Instructions

Thank you for attending this class. We hope you found the class informative, and we look forward to serving your MCLE needs in the future. Attached is a *Uniform Certificate of Attendance* and the supporting information your jurisdiction **may** require of you.

Please check your Certificate to ensure the information it contains is correct, then complete the Certificate as directed. You do **not** have to return this form to the District of Columbia Bar.

Please call us at (202) 626-3488 or email us at mcle@dcbar.org, if you have any questions.

Uniform Certificate of Attendance

This certificate should be filed with the appropriate MCLE Board(s) or Commission(s) within 30 days of activity.

Sponsor: District of Columbia Bar

Activity Title: 2025 National Vaccine Law Association Conference

Date: September 11 and 12, 2025

Location: Live Webinar

State Activity Number: _____
(for those states designating program numbers)

This program is eligible for a total of:

6.0 **CLE credits (60 minute hour)**

7.0 **CLE credits (50 minute hour)**

Of this total:

0.0 **Ethics credits (60 minute hour)**

0.0 **Ethics credits (50 minute hour)**

NOTE: Introductory remarks, keynote addresses, business meetings, breaks, receptions, etc., are not included in the computation of credit.

TO BE COMPLETED BY ATTORNEY:

By signing below, I certify that I attended the activity described above and am entitled to claim

_____ CLE credit hours, including _____ Ethics credits.

Attorney Name(Print): **Membership, Registration or Supreme Court Number**

Attorney Signature **Date**

State where credits are to be registered

Note: Complete a certificate for each state in which you are required to file. Rules for CLE in some states require the provider to file attendance with the regulator as a service to lawyers. Please confirm jurisdictional reporting requirements with the provider or state regulator. Should your jurisdiction require, we are attaching the class description, agenda, and speaker bio statement(s).

Acknowledged by:

Theresa Iannino

Sponsor Representative

2025 National Vaccine Law Association Conference
Offered by Webinar for MCLE Credit
Thursday, September 11, 2025, and Friday, September 12, 2025

Time: Thursday, September 11, 2025, 12:30 p.m. – 5:15 p.m. and Friday, September 12, 2025, 10:00 a.m. – 1:15 p.m.

Credits: Up to 6.0 general credit hours

Class Level: Intermediate

Description: The 2025 National Vaccine Law Conference convenes a multidisciplinary gathering of legal experts, public health leaders, and professionals from across the vaccine ecosystem for a robust exchange of ideas, practical learning, and collaboration. The conference provides a comprehensive legal forum covering the development, regulation, distribution, and administration of vaccines. You will have the opportunity to engage in focused learning tracks led by leading authorities, offering immediate takeaways to inform practice, policy, and advocacy in vaccine law.

Core topics include the legal dimensions of vaccine research and development, intellectual property protections, safety and injury compensation frameworks, and strategies for enhancing vaccine confidence and equity. The conference also explores the legal landscape shaping public health preparedness, vaccine financing, workplace vaccination policies, and the evolving responsibilities of healthcare providers and payors. As a hub for timely, research-driven dialogue, the conference continues to serve as a critical platform for shaping the future of vaccine law and access.

Faculty: See agenda.

Cosponsor: National Vaccine Law Association

Fees: $25 to $195. For more information concerning registration and conference fees, click here.

Categories:

CLE	Communities
Business & Corporations	Administrative Law & Agency Practice

Commercial & Consumer	Antitrust & Consumer Law
Constitutional	Corporations, Finance, and Securities Law
Elder	District of Columbia Affairs
Employment & Labor	Early Career Lawyers
Family	Family Law
Government	Health Law
Health	Intellectual Property Law
Intellectual Property	International Law
International	Labor and Employment Law
Litigation	Law Practice Management
Tort	Law Student
	Litigation
	Tort Law

2025 National Vaccine Law Association Conference
Offered by Webinar for MCLE Credit
Thursday, September 11, 2025, and Friday, September 12, 2025

Agenda

Thursday, September 11, 2025

12:30 p.m. – 1:00 p.m.

Welcome
(Non-CLE Eligible)

Description: Join us as we kick off the National Vaccine Law Association Conference. This session provides a warm welcome, introduces the conference agenda, and offers an overview of the Association's mission, initiatives, and community. Meet fellow attendees and begin your journey through a dynamic and timely legal exploration of vaccine law.

Speakers: Brian Dean Abramson, Florida International University College of Law; Shelley Fiscus, Association of Immunization Managers; and Dayna Bowen Matthew, George Washington University Law School

1:00 p.m. – 1:05 p.m.

- Panel Transition

1:05 p.m. – 2:05 p.m.

Plenary Session: Threats to the Vaccine Ecosystem
(1.0 CLE Credit Hour)

Description: This plenary session explores the growing threats facing the vaccine ecosystem. Our expert speaker will examine how public policy initiatives that undermine vaccine confidence pose significant risks to public health. You will gain

insight into the legal and regulatory dimensions of these threats and explore potential responses across public and private sectors.

Panel: Paul A. Offit, Children's Hospital of Philadelphia and Shelley Fiscus, Association of Immunization Managers (Moderator)

2:05 p.m. – 2:10 p.m.

- Panel Transition

2:10 p.m. – 3:10 p.m.

Concurrent Sessions

Session A: Vaccine Regulation/Development /IP
Vaccine Law and Future Developments
(1.0 CLE Credit Hour)

Description: This session provides a comprehensive overview of the regulatory journey from vaccine formulation through clinical trials, Emergency Use Authorization, full United States Food and Drug Administration licensure, and post-market surveillance. The panel places special emphasis on evolving regulatory priorities under the current Administration and how these changes are shaping the legal landscape for vaccine development.

Panel: Robert M. Califf, Duke University School of Medicine; Cathy Burgess, Alston & Bird LLP; Nicholas J. Diamond, Greenberg Traurig LLP; Jeremiah J. Kelly, Venable LLP; and Eva Temkin, Arnold & Porter Kaye Scholer LLP (Moderator)

Session B: Employer, Provider, Payor
Coverage and Payment Issues (Changes with ACA)
(1.0 CLE Credit Hour)

Description: This session examines vaccine coverage and reimbursement in light of major policy changes, including the Affordable Care Act and the Inflation Reduction Act. Our knowledgeable panel analyzes the evolving interplay between insurers, providers, and employers, and explores legal considerations affecting access and affordability.

Panel: Richard H. Hughes IV, Epstein Becker & Green PC; Jacob Madden, Simpson Thacher & Bartlett LLP; James M. Paul, Ogletree, Deakins, Nash, Smoak & Stewart PC; and Bola Popoola, Centers for Disease Control and Prevention (Moderator)

Session C: Public Health and Preparedness –
Trust Fall: A New Era for Vaccine and Public Health Authorities
(1.0 CLE Credit Hour)

Description: Public trust in vaccination and public health institutions is at a crossroads. This session delves into how public skepticism has grown, why it matters, and how authorities can navigate the challenges of today's legal, regulatory, and social climate to protect public health. Our esteemed panel evaluates both reactive and proactive legal tools for fostering public trust and effective preparedness.

Panel: Noel Brewer, UNC Gillings School of Global Public Health; Stacie S. Kershner, Georgia State University College of Law; Ana Santos Rutschman, Villanova University Charles Widger School of Law (Moderator); and Rose Weeks, Johns Hopkins Bloomberg School of Public Health

Session D: Safety and Public Confidence –
Perception, Communications, and the Law
(1.0 CLE Credit Hour)

Description: Explore the complex relationship between legal change, public perception, and misinformation. This session investigates how anti-vaccine rhetoric influences legislation, administrative regulation, and court decisions — and vice versa. Panelists will assess the legal avenues available to combat misinformation and bolster public confidence in vaccine safety and efficacy.

