 successfully championed the US House of Representatives to pass the Ryan Dant Health Care Opportunity Act, a bill designed to help those living on Medicaid assistance become gainfully employed. The Dant's journey has been documented on CBS 60 Minutes, CNN, *Biography Magazine*, *Readers Digest* in 13 languages around the world, *Golf Digest*, the *LA Times* and numerous newspapers and news outlets across the US.

Mark retired from police work in 2016 as Assistant Chief of Police with the Carrollton Texas Police Department after serving 32 years as a Patrol Officer, Detective, and Commander leading multiple divisions and Bureaus to include Patrol, Criminal Investigations, Intel, and SWAT. Mark spends his time now volunteering for the EveryLife Foundation, the Ryan Foundation, and numerous other rare disease organizations to help empower the patient advocate through the understanding that all of us have the power to turn action to hope and hope to reality.

Cartier Esham, PhD

Executive Vice President for Emerging Companies Section and Senior Vice President, Science and Regulatory Affairs
Biotechnology Innovation Organization (BIO)

Cartier Esham serves as Executive Vice President for Emerging Companies at the Biotechnology Innovation Organization (BIO). In this role, Dr. Esham manages and directs BIO's policy development, advocacy, research and educational initiatives for BIO's emerging companies, which comprise approximately 90% of BIO's membership. This includes capital formation policy and health policy impacting emerging companies, as well as research and analysis of the biopharmaceutical industry and life-science investment and financing. Among the priorities of BIO's Emerging Companies Section are: promoting a science-based FDA regulatory environment; supporting NIH funding and programs/initiatives such as SBIR and NCATS that promote the effective transfer of technology; and working to create a public and private market environment that incentivizes the research and development of innovative treatments and therapies. Prior to joining BIO, Dr. Esham was a Vice President and Director of Research at Dutko Worldwide, a private consulting firm in Washington, D.C. There she worked on a variety of environmental, education, science, technology and health care related issues both on the federal and state/local levels. Esham has a PhD in Microbiology from the University of Georgia, a Master's degree in Marine Biology from the University of North Carolina at Wilmington and a Bachelor of Science Degree from the University of Kentucky. She has published papers in peer-reviewed science journals on water quality, marine microbial ecology and bacterial phylogeny.

Julie L. Gerberding, MD, MPH

Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy, and Population Health
Merck & Co., Inc.

Julie L. Gerberding, MD, MPH, is Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy, and Population Health at Merck & Co., Inc., where she also has responsibility for the "Merck for Mothers" global program to prevent maternal mortality and the Merck Foundation. She joined Merck in January 2010 as president of Merck Vaccines and led efforts to make the company's vaccines more available and affordable to people in resource-limited countries around the world. She left her tenured faculty position at the University of California, San Francisco in 1998 to lead the U.S. Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion and then served as the CDC Director from 2002 to 2009. As director, she led the CDC through more than 40 emergency responses to public health crises, including anthrax bioterrorism, SARS, and natural disasters. She also advised governments around the world on urgent issues such as pandemic preparedness, AIDS, antimicrobial resistance, tobacco, and cancer.

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James C. Greenwood

President & Chief Executive Officer

Biotechnology Innovation Organization (BIO)

James C. Greenwood is President and CEO of the Biotechnology Innovation Organization (BIO) in Washington, D.C. BIO represents 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 countries worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, and industrial & environmental biotechnology products. BIO also produces the annual BIO International Convention, the world's largest annual gathering of the biotechnology industry, as well as other major investor and business conferences across the world.

Greenwood represented Pennsylvania's Eighth District in the U.S. House of Representatives from 1993 to 2005. Since 2005, his deep relationships on Capitol Hill and knowledge of politics and policy have substantially raised BIO's profile and enhanced the organization's advocacy work. During his time in Congress, he was a senior member of the Energy and Commerce Committee and widely viewed as a leader on health care and the environment. He crafted legislation to reform the Food and Drug Administration, and he led the fight in Congress to allow stem-cell research to be conducted by U.S. scientists to treat disease.

