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The Food and Drug Administration's Emergency Use Authorization:
Lessons Learned from the Past to Guide the Future
A Workshop

Speaker Biographies

Patrizia Cavazzoni, M.D., is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center's mission is to ensure that safe, effective and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019.

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA.

Dr. Cavazzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and is a fellow of the Canadian Royal College of Physician and Surgeons. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.

Dave A. Chokshi, MD, MSc, FACP, is Commissioner of the New York City Department of Health and Mental Hygiene. Dr. Chokshi most recently served as Chief Population Health Officer at NYC Health + Hospitals, where he built and grew an award-winning team dedicated to health system improvement, spanning innovative care models and analytics, primary care transformation, social determinants of health, community-based care management, and chronic diseases and prevention. He has taken care of patients as a primary care physician at Bellevue Hospital since 2014.

Dr. Chokshi's prior work experience spans the public, private, and nonprofit sectors, including positions with the New York City and State Departments of Health and the Louisiana Department of Health, before and after Hurricane Katrina. Dr. Chokshi served on the FEMA delegation to New York City after Hurricane Sandy in 2012. He also served as a White House Fellow and was the principal health advisor to the Secretary of Veterans Affairs.

Dr. Chokshi has written widely on public health and medicine including in The New England Journal of Medicine, JAMA, The Lancet, Health Affairs, Science, and Scientific American. In 2016, President Obama appointed him to the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health.

He trained in internal medicine at Brigham & Women's Hospital, where he received the Dunne Award for Compassionate Care, and was a clinical fellow at Harvard Medical School. During his training, Dr. Chokshi did clinical work in Guatemala, Peru, Botswana, Ghana, and India. He received his M.D. with Alpha Omega Alpha distinction from Penn, where he was elected by his peers to win the Joel Gordon Miller Prize. He also earned an MSc in global public health as a Rhodes Scholar at Oxford, and graduated summa cum laude from Duke.

Emer Cooke has been Executive Director of the European Medicines Agency since November 16, 2020.

She has over 30 years of experience in international regulatory affairs, with more than 18 of these in leadership roles. Before taking up her current role, she was the Director responsible for all medical product related regulatory activities at the World Health Organization (WHO) in Geneva between November 2016 and November 2020.

Ms. Cooke worked at EMA between 2002 and 2016. She joined the Agency as Head of Inspections and became Head of International Affairs in 2009. Prior to that, she was Principal Administrator in the Pharmaceuticals Unit of the European Commission between 1998 and 2002, with responsibility for inter alia, inspections, international activities including enlargement of the EU and selected legislative initiatives.

Ms. Cooke worked for the European Federation of Pharmaceutical industries and Associations (EFPIA) as Manager of Scientific and Regulatory Affairs from 1992 to 1995 and part time from 1996 to 1998. She also worked part time as an independent pharmaceutical policy advisor, based in the Czech Republic, from 1996 to 1998.

Ms. Cooke held a number of roles within the Irish pharmaceutical sector between 1985 and 1990 including two years as a pharmaceutical assessor at the Irish medicines regulatory authority.

Ms. Cooke holds a degree in pharmacy and two master's degrees in science and in business administration from Trinity College Dublin, Ireland.

Scott Becker, MS, is Chief Executive Officer of the American Public Health Laboratory Association. Over his 20+ year tenure, he has taken the APHL from a modest nonprofit focused on public health laboratory training to a center for quality laboratory systems with a budget of $75 million, a global reach and wide-ranging programs and services. Always energetic, Scott has expanded partnerships with the federal laboratory community, broadened APHL's membership, retained highly qualified staff – some over decades – and cultivated relationships with public health leaders that have proven instrumental to the association's growth. His active presence on Twitter and other social media platforms has strengthened APHL's brand and raised its visibility.

Scott manages an extensive portfolio, which includes APHL's strategic direction, policy development and fiscal management as well as liaison with APHL members, strategic partners and the Board of Directors. He oversees a staff of 200 located in the US and African countries, programs ranging across eight scientific disciplines, and training, communications and other member services.