Panel: Ashley Chambers, American Families for Vaccines; Claudia E. Haupt, Northeastern University; Dorit Rubinstein Reiss, University of California San Francisco College of Law (Moderator); and Jerry Williamson, Loyola University Chicago School of Law

Session E: Nuts and Bolts –
Intro to Vaccine Science and Biology: Refuting Myths and Memes
(1.0 CLE Credit Hour)

Description: Designed for legal professionals seeking foundational knowledge, this informative session unpacks the essential science behind vaccines. Our distinguished speaker addresses how scientific facts are often misrepresented in popular discourse and provides tools to help legal professionals identify and counteract widespread misinformation, disinformation, and viral myths.

Panel: Karen Ernst, Voices for Vaccines (Speaker) and Shelley Fiscus, Association of Immunization Managers (Moderator)

3:10 p.m. – 3:15 p.m.

- Panel Transition

3:15 p.m. – 4:15 p.m.

Concurrent Sessions

Concurrent Session A: Vaccine Regulation/Development/IP – Vaccine Pipeline
(1.0 CLE Credit Hour)

Description: From bench to bedside, this session explores the robust pipeline of vaccine and other prophylactic assets currently under development. The panel highlights promising clinical and preclinical innovations and assesses the legal and policy frameworks needed to support advancement and ensure equitable access.

Panel: Phyllis Arthur, Biotechnology Innovation Organization (BIO); Robert M. Califf, Duke University School of Medicine; Sarah Karlin-Smith, POLITICO; and Darshan Kulkarni, Kulkarni Law Firm (Moderator)

Concurrent Session B: Employer, Provider, Payor – Implementing and Administering an Effective Workforce Vaccine Mandate
(1.0 CLE Credit Hour)

Description: This session focuses on the legal, policy, and operational complexities of implementing workforce vaccine mandates. You will gain practical insights into employer obligations, employee rights, and strategies for achieving compliance while minimizing legal risk and workplace disruption.

Panel: [To be announced] and James M. Paul, Ogletree, Deakins, Nash, Smoak & Stewart PC (Moderator)

Concurrent Session C: Public Health and Preparedness – Global Health Security
(1.0 CLE Credit Hour)

Description: As global public health threats escalate, this session provides a timely assessment of global health security initiatives. Our expert panel discusses the evolving roles of international regulatory bodies, the shifting leadership position of the United States, and emerging legal and policy strategies for cross-border disease prevention and pandemic preparedness.

Panel: Ana Ayala, University of San Francisco School of Nursing and Health Professions; Julia Barnes-Weise, Global Healthcare Innovation Alliance Accelerator;

Simpson Thacher & Bartlett LLP (Moderator); and Ximena Benavides Reverditto, Yale Law School

Concurrent Session D: Safety and Public Confidence – Vaccine Liability and Injury Compensation
(1.0 CLE Credit Hour)

Description: This session offers an in-depth overview of the National Vaccine Injury Compensation Program and its related legal frameworks. You will gain a clearer understanding of how the system balances vaccine safety, public trust, and legal accountability in the context of rare adverse events.

Panel: David Carney, Green & Schafle, LLC; Brian H. Corcoran, Chief Special Master, United States Court of Federal Claims; Renée Gentry, The Law Office of Renée J. Gentry, Esq. (Moderator); and Heather Perlman, United States Department of Justice

Concurrent Session E: Nuts and Bolts – Intro to Vaccine Law (Regulations and IP)
(1.0 CLE Credit Hour)

Description: This foundational session introduces the core legal concepts governing vaccine development, including intellectual property protections, regulatory frameworks, and the role of government authority. Designed for newcomers and seasoned practitioners alike, the session lays essential groundwork for navigating the vaccine legal landscape.

Panel: Brian Dean Abramson, Florida International University College of Law and Vanessa K. Burrows, Simpson Thacher & Bartlett LLP

4:15 p.m. – 5:15 p.m.

Plenary Session: Understanding and Addressing Parental Risk Perception
(1.0 CLE Credit Hour)

Description: Parents play a pivotal role in vaccine decision-making. This insightful session explores how parents assess vaccine-related risks and benefits, particularly in the absence of visible disease. Drawing on public health communication strategies, our distinguished speaker examines how hesitancy arises and what legal and policy interventions may reshape parental attitudes amid the resurgence of preventable diseases.

Panel: Charlotte A. Moser, Children's Hospital of Philadelphia (Speaker) and René Najera, George Mason University, College of Public Health (Moderator)

5:15 p.m.

Thank You and Adjourn
(Non-CLE Eligible)

Speakers: Brian Dean Abramson, Florida International University College of Law and Shelley Fiscus, Association of Immunization Managers

Friday, September 12, 2025

10:00 a.m. – 10:05 a.m.

Welcome
(Non-CLE Eligible)

Speakers: Brian Dean Abramson, Florida International University College of Law; Shelley Fiscus, Association of Immunization Managers

10:05 a.m. – 11:05 a.m.

Plenary Session: Navigating Public Health Challenges Through Law and Policy: A Keynote Conversation with Dr. Chelsea Clinton
(Non-CLE Eligible)

Description: Join us for this keynote conversation with Dr. Chelsea Clinton that explores the intersection of public health and legal frameworks. Dr. Clinton will address today's most pressing health challenges and how legal systems and policy can foster more equitable and effective public health responses.

Panel: Dr. Chelsea Clinton, Clinton Foundation and Metrodora Ventures (Speaker) and Shelley Fiscus, Association of Immunization Managers (Moderator)

11:05 a.m. – 11:10 a.m.

- Panel Transition

11:10 a.m. – 12:10 p.m.

Concurrent Sessions

Concurrent Session A: Vaccine Regulation/Development/IP –
Federal Development of Vaccines: IP Case Studies
(1.0 CLE Credit Hour)

Description: This session unpacks how intellectual property law shapes vaccine innovation. Join our distinguished panel as they discuss the economics of patenting, federal involvement in R&D, and the balance between public interest and proprietary rights.

Panel: Richard Wilder, O'Neill Institute for National and Global Health Law; Michael Siekman, Goodwin Proctor LLP; and Ha Kung Wong, Venable LLP (Moderator)

Concurrent Session B: Practical, Administrative, and Legal Framework of Vaccination in the Academic Setting
(1.0 CLE Credit Hour)

Description: Exemptions to vaccine mandates are under new scrutiny in the post-pandemic world. Our esteemed speaker examines how courts are rethinking legal, religious, and medical objections, and what that means for employers, health care providers, and public agencies.

Panel: Robin Cogan, Rutgers University-Camden School of Nursing (Speaker) and Bola Popoola, Centers for Disease Control and Prevention (Moderator)

Concurrent Session C: Public Health and Preparedness –
The Changing Scope of Public Health Powers
(1.0 CLE Credit Hour)

Description: Public health powers once taken for granted are now being contested in courts and legislatures. This timely session maps the legal rollback and explores where public health authority stands at the federal, state, and local levels – and how it might evolve.

Panel: Robert Gatter, Saint Louis University School of Law, Center for Health Law; James G. Hodge, Jr., Sandra Day O'Connor College of Law at Arizona State University; and Montrece Ransom, National Coordinating Center for Public Health Training (Moderator)

Concurrent Session D: Safety and Public Confidence – Vaccine Advocacy
(1.0 CLE Credit Hour)

Description: In this forward-looking session, our panel examines both long-standing and new and emerging challenges facing vaccine advocates. The panel discusses

hesitancy and misinformation, government action by various parts and levels of government, and how advocates are navigating them – and what more we can do.

Panel: Abby Bownas, NVG LLC; Brent Ewig, Association of Immunization Managers; Amy Pisani, Vaccinate Your Family; and Dorit Rubinstein Reiss, University of California San Francisco College of Law (Moderator)

Concurrent Session E: Vaccines in the Courts
(1.0 CLE Credit Hour)

Description: This insightful session discusses legal obstacles to vaccine availability and to maintaining high vaccination rates. Our expert panel reviews recent developments in vaccine product liability, vaccine-related multidistrict litigation, and the impact of PREP Act preemption/immunity from the COVID-19 pandemic.

Panel: James M. Beck, Reed Smith LLP and Matthew P. Motta, Boston University's School of Public Health

12:10 p.m. – 12:15 p.m.

- Panel Transition

12:15 p.m. – 1:15 p.m.