From 2001 to 2004, Greenwood served as Chairman of the Energy and Commerce Committee Subcommittee on Oversight and Investigation with oversight authority over issues in the full Committee's jurisdiction. He led hard-hitting investigations into corporate governance at Enron, Global Crossing and WorldCom; terrorist threats to our nation's infrastructure; and waste and fraud in federal government agencies.

Prior to his election to Congress, Greenwood served six years in the Pennsylvania General Assembly (1981-86) and six years in the Pennsylvania Senate (1987-1992). Greenwood graduated from Dickinson College in 1973 with a B.A. in Sociology. From 1977 until 1980, he worked as a caseworker with abused and neglected children at the Bucks County Children and Youth Social Service Agency. Mr. Greenwood is married with three children and resides in Upper Makefield, Pennsylvania.

Jeanne Haggerty

Executive Vice President, Government Affairs and External Relations
Biotechnology Innovation Organization (BIO)

Jeanne Haggerty joined BIO in September 2006 as Director for Federal Government Relations. She was named Vice President in September 2014, Senior Vice President in August 2015 and Executive Vice President in July 2018.

Prior to joining BIO, Haggerty served as a Professional Staff Member for the House Committee on Energy and Commerce. She also worked for Senator Chuck Grassley (R-IA) on the Senate Aging Committee, for the Senate Finance Committee and in government relations at Epstein, Becker and Green.

Haggerty graduated from the University of Vermont.

Alexander Hardy, MBA

Chief Executive Officer
Genentech

Alexander Hardy became Genentech's Chief Executive Officer March 1, 2019.

Previously, he was head of Global Product Strategy, Roche Pharmaceuticals and served in a number of key leadership positions across Genentech and Roche for over 13 years. Alexander led cross-functional teams to develop and launch new medicines and indications in more than 100 countries worldwide. He also co-chaired Roche's late-stage portfolio committee, with direct accountability for new formulations and devices, geographic expansion, and post-marketing investments.

From 2014 to 2016, Alexander was head of Asia Pacific for Roche Pharmaceuticals, overseeing 19 countries and more than 6,000 employees. Prior to this, starting in 2005 Alexander held several senior management positions at Genentech including heading patient access services and leading commercial operations for a range of medicines and therapeutic areas from HER2-positive cancer to influenza and neuroscience.

Prior to Genentech, Alexander held leadership positions at Novartis as head of market access for Europe, country head for Denmark, and business unit head and director of strategic planning and new product development in the U.K.

Alexander completed his undergraduate education at Cambridge University in the U.K. and earned his MBA at the University of Michigan. He currently lives in the San Francisco Bay Area, and is married with three daughters.

Paul Hastings

Chief Executive Officer

Nkarta Therapeutics

Paul Hastings was appointed Chief Executive Officer of Nkarta in February 2018. Mr. Hastings was recently the Chairman and CEO of OncoMed Pharmaceuticals. Prior to joining OncoMed in 2006, Mr. Hastings was President and Chief Executive Officer of QLT, Inc. Previous to that, Mr. Hastings served as President and Chief Executive Officer of Axys Pharmaceuticals, which was acquired by Celera Corporation in 2001. From 1999 to 2001, Mr. Hastings served as the President of Chiron BioPharmaceuticals, a division of Chiron Corporation. Prior to that, he was President and Chief Executive Officer of LXR Biotechnology. Mr. Hastings also held a series of management positions of increasing responsibility at Genzyme Corporation, including serving as President of Genzyme Therapeutics Europe as well as President, Genzyme Therapeutics. Mr. Hastings also served as Vice President, Marketing and Sales and General Manager, Europe for Synergen, Inc., and previously held a series of marketing and sales management positions with Hoffmann-La Roche. Paul is Chair and CEO of Youth Rally Inc, a non-profit patient advocacy organization (www.rally4youth.org) that serves the needs of teens and adults with 53 different diagnoses of the bowel and bladder. Paul was diagnosed with Crohn's disease in 1973, and has been through multiple surgeries and treatments.