A veteran of public health events from anthrax, SARS and H1N1 to Ebola, Lung Injuries/Vaping, and now 2019-nCoV, Scott leads APHL's response to emergencies. He juggles situation updates, development of

protocols and resources, media interviews, and advocacy for emergency funding and policy changes. He also regularly convenes laboratory and federal partners to coordinate activities and resolve logistical issues before they impede response operations.

Earlier in his career, Scott served as deputy executive director for the Association of Schools & Programs of Public Health (ASPPH). During a sabbatical from ASPPH, he directed a WHO project to integrate HIV/AIDS into health profession curricula. He holds a BS in Business from the University of Maryland's Robert H. Smith School of Business, and an MS in Management, with a concentration in Nonprofit Management, from the University of Maryland University College.

Seth Berkley, MD, is Chief Executive Officer of Gavi, the Vaccine Alliance. A medical doctor and infectious disease epidemiologist, Dr. Seth Berkley joined Gavi, the Vaccine Alliance as its CEO in August 2011, spearheading its mission to save lives and protect people's health by increasing equitable and sustainable use of vaccines.

Since its inception in 2000, Gavi has helped to immunise a whole generation – over 822 million children – and prevented more than 14 million deaths, helping to halve childhood mortality in 73 lower-income countries.

Prior to Gavi, in 1996, Dr. Berkley founded the International AIDS Vaccine Initiative (IAVI), the first vaccine product development public-private sector partnership, where he served as President and CEO for 15 years. Under his leadership, IAVI created a virtual vaccine product development effort involving scientists from low-income countries, industry and academia – developing and testing HIV vaccines around the world. He also oversaw a global advocacy programme that ensured HIV vaccines received prominent attention in the media and in forums such as the G8, the European Union and the United Nations.

Previously, Dr. Berkley served as an officer of the Health Sciences Division at The Rockefeller Foundation. He has worked for the Center for Infectious Diseases of the US Centers for Disease Control and Prevention (CDC); the Massachusetts Department of Public Health; and the Carter Center, where he was assigned as an epidemiologist at the Ministry of Health in Uganda. Dr. Berkley played a key role in Uganda's first national

Dr. Berkley received his undergraduate and medical degrees from Brown University and trained in internal medicine at Harvard University. In 2013, he was awarded an Honorary Doctorate by Nelson Mandela University in Port Elizabeth, South Africa, for services to global public health and advancing the right to health care for all. In 2021, Dr. Berkley received an Honorary Doctor of Science degree from Makerere University School of Public Health in Uganda.

Luciana Borio, M.D., is a Venture Partner at ARCH Venture Partners. In this capacity, she advises on and helps develop new investment opportunities related to biologics manufacturing, clinical trials, novel therapies, and areas with large unmet clinical needs.

Dr. Borio is a specialist in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies. Prior to joining ARCH, she was a senior vice president at In-Q-Tel, an independent, non-profit, strategic investment firm that works to deliver innovative technology solutions to support the missions of the U.S. Intelligence Community. Past positions include serving as a member of President Biden's transition COVID-19 Advisory Board and Director for Medical and Biodefense Preparedness at the National Security Council (2017-2019), where she coordinated the response to the Ebola epidemic in West Africa, efforts to combat antimicrobial resistance, and the development of an Executive Order to modernize America's influenza vaccines. Prior to that, she was the Acting Chief Scientist of the U.S. Food and Drug Administration (2015-2017) and the Assistant Commissioner for Counterterrorism Policy of the FDA (2010-2017).

Dr. Borio is an adjunct Assistant Professor of Medicine at Johns Hopkins University (2003-present), where she continues to practice medicine part-time. She is also a senior fellow for global health at the Council on Foreign Relations.

Dr. Borio obtained her M.D. from George Washington University, completed a residency in internal medicine at New York-Presbyterian/Weill Cornell Medical Center, and a combined fellowship in infectious diseases at Johns Hopkins and critical care at the National Institutes of Health.