Plenary Session: Then and Now: What Past Epidemics Can Teach Us About Today – and Tomorrow
(1.0 CLE Credit Hour)

Description: In this timely presentation, our distinguished speaker explores the recent measles outbreaks in Canada, Mexico, and the United States through the lens of history, comparing them to epidemics of the 1990s – before measles was declared eliminated in the United States. Drawing on patterns in transmission, public health response, and vaccine coverage, the talk highlights how today's challenges echo those of the past, while also revealing new complexities in an era shaped by misinformation, shifting policies, and strained resources. Yet, amid the setbacks, our speaker offers a message of hope: history shows that even in the face of epidemics, political pressure, and budget cuts, public health and medicine have repeatedly come together to protect the most vulnerable, especially children.

Panel: René Najera, George Mason University, College of Public Health (Speaker) and Shelley Fiscus, Association of Immunization Managers (Moderator)

1:15 p.m.

Thank You and Adjourn
(Non-CLE Eligible)

Speakers: Brian Dean Abramson, Florida International University College of Law and Shelley Fiscus, Association of Immunization Managers

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2025 National Vaccine Law Association Conference

About the Speakers
(Listed Alphabetically)

Brian Dean Abramson is the lead author of the legal treatise, *Vaccine, Vaccination, and Immunization Law*, published by Bloomberg Law in cooperation with the American Health Law Association. He teaches the subject as an adjunct professor of vaccine law at the Florida International University College of Law and the University of Houston Law Center.

Prof. Abramson previously wrote for Bloomberg Law, for whom he first authored the vaccine injury claims chapter of Matthew H. Solomson's *Court of Federal Claims: Jurisdiction, Practice, and Procedure*, and for which he wrote extensively in the fields of health and international privacy law. He was a law clerk for the Honorable Pauline Newman of the United States Court of Appeals for the Federal Circuit and interned with the Honorable Susan G. Braden of the United States Court of Federal Claims.

Prof. Abramson received an MA in comparative sociology from Florida International University, followed by his JD, *summa cum laude*, from the Florida International University College of Law, and an LLM in intellectual property law with highest honors from the George Washington University Law School.

Phyllis Arthur is the executive vice president & head of healthcare policy and programs at the Biotechnology Innovation Organization (BIO). In this role, Phyllis is responsible for leading a robust portfolio of health-care policy issues with member companies, including pricing, reimbursement, access, infectious disease, national security, and capital formation. Previously, Phyllis served as senior vice president for infectious disease and emerging science policy, where she worked with member companies in vaccines, antimicrobial resistance, and biodefense on policy, legislative, and regulatory issues. Phyllis joined BIO in July 2009 as the director of healthcare regulatory affairs.

Prior to joining BIO, Phyllis worked in numerous marketing and sales positions for Merck & Co. in their Vaccine Division. Over her sixteen-year career at Merck, she launched several exciting new vaccines in the United States and internationally, including the first HPV vaccine GARDASIL. During her years in marketing, she worked closely with clinical and academic thought leaders on infectious diseases, oncology, and public health. In addition, Phyllis also led a large vaccine sales

organization of over seventy-five representatives and managers covering fourteen states.

Before graduate school, Phyllis worked as a research assistant at the Brookings Institution in Washington, D.C. There, she conducted economic analyses related to savings and investment policies for Organisation for Economic Co-operation and Development countries. Phyllis received her BA in economics and international politics from Goucher College and her MBA from the Wharton School of Business at the University of Pennsylvania.

Ana S. Ayala is an adjunct professor of public health at the University of San Francisco (USF) School of Nursing and Health Professions, and a senior scholar at the O'Neill Institute. She teaches Health Policy and Ethics at USF, the foundational course of the Master of Public Health program, equipping future public health leaders with critical tools to navigate the ethical, legal, and policy dimensions of population health. The class is an interdisciplinary examination of the ethical and policy dimensions of public health, providing an overview of each subject and explores how historic and current activities in these arenas promote (or hinder) socially just outcomes in the field of public health.

At the O'Neill Institute, Ana contributes to global health law and legal preparedness scholarship, capacity-building, and partnership building to strengthen health emergency preparedness, drawing on her experience in international law, global health security, and cross-sector engagement. She leads and supports initiatives that bridge law, global health, and international cooperation through research, technical engagement, and institutional advising on legal preparedness. Ana also represents the Institute in high-level academic and policy forums focused on global health law and legal preparedness.

Ana is admitted to the Maryland Bar. She earned an LLM in global health law from Georgetown University Law Center, a JD from the American University Washington College of Law, and a BA in anthropology and international studies from the University of Chicago.

Julia Barnes-Weise is the founder and executive director of the Global Healthcare Innovation Alliance Accelerator. Ms. Barnes-Weise received her JD from the University of North Carolina and her BA from Ohio Wesleyan University. Ms. Barnes-Weise trained as a lawyer, and is a global health policy consultant, business development executive, entrepreneur, and Certified Licensing Professional.

Ms. Barnes-Weise formerly had a faculty appointment at the Duke Sanford School of Public Policy and was previously a director of business development at Glaxo Wellcome (now GSK). Ms. Barnes-Weise has decades of experience negotiating

intellectual property licenses & alliance agreements and advising companies and institutions on partnering strategies.

James M. Beck joined Reed Smith LLP's life sciences health industry, product liability, and appellate groups in 2012. James handles complex personal injury and product liability litigation. He has overseen the development of legal defenses, master briefs, and dispositive motions in numerous multidistrict matters and mass tort litigation. On the appellate side, he has drafted major appellate briefs in significant product liability and related matters, including numerous amicus curiae briefs.

James is a member of the Product Liability Advisory Committee (PLAC) and has sat on PLAC's case selection committee since 1997. He has written over seventy amicus curiae briefs on product liability issues for PLAC. In 2011, James was awarded PLAC's John P. Raleigh Award, the eighth time the group's highest honor has been bestowed since PLAC's founding in 1982.

James wrote PLAC's successful amicus brief in the ground-breaking *Tincher v Omega Flex* case, where the Pennsylvania Supreme Court overturned thirty-five years of product liability precedent. Following *Tincher*, he organized the "Tincher Group" of defense counsel, which has produced scholarship and suggested post-*Tincher* jury instructions to prevent the defense win in *Tincher* from being undercut. He has also prepared amicus briefs for many other organizations, including AdvaMed, the American Bar Association, the American Medical Association and several state affiliates, the Business Roundtable, the Pennsylvania Defense Institute, the United States Chamber of Commerce, and the Washington Legal Foundation.

James edited the newsletter of the ABA's Mass Torts Litigation Committee for almost two decades, winning multiple ABA awards. He is also the founder and co-host of the award-winning *Drug & Device Law* blog.

Ximena Benavides Reverditto is an assistant professor of legal studies at the University of Georgia. Professor Benavides received her LLM and JSD from Yale Law School.

Professor Benavides researches and writes on industrial and informational policies of health-care innovation and life sciences at the intersection of law, ethics, and political economy, with a focus on private law theory. Prior to her current role, Professor Benavides was a lecturer and postdoctoral associate at the Ethics, Politics & Economics Program in Yale's Department of Political Science and was a Yale Institute of Global Health affiliated faculty member.

Abby Bownas, a partner with NVG LLP, is a coalition manager extraordinaire, currently running the Adult Vaccine Access Coalition (adultvaccinesnow.org). Abby is a subject matter expert in vaccine policy, diabetes-related policy issues, and

preventive health. She has broad reach in the patient advocacy world and a strong understanding of nutrition, housing policy, and community development.

Abby has significant experience with nonprofit organizations, including serving on the federal affairs team of the American Diabetes Association. She also has worked in the United States House of Representative and the United States Senate.

Noel T. Brewer is the Gillings Distinguished Professor in Public Health at UNC Gillings School of Global Public Health. Dr. Brewer received his PhD and MS in psychology from Rutgers University, and his BA in economics from the University of California, Santa Cruz.