Anna Hyde

Vice President, Advocacy and Access
Arthritis Foundation

Anna Hyde is the Vice President of Advocacy and Access at the Arthritis Foundation. She oversees both the federal and state legislative programs, in addition to grassroots engagement. Her focus is to raise the visibility of arthritis as a public health priority, build support for federal and state legislation that ensures access to affordable, high-quality health care, and enhance patient engagement in the policy-making process. Anna previously served as Senior Director of Advocacy and Access, managing the federal affairs portfolio and overseeing the state advocacy team.

Prior to joining the Arthritis Foundation in 2014, Anna worked as Senior Manager for Federal Affairs at the American Congress of Obstetricians and Gynecologists, where she managed a portfolio of issues including appropriations, physician workforce, and health IT. She began her health policy career as a Congressional Fellow for Energy and Commerce Committee members, where she drafted legislation and staffed Committee activities. Anna received a BA in History from Southern Methodist University, and taught junior high and high school history before moving to Washington, D.C. in 2007 to pursue an MA in Political Science from American University.

Annie Kennedy

Senior Vice President, Legislation & Public Policy
Parent Project Muscular Dystrophy

Annie Kennedy is Senior Vice President, Legislation & Public Policy, at Parent Project Muscular Dystrophy (PPMD). Focused on improving health outcomes for people living with Duchenne muscular dystrophy, Annie's work includes building strong partnerships with policy makers, federal agencies, Industry, and alliances that can serve as force multipliers in moving Duchenne community priorities forward. Current areas of emphasis include PDUFA VI, implementation of key provisions within 21st Century Cures including the Patient Focused Impact Assessment Act, MD-CARE Act implementation, engagement with the FDA and Industry around regulatory policy and therapeutic pipelines, recent AdComms for Duchenne products, a national newborn screening program, resources for adults with Duchenne, optimizing clinical trial infrastructure, and drug coverage, valuation, and access issues. Annie currently serves on the Board of Directors of Cure SMA, on the FasterCures Patients Count Leadership Council, as Co-Chair of the National Health Council's Medical Innovation Action Team and was recently a Design Team member of the NCATS/ORDR Tool Kit Project.

Emily Kramer-Golinkoff

Co-Founder
Emily's Entourage

Emily Kramer-Golinkoff is Co-Founder of Emily's Entourage, an innovative 501(c)3 foundation that accelerates research for new treatments and a cure for nonsense mutations of Cystic Fibrosis. She is also an internationally recognized patient advocate and speaker.

Named a White House Precision Medicine "Champion of Change," Emily's Entourage has awarded over $3.4 million in research grants since 2011 and led worldwide efforts to drive high-impact research and drug development on nonsense mutations of Cystic Fibrosis. The organization has been featured in national media outlets, including CNN.com, Time.com, People.com, and AOL.com.

Emily has a master's degree in bioethics and certification in clinical ethics mediation from the University of Pennsylvania, where she also completed her undergraduate degree. She has given talks at The White House, TEDx, University of Pennsylvania's Annenberg School for Communication Commencement, Stanford University's Medicine X Conference, and more, and in 2016, she was named the recipient of the Global Genes Rare Champion of Hope for Advocacy Award.

Freda C. Lewis-Hall, MD, DFAPA

Chief Patient Officer and Executive Vice President
Pfizer Inc.

During her 35-year career in medicine, Dr. Freda Lewis-Hall has been on the frontlines of healthcare as a clinician, a researcher, and a leader in the biopharmaceuticals and life sciences industries. The common thread throughout has been her passion to advocate for health equity and improved outcomes for all patients.

As newly appointed Chief Patient Officer, Dr. Lewis-Hall leads Pfizer's work to advance patient-focused programs and platforms – from drug discovery and development through patient access. Her commitment to patient-centricity serves patients around the world by seeking their voice and input, as well as understanding and responding to their needs, to help people live longer, healthier and more productive lives. Dr. Lewis-Hall previously served as Pfizer's Chief Medical Officer from 2009 to 2018.