Robert M. Califf, MD, MACC, is the Head of Clinical Policy and Strategy for Verily and Google Health. Prior to this Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

Ruth Faden, PhD, MPH, is the Founder of the Johns Hopkins Berman Institute of Bioethics, and was its Director from 1995 until 2016. She is also the Philip Franklin Wagley Professor of Biomedical Ethics. Her research focuses on structural injustice theory and public policy including national and global challenges in food, agriculture and climate, learning health care systems, women's health, health systems design and priority setting, and advances in science and technology. Currently Dr. Faden is working at the intersection of structural justice and the COVID-19 response, primarily in vaccine allocation and prioritization and K-12 education. Her latest book, with Madison Powers, is *Structural Injustice: Power, Advantage, and Human Rights* (September, 2019; Oxford University Press).

Michael Fraser, PhD, CAE, FCPP, is chief executive officer of The Association of State and Territorial Health Officials (ASTHO), the national nonprofit organization representing the public health agencies of the United States, the U.S. territories and freely associated states, and Washington, D.C.

Prior to joining ASTHO, he served many leadership positions including executive vice president and CEO of the Pennsylvania Medical Society, CEO of the Association of Maternal and Child Health Programs, and deputy executive director of the National Association of County and City Health Officials. He also served in several capacities at the U.S. Department of Health and Human Services.

Dr. Fraser received his doctorate and master's degrees in sociology from the University of Massachusetts at Amherst and a master's in management with a concentration on management, strategy, and leadership from the Eli Broad School of Management at Michigan State University.

He is a co-editor of *the Public Health Guide to Ending the Opioid Crisis* published by the Oxford University Press and a co-editor and author of the *Handbook of Strategic Skills for Public Health Practice,* to be published in 2021.

Monica Gandhi, MD, MPH, is an infectious diseases doctor, Professor of Medicine and Associate Chief in the Division of HIV, Infectious Diseases, and Global Medicine at the University of California, San Francisco (UCSF). She is also the Director of the UCSF Center for AIDS Research (CFAR) and the Medical Director of the HIV Clinic ("Ward 86") at San Francisco General Hospital. Her research focuses on HIV and women

and adherence measurement in HIV treatment and prevention and most recently, on how to mitigate the COVID-19 pandemic.

Richard J. Hatchett, MD, is Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI), a partnership of public, private, philanthropic and civil organizations that supports the development of vaccines against high priority public health threats and technology platforms to allow the rapid development of vaccines against emerging infectious diseases such as COVID-19. Dr. Hatchett was previously the acting Director of the U.S. Biomedical Advanced Research and Development Authority (BARDA) and served as Director of Medical Preparedness Policy on the Homeland and National Security Councils under Presidents Bush and Obama, respectively. He received his medical degree from Vanderbilt and completed clinical training in internal medicine and medical oncology at Cornell and Duke.

Aaron S. Kesselheim, MD JD MPH, is a Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Within the Division, Aaron created and leads the Program On Regulation, Therapeutics, And Law (PORTAL, www.PORTALresearch.org), an interdisciplinary research core focusing on intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. PORTAL is now among the largest, independent academic centers focusing on these issues in the country (Twitter: @PORTAL_research, @akesselheim). Dr. Kesselheim received his medical and legal training at the University of Pennsylvania and his M.P.H. at the Harvard School of Public Health. Author of over 450 publications in the peer-reviewed medical and health policy literatures, Aaron has testified before Congress on pharmaceutical policy, medical device regulation, generic drugs, and modernizing clinical trials, is a member of the FDA Peripheral and Central Nervous System Advisory Committee, and served on a National Academies of Science, Engineering and Medicine consensus committees on addressing the opioid epidemic and bioidentical hormone replacement. At the HMS Center for Bioethics, he co-teaches a course on health policy, law, and bioethics and organizes the monthly policy and ethics consortium.

Nicole Lurie, MD, MSPH, is currently the Strategic Advisor to the CEO of the Coalition for Epidemic Preparedness Initiatives (CEPI). She is also a Senior Lecturer at Harvard Medical School, a member of the research faculty at Massachusetts General Hospital and Professor of Medicine at George Washington University School of Medicine. She served an 8-year term as Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. In that role she led the HHS response to numerous public health emergencies, ranging from infectious disease to natural and man-made disasters and is responsible for many innovations in emergency preparedness and response. She also chaired the Public Health Emergency Medical Countermeasures Enterprise, a government-wide organization ultimately responsible for the development of medical countermeasures, including vaccines against pandemics and emerging threats.