Dr. Brewer's research examines vaccination, tobacco use, medical screening, and other cancer-related health behaviors. He has published over 375 papers on these topics, including on HPV vaccination and vaping warnings. He is one of the most cited researchers in the world according to Clarivate. Dr. Brewer also leads a center on improving clinical staff communication about HPV vaccination, funded by a $12 million grant from the National Cancer Institute. The center is developing ways to expand the use and impact of the Announcement Approach Training developed by Dr. Brewer and colleagues that teaches providers to recommend HPV vaccine more effectively.

Dr. Brewer advises the World Health Organization on the drivers of vaccination and served as a voting member of United States Centers of Disease Control's Advisory Committee on Immunization Practices.

Cathy L. Burgess is a partner with Alston & Bird LLP, where she leads the firm's United States Food and Drug Administration (FDA) compliance and enforcement team and co-leads the firm's FDA practice. Cathy advises clients on a range of matters affecting prescription and over-the-counter drugs, biologics, medical devices, foods, and cosmetics, and has extensive experience concerning current good manufacturing practice regulation and supply chain management.

For products regulated under the federal Food, Drug, and Cosmetic Act (FDCA), Cathy conducts risk liability assessments and works with clients to identify and analyze potential legal risks associated with their products. She advises clients on quality system remediation, adequacy of SOPs, investigation reports, inspection management, recalls, and responses to Form FDA 483s and warning letters. Cathy also conducts whistleblower investigations and special audits related to FDA compliance. She also assists clients in designing compliance programs, internal audit programs, and other risk mitigation strategies. She is recognized as a leading practitioner for life sciences in *Who's Who Legal*, ranked in *The Best Lawyers in America*© in FDA and Food and Beverage Law, and ranked Band 2 in *Chambers USA*

in Pharmaceutical/Medical Products Regulatory. Cathy is a recipient of the FDLI 2023 Distinguished Service and Leadership Award.

Before joining Alston & Bird, Cathy served as associate general counsel for the American Red Cross, where she was responsible for regulatory matters. A member of the District of Columbia Bar, Cathy received her JD from the Catholic University of America and a BSFS from Georgetown University.

Vanessa K. Burrows is a partner in Simpson Thacher & Bartlett LLP based in the firm's Washington, D.C. office. Vanessa represents clients in health-care regulatory matters, including those involving the Food and Drug Administration (FDA). Vanessa has advised pharmaceutical and medical device manufacturers, health-care and technology companies, hospitals, and other providers concerning regulatory and compliance needs, as well as with M&A and capital-raising transactions. Vanessa has extensive experience counseling clients with respect to FDA enforcement matters; health privacy, security, and breach issues; health-care fraud and abuse matters; and cannabis and hemp laws.

Previously, Vanessa held several government positions focused on health-care regulation. Her experience includes serving as HIPAA privacy officer and attorney for the Department of Public Health for the City of Chicago. Vanessa also advised members of Congress and their staffs on FDA matters as a legislative attorney with the Congressional Research Service, including laws that expanded FDA's regulatory and enforcement authorities, including the Food and Drug Administration Amendments Act of 2007, the Family Smoking Prevention and Tobacco Control Act, FDA Food Safety Modernization Act, and the Food and Drug Administration Safety and Innovation Act. She also handled health-care law, administrative law, and constitutional law matters during the creation and passage of the Patient Protection and Affordable Care Act (ACA) and the 2009 H1N1 pandemic.

Vanessa also writes for industry publications and authored an article in *Journal of Health Care Law and Policy* in 2021 titled, "Cannabis Considerations for Health Care Entities." She also co-authored an article titled, "2 Bills Reflect Gov't Interest in Health PE Investments," which was published by *Law360*.

Vanessa serves on the American University Washington College of Law (AUWCL) Health Law and Policy Program Alumni Advisory Council and as a leader on the American Health Law Association (AHLA) Fundamentals of Health Law Program Planning Committee. She was a member of *Law360's* 2022 Health Care Editorial Advisory Board and served as a judge for the AUWCL's National Health Law Writing Competition. Vanessa has also served on the Food and Drug Law Institute's Webinar

Committee and Publications Peer Review Committee, and as the vice chair of member engagement for the AHLA's Women's Leadership Council.

Vanessa received her JD, *cum laude*, from the American University, Washington College of Law, an MA, with honors, from Queen's University Belfast, and a BA, *magna cum laude*, from Valparaiso University. She is admitted to practice in the District of Columbia and Illinois.

Robert M. Califf is an adjunct professor of medicine in Duke University Medical School's Division of Cardiology and remains a practicing cardiologist. Dr. Califf was the commissioner of Food and Drugs (2016 – 2017 and 2022 – 2025) and deputy commissioner for Medical Products and Tobacco (2015 – 2016) for the United States Food and Drug Administration (FDA).

Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, health-care quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in peer-reviewed literature.

Dr. Califf is a member of the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)), one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous IOM committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and the FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Institute of Environmental Health Sciences; and the Council of the National Institute on Aging.

He has led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative, a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory Coordinating Center, and co-primary investigator of the Patient Centered Outcomes Research Institute Network.

Dr. Califf completed his cardiology fellowship at the Duke University School of Medicine and his internal medicine residency at the University of California San

Francisco School of Medicine. He is a graduate of the Duke University School of Medicine.

David J. Carney, a partner with Green & Schafle LLC, focuses his practice on representing individuals who have been catastrophically injured by vaccines. Since 2010, he has represented victims who have suffered adverse reactions from the administration of vaccines in the United States Court of Federal Claims in Washington, D.C. Through his efforts in the vaccine court, David has successfully obtained many multi-million dollar and six-figure settlements for his clients in all fifty states.

In his career, David has received extensive experience in representing individuals diagnosed with Guillain-Barre Syndrome, chronic inflammatory demyelinating polyneuropathy, acute disseminated encephalomyelitis, transverse myelitis, encephalitis, polymyositis, lupus, optic neuritis, and multiple sclerosis. David has also consistently succeeded in prosecuting shoulder injury cases because of improperly administered vaccines.

David is an active member in the Vaccine Injured Petitioner's Bar Association (VIP Bar), the organization that advocates for the rights of victims who have been injured because of a vaccination. In June 2023, he was voted in as the president of the association. David routinely lectures at legal conferences on vaccine-related topics. In 2017 and 2018, David served as the secretary of the Executive Board and has been an active member of the American Association for Justice (AAJ), the national organization dedicated to creating an equal justice system for injured victims.

Aside from his steadfast dedication to the VIP Bar and AAJ, David is a member of the Pennsylvania Association for Justice, the Philadelphia Bar Association, and the Philadelphia Trial Lawyers Association. Finally, he is also an author of *The Legal Intelligencer's Pennsylvania Causes of Action*, all six editions, which serve as a quick starting point for Pennsylvania civil actions. The books compile outlines and index theories of recovery under Pennsylvania law and provide defenses and applicable statutes of limitation with tables of authorities.

David earned his BA in political science from the Pennsylvania State University while also obtaining a minor in business law. David then went on to earn his JD from Widener University School of Law (now the Delaware Law School), where he was a recipient of the Widener Scholar scholarship. While in law school, David was a member of *The Widener Law Review* for two years and served on the editorial board during his third year. He currently serves as a mentor in the Widener Law Mentoring

Program, where he mentors current law students concerning law school and the role of lawyers and judges in the profession.

Prior to entering private practice, David served as a judicial law clerk intern to the Honorable Allan L. Tereshko in the First Judicial District in the Philadelphia County Court of Common Pleas, Civil Trial Division.

Ashley Chambers is a proud Virginian but has called the Valley of the Sun her home for almost fifteen years. At the College of Charleston in South Carolina, Ashley double majored in political science and Hispanic studies. After graduating, Ashley attended the George Washington University Law School, where she focused on criminal and constitutional law. After law school, Ashley was offered a position at a law firm in Phoenix, and she picked up and moved cross-country.

Ashley was a criminal lawyer in Arizona for a decade, with experience in both the private and public sectors. After having children, Ashley knew she wanted to focus on issues directly impacting children's health. Ashley is currently the executive director at Arizona Families for Vaccines, where she focuses on building a grassroots pro-vaccine movement, and bringing those stories to the Arizona Capitol. Ashley also serves as director of legal affairs for American Families for Vaccines (formerly known as SAFE) and specializes in building partnerships and coalitions with diverse stakeholders.