Before joining Pfizer in 2009, Dr. Lewis-Hall held senior leadership positions with Vertex, Bristol-Myers Squibb, Pharmacia and Eli Lilly and Company. Prior to joining industry, she served as Vice Chairperson and Associate Professor in the Department of Psychiatry at Howard University College

of Medicine and was an advisor to the National Institute of Mental Health. Dr. Lewis-Hall graduated from Johns Hopkins University and earned her medical doctorate at Howard University College of Medicine.

Dr. Lewis-Hall appears regularly on health-related television programs in major global markets, including CBS-syndicated shows such as The Doctors and Dr. Phil. She also shares health and medical information through GetHealthyStayHealthy.com. She currently serves on numerous boards including SpringWorks Therapeutics, Dell Medical School, Harvard Medical School, FasterCures, the Foundation for the NIH, and the Patient-Centered Outcomes Research Institute.

Mike Mattoon

Vice President, Federal Government Relations
Biotechnology Innovation Organization (BIO)

Mike Mattoon serves as Vice President of Federal Government Relations at the Biotechnology Innovation Organization (BIO), where he oversees all of BIO's federal engagement. Prior to BIO, Mike was Director, Government Affairs and Public Policy at Vertex Pharmaceuticals, and previously in federal government affairs at Boston Scientific.

Mike graduated from Boston University and has a Masters in Political Management from The George Washington University.

Gwen Mayes, JD, MMSc

Founder and Chief Concept Officer
Patient Story Coach
GwenCo Health

Gwen Mayes is the Founder and Chief Concept Officer for GwenCo Health, a health care consulting business focused on building the skills and knowledge patients need to serve in policy development with the same rigor and influence given to stats and data. As a Patient Story Coach, Gwen designed PREP – *Presentation Review for Expert Patients* – to lay the foundation for this effort and assist industry with preparing patients for advocacy on a national level.

Immediately prior, Gwen led Advocacy Relations for Bayer Women's Healthcare from 2013-2019 and earlier following the passage of the Affordable Care Act, she was the EVP of Public Policy for the National Patient Advocate Foundation from 2010-2013. A cardio-thoracic Physician Assistant by training, Mayes began her career at Emory University where she led the organ procurement efforts for the establishment of the heart transplant program. From 1988-1998, she held several positions with the US Department of Health and Human Services in Washington, DC,

including the Surgeon General's Office and the HRSA Office on Organ Transplantation. Returning to her native state, Kentucky, she served as the first Executive Director of the Kentucky Office of Women's Physical and Mental Health for the Commissioner of Public Health. Once again in Washington, she served as the first Director of Government Affairs and Reimbursement for Abiomed, an innovator in cardiac device support, between 2005-2010.

Gwen has also been a freelance writer since 2000; her clients include the Center for Medical Technology Policy, *Medscape*, *Transplant News*, Johns Hopkins School of Medicine, Applied Policy, and Healthy Women. Mayes received her AB in Biology and Pre-Medical Studies from Transylvania University, her MMSc in Intensive Respiratory Care from Emory University in Atlanta, GA, and her JD with honor in Healthcare from the University of Maryland. She is a resident of Annapolis, MD and spends as much time as possible sailing on the Chesapeake Bay and organizing writing workshops.

U.S. Senator Bob Menendez (D-NJ)

Senator Bob Menendez's story is a quintessential American story. He grew up the son of Cuban immigrants in a tenement building in Union City and has risen to become one of 100 United States Senators. He served as Chairman of the Senate Foreign Relations Committee in the 113th Congress. The Committee is one of the oldest and most revered Committees in the Senate, at a time when world affairs has a dramatic impact on our economy at home.

In 1974, at the age of 20, he was first elected to the Union City School District's Board of Education. In 1986, he won the election for Mayor of Union City. In 1988, while continuing to serve as mayor, he was elected to represent the state's 33rd district in the General Assembly of New Jersey and, within three years, moved to the New Jersey State Senate, upon winning the March 1991 special election for the 33rd Senate district. The next year he won a seat in the Congress of the United States for the House of Representatives and represented New Jersey's 13th congressional district for six two-year terms, from 1993 to 2006. In January 2006, he was appointed to fill the U.S. Senate seat being vacated by Jon Corzine (who had been elected 54th Governor of New Jersey), and was elected to a full six-year term in November; he was reelected in 2012 and 2018.