Prior to federal service, she was the Paul O'Neill Professor of Policy Analysis at RAND, where she started and led the public health preparedness program and RAND's Center for Population Health and Health Disparities. She has also had leadership roles in academia, as Professor of Medicine and Public Health at the University of Minnesota, as Medical Advisor to the Commissioner, Minnesota Department of Health, and as Principal Deputy Assistant Secretary for Health at the US Department of Health and Human Services. Dr. Lurie received her BA and MD degrees from the University of Pennsylvania, and completed her residency

and public health training at UCLA. Her research has focused on access to and quality of care, health system redesign, equity, mental health, public health and preparedness. She is recipient of numerous awards and is a member of the National Academy of Medicine. She continues to practice clinical medicine in a community clinic in Washington D.C.

Peter Lurie, MD, MPH, is President of the Center for Science in the Public Interest, a food and health advocacy group. Previously, Lurie was the Associate Commissioner for Public Health Strategy and Analysis at the Food and Drug Administration, where he worked on antimicrobial resistance, transparency, caffeinated beverages, drug shortages, expanded access to investigational drugs, laboratory developed tests, and prescription drug abuse. Prior to that, he was Deputy Director of Public Citizen's Health Research Group, where he addressed drug and device issues, coauthored the organization's *Worst Pills, Best Pills* consumer guide to medications, and led efforts to reduce worker exposure to hexavalent chromium and beryllium. Earlier, as a faculty member at the University of California, San Francisco and the University of Michigan, he studied needle exchange programs, ethical aspects of mother-to-infant HIV transmission studies, and other HIV policy issues domestically and abroad.

Dr. Murray Lumpkin, MD, became Deputy Director – Integrated Development and Lead for Global Regulatory Systems Initiatives at the **Bill and Melinda Gates Foundation** in 2014. He leads the Foundation's strategic initiatives around global regulatory systems optimization working with the World Health Organization and other multinational organizations, regional and other regulatory harmonization initiatives, and national regulatory authorities. These initiatives are focused on making more efficient and effective (without sacrificing product quality) the regulatory processes through which products must pass to be developed, marketed, and overseen after approval in low-income countries.

He retired from the FDA in 2014 after just over 24 years of service. From 2011 to 2014, he was the Commissioner's Senior Advisor and Representative for Global Issues. From 2001-2011, he was responsible for the policy development and operational aspects of the FDA's international activities (as Deputy Commissioner for International and Special Programs 2005-2011) during which, under his leadership, FDA's foreign posts were established and FDA's confidentiality arrangements, working relationships, and harmonization activities with foreign counterpart agencies were designed and implemented. From 1993-2000, he was the Deputy Center Director (Review Management) of FDA's Center for Drug Evaluation and Research (CDER), and from 1989-1993, he was the Director of CDER's Division of Anti-infective Drug Products.

He is an MD with post-graduate training in pediatrics and pediatric infectious diseases at the Mayo Clinic. As a Fulbright Scholar, he completed an MSc in medical parasitology at the London School of Hygiene and Tropical Medicine and received his certification in tropical medicine and hygiene.

Peter Marks, MD, PhD, is Director of the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings

teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

Dr. Analia Porrás is the Unit Chief of the Medicines and Health Technologies Unit, Department of Health Systems and Services (HSS/MT) at the Pan American Health Organization (PAHO)/ World Health Organization (WHO). She leads the team responsible for providing technical cooperation to Latin America and the Caribbean to improve equitable access to quality, safe and effective medicines, and other health technologies. HSS/MT provides support to member states in a vast array of areas, from regulation to rational use of medicines and other health technologies, pharmaceutical policies, and innovation and manufacturing, among others. In addition, the team plays a critical role in ensuring the quality of pharmaceuticals, vaccines and in vitro diagnostics procured through the PAHO revolving funds.

Dr. Porrás, a national of Argentina, has held several clinical, research and academic positions before joining PAHO in 2007. She received her Medical Degree (1989) from the University of Buenos Aires, Argentina, a PhD in Molecular and Cellular Biology (1997) from Northwestern University, Illinois, USA, and a master's in science in Health Economics, Policy and Management (2013) from the London School of Economics and Political Science, London, United Kingdom.