Ashley is passionate about translating legal jargon and legislation into easily understandable language for diverse stakeholders, including everyday citizens, community groups, businesses, and policymakers, thereby empowering them to make informed decisions about their lives and communities.

Justin A. Coen is a partner in Venable LLP's FDA law group, where he guides companies through the complexities of drug, biologic, and device development. He advises clients on every stage of product development, pre- and post-approval regulatory compliance, and commercialization strategies. Justin also has extensive experience negotiating research and development agreements, licenses, and purchase contracts, including contracts with the federal government.

Prior to joining Venable, Justin served as a senior regulatory attorney in the Office of the Staff Judge Advocate, United States Army Medical Research and Development Command, and he has advised the United States Senate Committee on Finance.

Justin works with a range of clients, including pharmaceutical companies, medical device manufacturers, and biotech startups to help them navigate complex regulatory requirements and achieve their business objectives. His expertise includes evaluating marketing application approaches, marketing exclusivity claims, pre- and post-approval GxP compliance, expedited approval mechanisms, priority review vouchers,

product labeling issues, Animal Rule product development, combination products, and advertising and promotion. He also draws on his experience in health-care policy to help clients understand and shape potential legislative and regulatory changes and, when necessary, respond to government investigations.

Robin Cogan is a nationally certified school nurse (NCSN), currently working as a New Jersey school nurse in the Camden City School District. Robin is the National Association of School Nurses director for the New Jersey State School Nurses Association. She is proud to be a Johnson & Johnson School Health Leadership fellow and past program mentor.

Robin is the honored recipient of multiple awards for her work in school nursing and population health. These awards include, the National Association of School Nurses President's Award (2019 and 2020), 2018 NCSN School Nurse of the Year (2017), Johnson & Johnson School Nurse of the Year, and the New Jersey Department of Health 2017 Population Health Hero Award.

Robin serves as faculty in the School Nurse Certificate Program at Rutgers University-Camden School of Nursing, where she teaches the next generation of school nurses. She was presented with the 2018 Rutgers University-Camden Chancellor's Teaching Excellence Award for Part-time Faculty. Robin writes a weekly blog called *The Relentless School Nurse*. Robin's work is included as a case study in *The Future of Nursing Report 2020 – 2030*.

Brian H. Corcoran was appointed as a special master of the United States Court of Federal Claims on January 13, 2014. He graduated, *cum laude*, with high honors in his major, from Dartmouth College. He received his JD from the University of Virginia School of Law. He was designated chief special master by the court to succeed Nora Beth Dorsey, effective October 1, 2019.

Mr. Corcoran is a seasoned trial attorney with experience in a wide variety of legal matters, including intellectual property, general commercial disputes, tax matters, and pro bono civil rights and employment discrimination matters. Until 2008, he was employed in the private sector, rising to partner in the Washington, D.C. office of Katten Muchin Rosenman LLP. From 2008 – 2014, Mr. Corcoran worked for the United States Department of Justice, Tax Division, as a trial attorney, where he obtained numerous permanent injunctions against fraudulent tax preparers and the promoters of illegal tax schemes across the United States.

Mr. Corcoran is admitted to the District of Columbia and New York bars, as well as numerous federal district courts.

Nicholas (Nick) J. Diamond is a partner at Greenberg Traurig LLP based in the firm's Houston, Texas, office. He is a regulatory attorney with extensive international

experience counseling clients across the food, health care, life sciences, medical devices, and technology sectors. While his practice primarily focuses on compliance counseling, he also has experience in global policy advocacy, commercial transactions, enforcement actions and investigations, and ethics and governance.

Nick provides comprehensive compliance and corporate counsel for entities and products the United States Food and Drug Administration (FDA) regulates. He has experience counseling clients on matters falling under FDA's jurisdiction, such as animal and veterinary products, including animal drugs and drug compounding; cosmetics; food (both human and animal), beverage and dietary supplements; human pharmaceuticals and biotechnology products spanning all therapeutic areas; medical devices (especially software-as-a-medical-device) and diagnostics; and vaccines.

Nick is also an adjunct professor of law at Georgetown University Law Center and the University of Houston Law Center, among other academic affiliations.

Karen Ernst is director of Voices for Vaccines. She is a nationally known expert in building vaccine confidence through peer-to-peer networking and interactions. Much of her work involves creating alliances between families and partner organizations to increase vaccine uptake and reimagine advocacy work. Personal experiences with vaccine-preventable diseases and vaccine hesitancy brought her into the advocacy world.

Previously, Ms. Ernst was an English teacher, having taught written composition at St. Catherine University in Saint Paul, Minnesota, and English classes at the high school level. She also wrote a history of the Twin Cities Habitat for Humanity and created their *Speaker's Bureau Handbook*.

Ms. Ernst holds an MA in English literature and writing from Hamline University in Saint Paul, Minnesota.

Brent Ewig is the chief policy and government relations officer for the Association of Immunization Managers (AIM). Brett manages the immunization policy landscape and develops resources to support AIM members engaging in effective policy development. He represents AIM in policy-related coalitions and promotes AIM positions where appropriate, including AIM's support for adequate resources for jurisdictions.

Brent previously served as AIM's policy advisor consultant. He was also the director of policy and government affairs at the Association of Maternal & Child Health

Programs. Brent holds a BA in English from Valparaiso University and an MSPH from the Johns Hopkins University.

Michelle Fiscus is the chief medical officer of the Association of Immunization Managers (AIM), where she ensures the scientific and clinical accuracy of AIM's products and communications, fosters collaboration with partner organizations, and provides clinical and immunization program manager insights into strategies to improve immunization rates.

Dr. Fiscus is a board-certified pediatrician and former medical director of Tennessee's Vaccine-Preventable Diseases and Immunization Program. Dr. Fiscus received her undergraduate and medical degrees from Indiana University and completed her residency in pediatrics at the James Whitcomb Riley Hospital for Children in Indianapolis. Dr. Fiscus recently completed a four-year term on the American Academy of Pediatrics Board of Directors and has served on workgroups for the Advisory Committee on Immunization Practices.

Robert (Rob) Gatter is a professor of law at Saint Louis University School of Law in the Center for Health Law Studies, where he teaches various courses. He has been the faculty director or co-director of the Center for Health Law Studies for more than fifteen years. Prior to joining the faculty at Saint Louis University, Rob was on the faculty at the Penn State University's Dickinson School of Law, where he also served as associate dean for academic affairs. Early in his academic career, he was a bioethics fellow at the University of Minnesota and taught at the Chicago-Kent College of Law. Additionally, he practiced health law and commercial litigation in Denver, Colorado.

He is a co-author of *Health Law: Cases, Materials & Problems* (West Academic) and has published numerous articles and book chapters on public health law, informed consent, and human subjects research regulation among other topics. Rob has expertise in a variety of health law topics including public health, informed consent, end-of-life decisions, conflicts of interest, and theoretical descriptions of health.

Rob earned his JD from the University of Pennsylvania Carey Law School, an MA in bioethics from the Medical College of Wisconsin, and a BA from the Johns Hopkins University.

Renée Gentry, the founder of The Law Office of Renée J. Gentry, Esq., is a leading expert on vaccine injury litigation in the National Vaccine Injury Compensation Program (NVICP) with over twenty years of experience in all phases of cases from entitlement to damages and appeals.

She has chaired numerous conferences on vaccine injury litigation and has been a featured speaker regarding the NVICP at judicial conferences, vaccine injury

litigation boot camps for new practitioners, and a Court of Federal Claims "brown bag" series on the use of experts in the NVICP. Ms. Gentry is a founding member of the Vaccine Injured Petitioners Bar Association, where she served as president for four years, and currently serves as senior counsel to the association. She is a member of the United States Court of Federal Claims Bar Association and previously served on its Board of Governors. She was the 2020 recipient of the Court's Golden Eagle Award. Ms. Gentry is a member of the American Association for Justice and currently serves as co-chair of its Vaccine Litigation Group.