Bob received his B.A. from St. Peter's College in Jersey City and his law degree from Rutgers University. He currently lives in Paramus and has two children, Alicia and Robert.

Kenneth I. Moch

President and Chief Executive Officer

Cognition Therapeutics, Inc.

Kenneth Moch is President & CEO of Cognition Therapeutics, a clinical stage neuroscience company focused on the development of small molecule therapeutics designed to protect and restore synaptic function in Alzheimer's disease and other neurodegenerative disorders.

Ken has broad expertise building, financing and leading private and public life science companies from start-up through commercialization. He has played a key role in building five life science companies resulting in multiple marketed products, and has been responsible for the successful completion of more than 30 public offerings and private placements, including two IPOs. Ken previously served as President & CEO of four life science companies: Chimerix, Inc., an antiviral therapeutics company; BioMedical Enterprises, a manufacturer and marketer of nitinol orthopedic implants; Alteon, Inc., a developer of small molecule therapeutics for cardiovascular aging and diabetic complications; and Biocyte Corporation, where he pioneered the storage and therapeutic use of cord blood stem cells and launched the first cord blood stem cell storage bank. Ken started his career in biotech drug development as a co-founder and Vice President of The Liposome Company, Inc., a pioneer in the use of liposomes for the delivery of anticancer and antifungal drugs. He has also been a Managing Partner of The Salutramed Group, LLC, a Managing Director of Healthcare Investment Banking at ThinkEquity Partners and a management consultant with McKinsey & Company, Inc.

Building on his longstanding focus on health policy and improving the quality of healthcare, Ken has served for over a decade on the Governing Board of the Biotechnology Innovation Organization (BIO), where he chairs BIO's Bioethics Committee and co-chairs the Emerging Companies Section Regulatory Policy Subcommittee, which is focused on the complexities and decline in the R&D landscape for highly prevalent chronic diseases. He is a past Chairman of the Board of BioNJ and a past member of the Executive Committee of the New York Biotechnology Association.

Ken is a founding member of the NYU Working Group on Compassionate Use and Pre-Approval Access. In August 2014, Ken and Arthur Caplan, PhD, the Head of Medical Ethics at NYU Medical Center, co-authored an article in Health Affairs on the ethical issues surrounding access to experimental medicines, "Rescue Me: The Challenge of Compassionate Use in the Social Media Era." and in December 2017 Ken authored an article entitled "Ethical Crossroads: Expanded Access, Patient Advocacy and the #SaveJosh Social Media Campaign."

Ken currently serves as a member of the Boards of Zynerba Pharmaceuticals and Gamida Cell, Ltd. He served for over a decade on the Board of M2Gen, the personalized medicine subsidiary of the Moffitt Cancer Center.

He holds an A.B. in biochemistry with a minor in health policy from Princeton University and an MBA from the Stanford University Graduate School of Business.

Elisabeth M. Oehrlein, PhD, MS

Senior Director, Research and Programs

National Health Council

Elisabeth M. Oehrlein, PhD, MS, is Senior Director, Research and Programs at the National Health Council, joining the organization in July 2018. In this role Dr. Oehrlein crafts the NHC's annual research and programmatic agenda in service to our mission. She conducts research, writes white papers, presents at conferences, secures grants, and executes a variety of research and programmatic projects for the NHC. Dr. Oehrlein is a mixed-methods researcher with experience and expertise in epidemiologic, qualitative, and patient-engagement methods, as well as patient-focused medical product development and patient centricity. She holds a BA degree from Franklin & Marshall College, an MS in Epidemiology from the University of Maryland School of Medicine's Department of Epidemiology and Human Genetics, and a PhD in Pharmaceutical Health Services Research with a concentration in Comparative Effectiveness Research/ Patient-Centered Outcomes Research from the University of Maryland School of Pharmacy. Dr. Oehrlein is an active member of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and serves as Co-Chair of the Digest of Databases and on the leadership group for the Patient-Centered Special Interest Group.