June Raine, MSc, CBE, is Chief Executive of the Medicines and Healthcare products Regulatory Agency in the United Kingdom. She qualified in medicine at Oxford University, and undertook postgraduate research leading to an MSc in pharmacology. After general medical posts and Membership of the Royal Colleges of Physicians (MRCP), she joined the then Medicines Division in 1985, and has worked in several licensing areas including the Review of Medicines, new drugs and abridged. Prior to becoming Chief Executive, June was Director of Vigilance and Risk Management of Medicines from 1999 to 2019.

As Chief Executive, June chairs the Executive Committee, which is the highest decision-making body in the agency.

Helen Rees, GCOB, OBE, MB BChir, MA (CANTAB), MRCGP, DCH, DRCOG mASSAf, is the Executive Director of Wits RHI. Helen Chairs the Board of the South African Health Products Regulatory Authority and also Chairs the World Health Organisation's AFRO Region Immunization Technical Advisory Group. She has extensive involvement in national, regional and global response efforts to COVID-19 including the development of COVID-19 vaccines, their potential rollout and utilization.

She is a member of the South African Ministerial Advisory Committee on COVID-19 and a member of the South African Ministerial Advisory Committee on COVID-19 vaccines. She Chairs the South African VACC-MAC COVID-19 Variant Technical Working Group and is a member of the South African National Essential Medicine Committee on COVID-19. Helen is involved with the oversight of the COVAX facility that GAVI, CEPI and WHO are jointly driving. She is a member of the COVAX committee on COVID-19 maternal immunization and a member of the WHO IHR Emergency Committee on COVID-19, member of the WHO Expert Committee on COVID-19 vaccines, and a member of WHO's Scientific and Technical Advisory Group on Infectious Hazards.

Helen has chaired the WHO's International Health Regulation Polio Emergency Committee since 2014 and Co-Chairs the WHO SAGE Working Group on Ebola Vaccines. Helen is a member of the Global Alliance for Vaccines and Immunization Board and chairs the Gavi Programme and Policy Committee. She is a member of the Coalition for Epidemic Preparedness and Innovation Board and chairs the CEPI Scientific Advisory Committee.

Jörg Schläpfer, PhD, is Head of Management Services and International Affairs at the Swiss Agency for Therapeutic Products (Swissmedic). He holds a PhD from the Division of Molecular Genetics, Institute of Animal Genetics, Nutrition and Housing at the University of Berne. Prior to joining Swissmedic in 2015, Dr. Schläpfer worked on various regulatory issues in various positions at Berne Biotech AG, Novartis Pharma Schweiz AG.

Jeffrey E. Shuren, MD, JD, is Director of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration, a position he has held since 2010. He previously served as Acting Center Director, beginning in September 2009. The center is responsible for assuring the safety, effectiveness, and quality of medical devices; assuring the safety of radiation-emitting products (such as cell phones and microwave ovens); and fostering device innovation.

Dr. Shuren received his BS and MD from Northwestern University under its Honors Program in Medical Education. He completed his medical internship at Beth Israel Hospital in Boston, his neurology residency at Tufts New England Medical Center, and a fellowship in behavioral neurology and neuropsychology at the University of Florida. He received his J.D. from the University of Michigan.

Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including acting deputy commissioner for policy, planning, and budget; associate commissioner for policy and planning; special counsel to the principal deputy commissioner; assistant commissioner for policy; and medical officer in the Office of Policy.

As director of the Division of Items and Devices, Coverage and Analysis Group at the Centers for Medicare and Medicaid Services, Dr. Shuren oversaw the development of Medicare national coverage determinations for drugs, biologics, and non-implantable devices.