In addition to her private practice, Ms. Gentry is the director of the Vaccine Injury Litigation Clinic at the George Washington University Law School and is a distinguished professorial lecturer in law. In addition to the Clinic, Ms. Gentry previously taught Disability Rights Law and the health-care component of the Systemic Racism Reading Group. She received her BA from Drake University, and her JD from Washington University School of Law.

Claudia E. Haupt is professor of law and political science at Northeastern University. She teaches a range of constitutional law courses both in the School of Law and the Department of Political Science, College of Social Sciences and Humanities. A First Amendment scholar whose current work is situated at the intersection of free speech, health, and technology, Professor Haupt has published extensively on professional speech. Her further research interests include comparative constitutional law and law and technology with a focus on online speech.

Prior to joining the Northeastern faculty in 2018, Professor Haupt was a resident fellow with the Information Society Project at Yale Law School, where she continues to be an affiliated fellow, and a research fellow with the Solomon Center for Health Law and Policy at Yale Law School. Her visiting positions include being a visiting professor of law at Yale Law School and academic visitor at the University of Oxford Faculty of Law. She has also held academic appointments at Columbia Law School and the George Washington University Law School.

Before entering academia, Professor Haupt clerked at the Regional Court of Appeals of Cologne and practiced law at the Cologne office of Graf von Westphalen, with a focus on information technology law. She is admitted to practice in Germany and New York. She holds a PhD in political science from the University of Cologne, a JSD from Columbia Law School, an LLM, with highest honors, from the George Washington University Law School and her first law degree from the University of Cologne.

Professor Haupt has published numerous articles in law reviews, including the *Yale Law Journal*, *Vanderbilt Law Review*, *Washington University Law Review*, *Boston University Law Review*, and the *University of Pennsylvania Journal of Constitutional Law*, among others. She also has written for medical journals, including the *Journal of the American Medical Association* and the *AMA Journal of Ethics*, among others.

Her first book was *Religion-State Relations in the United States and Germany: The Quest for Neutrality* (Cambridge University Press 2012). Her second book, *Professional Speech*, is forthcoming with Cambridge University Press.

James G. Hodge, Jr. is the Peter Kiewit Foundation Professor of Law at the Sandra Day O'Connor College of Law and director of the Center for Public Health Law and Policy at Arizona State University. Through scholarship, teaching, and applied projects, Professor Hodge delves into multiple areas of health law, public health law, global health law, ethics, and human rights issues.

From 2010 – 2023, he served as the founding director of the Western Region Office of the Network for Public Health Law funded by the Robert Wood Johnson Foundation. Professor Hodge is a prolific scholar, having published more than 300 articles in journals of law, medicine, public health, and bioethics; two books in public health law; twenty-five book chapters; and guest edited four symposium issues in the *Journal of Law, Medicine, and Ethics*; *Jurimetrics*; and the *Annals of Health Law*.

Richard H. Hughes IV, a member of Epstein Becker & Green PC, is a health lawyer, strategic advisor, advocate, and teacher. His advice and counsel are sought after by leading biopharmaceutical companies, investors, startups, industry trade associations, advocacy organizations, members of Congress and congressional committees, and federal agencies.

Richard previously served as vice president at a major vaccine manufacturer during the COVID-19 pandemic and as managing director of a leading Washington health-care advisory firm. He also held leadership roles at a leading biopharmaceutical company and the Association of State and Territorial Health Officials, and he was a gubernatorially appointed member of the Arkansas State Board of Health.

Richard is a professorial lecturer in law at the George Washington University Law School, where he devotes his time to teaching and mentoring students. He previously served as a professorial lecturer in Health Policy & Management at the GW Milken Institute School of Public Health. He proudly serves on the board of Vaccinate Your Family, a nonprofit organization devoted to protecting people of all ages from vaccine-preventable diseases.

Richard is a popular public speaker at industry events and conferences, frequently publishes articles and commentaries, and is regularly quoted in prominent news media outlets, including *The Wall Street Journal, The New York Times, The Washington Post, The Guardian,* NPR's *Marketplace, Politico, Forbes, Axios, Bloomberg Law, Law360, Fierce Healthcare, Roll Call, The Washington Blade,* and *The Hill.*

Sarah Karlin-Smith is a health-care reporter at POLITICO, specializing in the policy and politics that affect the pharmaceutical industry and patients needing

medicine. Her work explores how government policies influence how drugs are developed, what diseases scientists prioritize, and who gets access to medicines and at what cost. Sarah also focuses on complex bioethical topics like DNA editing of human embryos, terminally ill patients' access to experimental drugs, and how society regulates anti-aging drugs. Sarah has covered health care for eight years. Prior to joining POLITICO in 2015, she followed the United States Food and Drug Administration and drug policy at *The Pink Sheet* and *FDAnews*.

Sarah was selected for and attended a 2018 International Women's Media Foundation reporting fellowship in Rwanda. In 2016, she attended Harvard Medical School's media fellowship on bioethics and, in 2014, was an Association of Health Care Journalists-National Library of Medicine fellow. She graduated with special honors in journalism and mass communication from the George Washington University where she minored in American studies. During her junior year, she spent a semester abroad in Ifrane, Morocco.

Jeremiah J. Kelly, a partner with Venable LLP, focuses his practice on helping companies navigate the complexities of the United States Food and Drug Administration (FDA) and its regulation of drugs, biologics, medical devices, and combination products. Jeremiah helps companies from "bench to bedside." He supports companies along the development and commercialization pathway, from pre-clinical, clinical, and pre-market applications for FDA approval, licensure, clearance, or authorization to post-market compliance. Before joining Venable, Jeremiah served as the chief of the FDA Regulatory Law Division in the Office of the Staff Judge Advocate, United States Army Medical Research and Development Command (USAMRDC), and in the FDA Office of the Commissioner.

Jeremiah's practice includes overall regulatory strategy and support for investigational new drug applications or investigational device exemptions. He also provides support for pre-market applications, including 505(b)(1) and 505(b)(2) new drug applications, biologics license applications, emergency use authorizations for drugs and biologics, 510(k) programs, premarket approval applications, de novo requests for medical devices, and GxPs.

Jeremiah advises clients on expedited approval mechanisms, Hatch-Waxman and Biologics Price Competition and Innovation Act of 2009 regulatory frameworks, regulatory incentives (e.g., marketing exclusivity and priority review vouchers), product labeling, risk evaluation and mitigation strategies, advertising and promotion, responses to FDA compliance actions (e.g., negative 483 or warning letters), and inputs and challenges to FDA rulemaking under the Administrative Procedures Act. Jeremiah helps companies shape legislative changes to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

His practice also includes unique expertise in agreements with the research and development elements of the federal government. He has drafted and negotiated

cooperative research and development agreements, Federal Acquisition Regulation and Defense Federal Acquisition Regulation contracts, grants and cooperative agreements, other transaction agreements, experimental supply agreements, and patent license agreements to create win-win collaborations between industry and the government.

As the chief of the FDA Regulatory Law Division, JAG, USAMRDC, Jeremiah advised USAMRDC and the United States Department of Defense's Joint Program Executive Office for Chemical, Biological, Nuclear and Radiological Defense (JPEO-CBRND) on the development and regulation of medical countermeasures to treat the unique needs of United States soldiers. During the COVID-19 pandemic, he served as the chief coordinating counsel of the JPEO-CBRND Joint Assisted Acquisition Legal Cell, managing, staffing, and negotiating over $83 billion in COVID vaccine, therapeutic, and diagnostic capabilities for the federal government's COVID-19 response. Prior to his DOD service, Jeremiah spent over seven years in the FDA Commissioner's Office in the Office of the Chief Counsel and the Office of Legislation, and three years as a litigator at a large private sector law firm.

Stacie Kershner is the deputy director for the Center for Law, Health & Society at Georgia State University College of Law. Professor Kershner received her JD from Georgia State University College of Law and her BA in sociology/anthropology from Agnes Scott College.