Carl Schmid, MBA

Deputy Executive Director

The AIDS Institute

Carl Schmid has been with The AIDS Institute, a national nonpartisan, public policy, advocacy research, and education organization that advocates for people with HIV and viral hepatitis, since February 2004. He leads the Institute's federal policy work before the executive agencies and the Congress.

Schmid helps lead the HIV and hepatitis communities' advocacy efforts in Washington DC to ensure domestic HIV and hepatitis programs, including the Ryan White Program, CDC HIV and hepatitis prevention programs, and NIH AIDS Research, are based on sound public policy and fully funded. He is a Convening Group member of the Federal AIDS Policy Partnership and co-chairs its AIDS Budget and Appropriations Coalition. He has expertise in health care financing systems, including Medicaid and Medicare, and led efforts to ensure that Affordable Care Act implementation meets the needs of people living with or at risk of HIV and hepatitis.

As part of the Institute's work in advocating for people with HIV and hepatitis, Schmid works extensively with other patient and disease groups on collective efforts to ensure that patients, particularly those with chronic conditions, have access to quality and affordable health care. In January 2018, Schmid was appointed as a consumer representative to the National Association of Insurance Commissioners.

In December 2018, Health and Human Services Secretary Alex Azar appointed Schmid as Co-Chair of the Presidential Advisory Council on HIV/AIDS, a group that he served on from 2007-09 and chaired its Domestic Subcommittee. In 2010, he was named by POZ Magazine as one of the 100 most effective AIDS fighters and by Whitman Walker Health as one of the 25 individuals who have played prominent roles in the fight against HIV in DC. In 2016, he was named the Champion of the Year by the ADAP Advocacy Association.

Mr. Schmid earned a B.A. in Public Affairs and a M.B.A. in International Affairs from the George Washington University in Washington, D.C.

Samir Shaikh, MBA

Deputy Director, Patient Affairs Staff, Office of the Commissioner, Office of Clinical Policy and Programs
U.S. Food and Drug Administration (FDA)

Samir Shaikh works at the U.S. Food and Drug Administration (FDA) and serves as the Deputy Director for the Patient Affairs Staff (PAS) in the Office of the Commissioner. PAS leads and enhances patient engagement activities across the medical product Centers—facilitating dialogue and collaboration between patients, their advocates, and the FDA to incorporate patient perspective into regulatory decision making. Prior to the FDA, Samir worked in academia and the pharmaceutical industry conducting research in Epilepsy, Alzheimer's and Vaccines. Samir received his Bachelor's Degree from The University of Chicago and MBA from Johns Hopkins University.

Andrew Sperling, JD

Director of Legislative and Policy Advocacy
National Alliance on Mental Illness (NAMI)

Andrew Sperling has been Director of Legislative and Policy Advocacy at NAMI since 1996. In that role, he oversees NAMI's federal policy agenda in Congress and before federal agencies. He also serves as a consumer representative to the National Association of Insurance Commissioners and as co-chair of the Consortium for Citizens with Disabilities Housing Task Force. Andrew received his B.A. from Tulane University, his MA from The George Washington University and his J.D. from Franklin Pierce Law Center.

Andrew Spiegel, JD

Executive Director
Global Colon Cancer Association

Andrew Spiegel has nearly two decades of experience in the patient advocacy arena. Spiegel co-founded the Colon Cancer Alliance, now the leading US based national patient advocacy organization dedicated to colon cancer. Mr. Spiegel, an attorney, besides being a co-founder of the organization and longtime board member of the Alliance became CEO in January of 2008 and he ran the CCA for nearly 5 years, before undertaking his next venture, the Global Colon Cancer Association (GCCA).

Currently, Spiegel is co-founder and executive director of the GCCA, an international patient advocacy organization. This organization is an

international community of nearly 50 colon cancer patient advocacy organizations and stakeholders dedicated to end the worldwide suffering of the 3rd leading cause of cancer deaths.