Mariângela Batista Galvão Simão, MSc, is Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals. Most recently, she was Director of Community Support, Social Justice and Inclusion at UNAIDS. In addition to her work at UNAIDS, she brings more than 30 years of experience working in the Brazilian public health system and has played an active role in enhancing access and decentralizing health services in the country. Between 2006 and 2010, she served as Director of the National STD/AIDS and Viral Hepatitis Department in the Brazilian Ministry of Health, where she led successful price negotiations with pharmaceutical companies to lower the price of HIV medication. During this time, she also represented the Brazilian Ministry of Health in the negotiations that led to the constitution of UNITAID in 2006, including its governing body, where she served as a board member until 2008. She was trained as a pediatrician in Brazil and holds an MSc degree in public health from University of London, United Kingdom.

Soumya Swaminathan, MD, MBBS, was appointed WHO's first Chief Scientist in March 2019. A paediatrician from India and a globally recognized researcher on tuberculosis and HIV, she brings with her 30 years of experience in clinical care and research and has worked throughout her career to translate research into impactful programmes. Dr. Swaminathan was Secretary to the Government of India for Health Research and Director General of the Indian Council of Medical Research from 2015 to 2017. In that position, she focused on bringing science and evidence into health policy making, building research capacity in Indian medical schools and forging south-south partnerships in health sciences. From 2009 to 2011, she also served as Coordinator of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases in Geneva.

She received her academic training in India, the United Kingdom, and the United States of America, and has published more than 350 peer-reviewed publications and book chapters. She is an elected Foreign Fellow of the US National Academy of Medicine and a Fellow of all three science academies in India. The Science division's role is to ensure that WHO stays ahead of the curve and leverages advances in science and technology for public health and clinical care, as well as ensuring that the norms, standards and guidelines produced by WHO are scientifically excellent, relevant and timely. Her vision is to ensure that WHO is at the cutting edge of science and is able to translate new knowledge into meaningful impact on population health worldwide.

Anne Zink, MD, FACEP is Chief Medical Officer for the State of Alaska. She grew up in Colorado and moved through her training from College in Philadelphia to Medical School at Stanford and then Residency at University at Utah. As a mountaineering guide she had fallen in love with Alaska and after residency in Emergency Medicine became lucky enough to call Alaska home. Alaska is a small, isolated microcosm on the US health care where certain forces like the distance, lack of referral centers, and community involvement help create better systems of care that are directly related to bedside care. She quickly became involved in helping improve systems of care as the medical director of her group, then in her hospital and with state and federal legislation, including state legislation to improve care coordination, opioid addiction treatment option, integration between private systems and the VA, DOD, and IHS facilities and more.

Dr. Zink had the honor of becoming the State of Alaska Chief Medical Officer in July 2019. In all the work she does, she strives to create work environments, policies, and practices that are data-driven, foster collaboration and build system efficiencies that put patients first.

Patricia A. Zettler, JD, is an Associate Professor of Law at The Ohio State University Moritz College of Law, a faculty member of the Drug Enforcement & Policy Center housed at the College of Law, and a Member of The Ohio State University Comprehensive Cancer Center. Professor Zettler's teaching areas include *Torts*, *Legislation and Regulation*, *Health Law*, and *Food and Drug Law*.

Professor Zettler's research focuses on the regulation of medicine, drugs and other medical products, and tobacco products, with an emphasis on the U.S. Food and Drug Administration (FDA).

Before joining the Ohio State faculty in 2019, Professor Zettler was a faculty member of the Center for Law, Health & Society at Georgia State University College of Law. At Georgia State Law, she was selected as the 2018 winner of the Patricia T. Morgan Award for Outstanding Scholarship among the faculty. Prior to Georgia State, she was a fellow at the Center for Law and the Biosciences at Stanford Law School.

In addition to Professor Zettler's academic work, she served as an associate chief counsel in the FDA's Office of the Chief Counsel. In that role, she advised the FDA and the Department of Health and Human Services on various issues including drug safety, human subjects protection, expanded access to investigational drugs, over-the-counter drugs, dietary supplements, prescription drug advertising and promotion, incentives for developing antibiotics, and advisory committees. Professor Zettler also has bioethics experience through work at the Program in Medical Ethics at the University of California San Francisco and at the Department of Bioethics at the National Institutes of Health.

Professor Zettler graduated with distinction from Stanford Law School in 2009. She received a BA in psychology, with distinction and departmental honors, from Stanford University in 2002, where she played on the varsity lacrosse team.