Professor Kershner's current research focuses on communicable disease prevention, legal preparedness for public health emergencies, and the impact of COVID-19 on at-risk populations. Prior to her current role, Professor Kershner served as an ORISE fellow with the United States Centers for Disease Control and Prevention Public Health Law Program, where she conducted research on a variety of topics, including emergency preparedness, control of communicable disease, and injury prevention. She also designed and implemented tools and training for best and promising practices in public health law for federal, state, and local public health officials and their legal counsel, as well as stakeholders from other sectors, such as education, transportation, law enforcement, and the judiciary.

Darshan Kulkarni, principal attorney of the Kulkarni Law Firm, focuses his practice on helping companies regulated by the United States Food and Drug Administration (FDA) successfully bring their products to market. He has over twenty years of experience in providing legal, medical, and regulatory services, and has served as a pharmacist for over a decade making him uniquely well-positioned to help clients through all stages of the development process.

He advises clients on issues ranging from FDA regulatory strategy, clinical trial negotiations, manufacturing audits, FDA compliant promotional and non-promotional review, and FDA responses to genericization and other interdependent processes. Prior to starting his firm, Darshan was the global corporate counsel for an

international pharmaceutical holding company, where he provided various services, including writing licensing and employee contractor agreements, warning letters, and SOPs. He was also responsible for developing a quality system for the facility and engaging with the FDA.

In his spare time, Darshan regularly contributes to his pharmacy podcast *Gavel & Pestle* and has contributed to several books on federal regulatory law, including multiple editions of the *Research Compliance Professional's Handbook*.

Jacob Madden is a health care and life sciences regulatory associate at Simpson Thacher & Bartlett LLP based in New York. He advises a diverse group of clients, including private equity firms, underwriters, pharmaceutical and medical device manufacturers, biotechnology companies, health-care providers, veterinary practices, restaurants, and food franchisors and manufacturers in connection with health care and FDA regulatory matters, mergers and acquisitions, and capital markets transactions.

Jacob is a member of the editorial board of the American Health Law Association's *Journal of Health and Life Sciences Law*. Jacob earned his JD from Yale Law School, where he was co-editor-in-chief of the *Yale Journal of Health Policy, Law, and Ethics*, and his BS, *summa cum laude*, from the University of Redlands, where he serves on the Board of Trustees. After graduating from law school, Jacob completed a postdoctoral fellowship at Harvard Medical School, Brigham and Women's Hospital, and Boston University School of Law, focusing his research on the intersection of law and infectious diseases.

Charlotte A. Moser graduated from Wilkes University with a bachelor's degree in biology and a minor in chemistry. She also received a master's degree in communication from Drexel University. After graduating from Wilkes, Charlotte has spent her career working at the Children's Hospital of Philadelphia, where she started as a lab supervisor and researcher in the fields of immunology and virology.

In 2000, Charlotte helped create an educational outreach program, known as the Vaccine Education Center, to address common vaccine safety concerns by presenting the science related to vaccines, immunology, and infectious diseases in compelling and approachable ways. For more than two decades, the Vaccine Education Center has served as a national and international resource for those seeking answers about vaccines.

Charlotte has been a contributing author on numerous scientific papers and is the co-author of a book about vaccines for parents titled, *Vaccines and Your Child: Separating Fact from Fiction*. A newer version of this book is currently being written and will include vaccine information for family members of all ages. As co-director of the Vaccine Education Center, she created the Parents PACK program for parents and the public and co-created the Vaccine Update program for health-care

providers. She has also helped to integrate the Vaccine Makers Project, an outreach project for classrooms, into a Vaccine Education Center-based program. In response to COVID-19, Charlotte conceived and oversaw development of www.COVIDVaccineAnswers.org, a dedicated webpage related to COVID-19 vaccines, which continues to be updated as needed to address the public's questions about COVID-19 vaccines.

Through writing and development of resources and novel programming, Ms. Moser has spent considerable time thinking about how to address vaccine concerns in different settings and for different audiences.

Matthew P. Motta is an associate professor of health law, policy, and management at Boston University's School of Public Health. Previously, he was an assistant professor of political science (American politics, research methods) at Oklahoma State University in Stillwater, Oklahoma, and Science of Science Communication postdoctoral fellow at the Annenberg Public Policy Center at the University of Pennsylvania. Professor Motta was also based at the Yale Law School, where he was an affiliated postdoctoral scholar at the Cultural Cognition Project.

Dr. Motta's research focuses on a wide range of topics related to American politics, public opinion, science communication, and both health and environmental policy. He is especially interested in identifying the social and political determinants of anti-science attitudes and investigating their health policy impact. He is also interested in designing communication strategies that promote effective engagement between the public and the scientific community on politically contentious issues. His forthcoming book, *Anti-Scientific Americans* (Oxford University Press, 2024), explores the prevalence, origins, and the consequences of anti-intellectualism in the United States and is currently available for pre-order on Amazon.

His research has been published in academic journals across the social and medical sciences spectrum (e.g., *American Journal of Public Health*, *Social Science & Medicine*, *Vaccine*, *Nature Climate Change*, and *Scientific Reports*) and featured in popular press outlets like *The New York Times, The Washington Post*, *Scientific American*, PBS Newshour, and *CBS Evening News*. He is also a political analyst for Spectrum News and regularly comments on both his research and current events for print and television outlets. He is available for commentary on both local and national politics (including discussions on health politics and policy).

As part of his research activities, Professor Motta also conducts public health opinion research as a research fellow at the Policy Lab at Brown University and piloting health communication campaign strategies as affiliated faculty with Harvard's TH Chan School of Public Health.

Professor Motta received his PhD in political science from the University of Minnesota, where he was also a National Science Foundation (NSF) Graduate

Research Fellow and doctoral dissertation fellow. He earned a BA in government from Wesleyan University.

René F. Najera, an epidemiologist, is director of public health and history of vaccines and the Susan and Stanley Plotkin Chair in Public Health at the College of Physicians of Philadelphia. He is the editor of *The History of Vaccines* project, with a focus on news and information on vaccines, vaccine science, vaccine research, and the public health implications of vaccine policy. Dr. Najera has also worked as a senior epidemiologist at the Fairfax County Health Department in Fairfax, Virginia.

Dr. Najera has a DrPH from the Johns Hopkins University Bloomberg School of Public Health, an MPH from the George Washington University, and a BS in medical technology from the University of Texas at El Paso. He is affiliated with the Department of Epidemiology of the Johns Hopkins University Bloomberg School of Public Health and with George Mason University's Department of Global and Community Health.

Paul A. Offit is director of the Vaccine Education Center and professor of pediatrics in the Division of Infectious Diseases at Children's Hospital of Philadelphia. He is the Maurice R. Hilleman Professor of Vaccinology at the Perelman School of Medicine at the University of Pennsylvania.

Dr. Offit is an internationally recognized expert in the fields of virology and immunology and was a member of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention. He is a member of the Food and Drug Administration Vaccines and Related Biological Products Advisory Committee, a founding advisory board member of the Autism Science Foundation and the Foundation for Vaccine Research, a member of the Institute of Medicine, and co-editor of the foremost vaccine text, *Vaccines*.

He is a recipient of many awards including the J. Edmund Bradley Prize for Excellence in Pediatrics from the University of Maryland Medical School, the Young Investigator Award in Vaccine Development from the Infectious Disease Society of America, a Research Career Development Award from the National Institutes of Health, and the Sabin Vaccine Institute Gold Medal.

Dr. Offit has published more than 160 papers in medical and scientific journals in the areas of rotavirus-specific immune responses and vaccine safety. He is also the co-inventor of the rotavirus vaccine, RotaTeq, recommended for universal use in infants by the United States Centers for Disease Control and Prevention. For this achievement, Dr. Offit received the Luigi Mastroianni and William Osler Awards from the University of Pennsylvania School of Medicine, received the Charles Mérieux Award from the National Foundation for Infectious Diseases, and was honored by Bill and Melinda Gates during the launch of their foundation's Living

Proof Project for global health. Dr. Offit has received numerous other awards and recognitions during his career.