In addition to his work in the colon cancer community, Spiegel is an active advocate for healthcare policies both in the US and now worldwide. He is a co-founder and currently serves on the steering committee of the Alliance for Safe Biologic Medicines (ASBM). He is on the Board of Directors, and in December 2014 was elected to Chair, of the Digestive Disease National Coalition (DDNC), a founding member of the Coalition to Increase Clinical Trial Participation and in May of 2016 he began a three year term as a member of the Board of Directors of the International Alliance of Patient Organizations (IAPO) where he chaired the fundraising committee. Spiegel has won multiple awards for his work in patient advocacy.

Spiegel is a 1986 graduate of Temple University in Philadelphia where he earned a Bachelor's degree in Political Science with minors in English and Philosophy. He is a 1989 graduate of the Widener University School of Law. After working for a Philadelphia litigation firm, Spiegel opened his own law firm in 1995.

Pam Traxel

Senior Vice President

American Cancer Society Cancer Action Network (ACS CAN)

Pam Traxel serves as the Senior Vice President for ACS CAN, the advocacy affiliate of the America Cancer Society. Pam is responsible for helping ACS CAN develop relationships with companies and individuals to help further the fight against cancer through dynamic partnerships, events, and forums. Pam began her career with ACS CAN in 2007. She has been integrally involved in helping to establish ACS CAN as a nationwide advocacy organization that influences and shapes public policy at all levels of government to impact our mission and to represent the voices of all cancer patients and their families.

Erin Trish, PhD

Associate Director
USC Schaeffer Center
Assistant Professor, Department of Pharmaceutical and Health Economics
USC School of Pharmacy

Erin Trish is associate director of the USC Schaeffer Center and an assistant professor of pharmaceutical and health economics at the USC School of Pharmacy. In addition, she is a nonresident fellow in Economic Studies at the Brookings Institution and a scholar with the USC-Brookings Schaeffer Initiative for Health Policy.

Her research focuses on the intersection of public policy and health care markets, with recent projects focused on surprise medical bills, prescription drug spending, health care market concentration, and health care reform. Her research has been funded by grants from the Robert Wood Johnson Foundation and the Laura and John Arnold Foundation and published in leading health policy, health economics, and medical journals. She has testified in the California State Assembly and presented her research at numerous federal agencies, including the Congressional Budget Office, Federal Trade Commission, Office of the Assistant Secretary for Planning and Evaluation, and the Center for Consumer Information and Insurance Oversight. In 2018 she received the Seema Sonnad Emerging Leader in Managed Care Research Award.

Trish completed a postdoctoral fellowship at the USC Schaeffer Center and the Fielding School of Public Health at the University of California, Los Angeles. She received her PhD in Health Policy and Economics from the Johns Hopkins Bloomberg School of Public Health and her BS in Biomedical Engineering from Johns Hopkins University.

Ashley Valentine

Co-Founder and President
Sick Cells

Ashley is a Co-Founder and President of Sick Cells nonprofit. She is the youngest sibling of her family. Her older brother and Co-Founder of Sick Cells, Marqus Valentine, has sickle cell anemia, Hgb ss. Growing up, Ashley spent much of her childhood charming hospital playroom attendants while Marqus was frequently hospitalized for pain crises, fever, and multiple complications from SCD.

While in high school, Ashley first recognized the disparities for SCD when her brother developed seizures due to strokes caused by sickle cell. As a result, he lost his motor skills. The family's insurance would not cover Marqus' rehabilitation, because sickle cell is an unknown chronic disease.

The insurance company told the Valentine family that Marqus was considered "not disabled enough" for medical help. Ashley and the family worked together to rehab Marqus at home. They taught him how to hold a fork again and redeveloped his ability to speak, leading to a successful recovery. This event solidified the drive in Ashley to educate others about SCD and advocate on behalf of her family and the sickle cell community.

As an adult, Ashley completed her Master's in Research Methods from the University Of Aberdeen, Scotland. She focused on disparities in healthcare for people with SCD in London. After graduate school, she worked with University of Illinois in Chicago's sickle cell program and later transitioned into policy work in Washington, DC. While working as a policy researcher, Ashley successfully wrote sickle cell disease into part of an $8 million Centers for Medicaid and Medicare Services (CMS) funding opportunity to address disparities for adults in the emergency department.

To date, Ashley work with Sick Cells has activated the SCD community to pass federal legislation in 2018 and become stakeholders in the rare disease space. In 2019, Ashley and her brother, Marqus, were named the Chicago Red Cross Heroes and inducted into the Fresenius Kobi Blood Donation Hall of Fame for their work in federal legislation and brining awareness to sickle cell disease and the needs of the community.

Amy Walter

National Editor of The Cook Political Report and Host of WNYC's The Takeaway Fridays

For more than 20 years, Amy Walter has built a reputation as an accurate, objective, and insightful political analyst with unparalleled access to campaign insiders and decision-makers. Known as one of the best political journalists covering Washington, she is national editor of the non-partisan Cook Political Report and a frequent on-air analyst. In addition to her weekly appearance on the popular "Politics Monday" segment on the PBS NewsHour, Amy also hosts WNYC's nationally-syndicated public radio news program, "Politics with Amy Walter" on The Takeaway. She is also a regular Sunday panelist on NBC's Meet the Press and CBS's Face The Nation, and appears frequently on Special Report with Bret Baier on FOX. She is the former political director of ABC News.

In her presentations, Walter expertly breaks down the electoral process, congressional culture, and the Washington political scene. Her astuteness, wit, and range of expertise creates an engaging, compelling presentation, and her reliable and accurate analysis has earned her numerous accolades. Exclusively represented by Leading Authorities speakers bureau, Amy Walter takes audiences on an insider's tour of Washington through the eyes of the woman with her finger on the pulse of politics.

Before ABC, she was the editor-in-chief of The Hotline, Washington's premier daily briefing on American politics. There she served as the political publication's primary voice for three years, and she provided regular analysis of the national political environment in her weekly National Journal column, On the Trail. Walter has provided election night coverage and analysis since 1998 and was a member of CNN's Emmy-award winning election night team in 2006.

Walter graduated summa cum laude from Colby College. She was also honored by her alma mater her with an honorary PhD, and is as a Trustee Emeritus. She is also a member of the Board of Advisors for the University of Chicago's Institute of Politics.

Pat Wildman

Vice President, Advocacy and Government Relations
Lupus Foundation of America

Patrick Wildman is Vice President of Advocacy & Government Relations for the Lupus Foundation of America. In this role, Pat is responsible for developing and implementing strategies to advance the Foundation's public policy priorities. This includes leading the Foundation's interaction with government officials and agencies and handling legislative and regulatory issues related to the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, the Social Security Administration, Department of Defense and Department of Veterans Affairs. Pat also oversees the Foundation's Patient Focused Drug Development efforts including working with the Lupus and Allied Diseases Association, the Lupus Research Alliance and the FDA to host an externally-led PFDD meeting. Pat has over 20 years of legislative and regulatory policy and advocacy experience, including as staff for a Member of Congress and at The ALS Association as Senior Vice President of Public Policy where he led the organization's federal legislative and regulatory policy program. While at The ALS Association, Pat oversaw several PFDD initiatives, including the development of a patient-led Draft Guidance for ALS drug development and partnering with FDA to host a Part 15 Public Hearing on ALS. A native of Massachusetts, Pat received his B.A. from Dartmouth College.

Bernhardt Zeiher, MD, FCCP, FACP

Chief Medical Officer, Medical & Development
Astellas

Dr. Bernhardt G. Zeiher has an extensive background in the biopharma industry and is currently Chief Medical Officer and President, Global at Astellas. In this role, he has responsibility for Global Development Operations and Global Clinical Pharmacology and Exploratory Development (GCPED), in addition to development portfolio therapeutic area leadership. Dr. Zeiher has more than 15 years of experience in the pharmaceutical industry. Prior to joining Astellas, he was the Vice President of the inflammation/immunology therapeutic area at Pfizer. He earned his medical degree at the Case Western Reserve University School of Medicine. After medical school, he completed an internal medicine residency at University Hospitals of Cleveland and a fellowship in Pulmonary and Critical Care Medicine at University of Iowa Hospitals and Clinics.

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