James M. Paul, a shareholder in Ogletree, Deakins, Nash, Smoak & Stewart PC, has extensive trial and appellate experience in handling labor and employment law litigation in federal and state courts, and before the Equal Employment Opportunity Commission, Department of Labor, Department of Justice, and several other federal and state agencies. He also holds the national Society for Human Resource Management's SHRM-SCP certification, is the immediate-past state director for the Missouri SHRM State Council and regularly advises employers on all labor and human resource management issues to prevent or resolve employee issues before they escalate into legal disputes.

As co-chair of Ogletree Deakins's disability access practice group, Jim advises clients on the legal requirements for accommodating disabled individuals and defends Americans with Disabilities and Rehabilitation Act lawsuits nationally.

Prior to private practice, Jim served as judicial law clerk to the Honorable Ray Price, Jr. of the Missouri Supreme Court and then as a Missouri assistant attorney general. As an assistant attorney general, he represented the Missouri Department of Labor and Industrial Relations, the Missouri Division of Labor Standards, and the Missouri Commission on Human Rights by enforcing state discrimination and wage and hour laws. He also worked in Washington, D.C. on legislative issues for the late Missouri Governor Mel Carnahan and has taught Trial Advocacy at Saint Louis University as an adjunct professor.

Heather L. Pearlman is deputy director of the Constitutional and Specialized Torts Branch in the United States Department of Justice's Civil Division, where her primary responsibility is managing litigation arising under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act).

She has dedicated her entire professional career to public service following law school. Heather spent several years working as a legislative counsel on Capitol Hill, moving to the Department of Justice's Office of Legislative Affairs in 1999 to serve as an attorney advisor. In June 2001, she began working as a trial attorney defending Vaccine Act cases. She has handled all aspects of Vaccine Act litigation at the Court of Federal Claims and the United States Court of Appeals for the Federal Circuit. From 2001 – 2008, she also oversaw the adjudication of thousands of claims brought under the Radiation Exposure Compensation Act by individuals who became ill while

living downwind of the Nevada Test Site during periods of atmospheric nuclear testing.

Heather is admitted to practice law in the District of Columbia, New Jersey, and New York. She received her BA in history and political science from the University of Wisconsin-Madison and her JD from Roger Williams University School of Law.

Amy Pisani of Vaccinate Your Family (VYF) is a distinguished expert in the field of vaccine advocacy and education, with a remarkable tenure dating back to 1996 when she joined Every Child By Two (now known as Vaccinate Your Family). As the chief executive officer, she has played a pivotal role in shaping the trajectory of immunization accessibility in the United States.

In alignment with VYF's founding principles, Amy has spearheaded collaborative initiatives that unite elected officials, community leaders, and representatives from national and local organizations in the fight against vaccine-preventable diseases. She guides the team in legislative education, fosters partnerships with like-minded advocates, collaborates with the media to ensure evidence-based reporting on vaccines, and employs diverse communication channels to educate the public.

Amy has been at the helm through VYF's remarkable growth in the organization's social media effectively reaching over four million individuals annually. Through platforms like Facebook, X (formerly Twitter), Instagram, and YouTube, VYF disseminates science-based information that underscores the importance of timely vaccinations and the safety of vaccines. In addition to this digital outreach, VYF's website, available in both English and Spanish, attracts over one million visitors each year and has earned the prestigious Vaccine Safety Net Seal of Approval from the World Health Organization.

Amy's dedication extended to the urgent need for equitable access to COVID-19 vaccines. She played a pivotal role in various initiatives, including the Made to Save Collaborative, the HHS COVID Community Corps, and the White House Equity Panel. VYF continues to bring together partners who united in the fight against COVID-19 through the VYF-hosted Vaccination Collaborative. This platform facilitates the exchange of invaluable insights, research, and communication strategies, shaping evidence-based programs and policy efforts to ensure universal access to all vaccines.

Amy remains at the forefront of public health advocacy by actively engaging in conferences, hosting and presenting at congressional briefings, and vigilantly monitoring and responding to regulatory and policy changes that impact

immunization delivery. The campaigns developed under her guidance have educated hundreds of millions of individuals worldwide, leaving an indelible mark on the field.

In addition to her work with VYF, Amy demonstrates her commitment to public health in various capacities. She proudly serves as the president of her local Rotary Club and has been recognized as a Paul Harris fellow for her contributions. From 2011 – 2015, she served as a public member of the United States Department of Health and Human Services' National Vaccine Advisory Committee. Presently, she is a founding member of the 317 Coalition, ensuring stable congressional immunization funding, and sits on the steering committee of the Adult Vaccine Access Coalition, the HPV Roundtable, and several other coalitions that share VYF's mission.

Amy's rich career history extends beyond pediatrics. She gained extensive health-care advocacy experience during her roles as the education program coordinator at the Optical Society of America, senior staff specialist for the American Nurses Association, and program director for the American Nurses Foundation. Her early career was dedicated to advancing the deaf community. Amy holds a MS from Gallaudet University for the Deaf in Washington, D.C., and an undergraduate degree in psychology from the Catholic University of America, also in Washington, D.C.

Adebola (Bola) Popoola is a policy public health analyst at the Centers for Disease Control and Prevention (CDC). In her role at CDC, Bola leads a team of researchers in policy development and implementation, legal epidemiology research, and policy analysis. Through her work, she has published research papers and products and presented her work at national conferences.

Bola began her career as a county epidemiologist at a local health department, where she led investigations and control of communicable diseases and outbreaks occurring in the county. Later transitioning to the private sector as a consultant, she conducted global trend analyses of chronic and infectious diseases.

Bola holds a law degree, dual master's degrees in biomedical science and public health, and dual bachelor's degrees in chemistry and biology. She also holds a graduate certificate in global health engagement.

Montrece McNeill Ransom currently serves as the director of the National Coordinating Center for Public Health Training for the National Network of Public Health Institutes.

Ms. Ransom was appointed as a presidential management fellow and worked at the Centers for Disease Control (CDC) for almost twenty years. For the last ten years of her service, Ms. Ransom has led CDC's public health law-related training and workforce development efforts. She received her law degree from the University of Alabama, her MPH from Emory University's Rollins School of Public Health, and her

executive leadership coaching certification from Georgetown University. In addition, she has received a certificate in training and facilitation from the Association of Talent Development.

Ms. Ransom is the ABA Health Law Section's 2019 Champion of Diversity and Inclusion Awardee, and the 2017 recipient of the American Public Health Association Jennifer Robbins Award for the Practice of Public Health Law. She is the president-elect of the American Society for Law, Medicine, and Ethics and serves on the Advisory Committee for the Georgia Campaign for Adolescent Power and Potential.

Devoted to helping people reach their human potential, Ms. Ransom also spends a lot of time working on career pathing and professional development with new public health practitioners and public health lawyers. She is also a well-known public speaker, peer-reviewed published author, the co-editor of the George Wyner textbook *Public Health Law: Concepts and Case Studies*.

Dorit Rubinstein Reiss is a professor of law at the University of California San Francisco College of Law. She received her undergraduate degree in law and political science from the Faculty of Law at the Hebrew University of Jerusalem, where she served as editor in chief of the *Jerusalem Review of Legal Studies*. She then clerked for a year and a half in the Israeli Ministry of Justice's Department of Public Law working on a variety of constitutional and administrative law issues.

Professor Reiss received her PhD from the Jurisprudence and Social Policy Program at UC Berkeley. Her initial research examined accountability of agencies at the state, national, and international level, including the California Public Utilities Commission, the Federal Aviation Administration, and other agencies in the United States and Europe. Increasingly, however, her research and activities focus on legal and policy issues related to vaccines. She writes about school mandates, policy responses to non-vaccinating, tort issues, and administrative issues related to vaccines.

Ana Santos Rutschman is professor of law at Villanova University Charles Widger School of Law, where she teaches and researches topics related to health law, intellectual property, innovation in the life sciences, and law and technology. She is a nationally and internationally recognized expert on vaccine law and policy, the regulation of emerging health technologies, and access to medicines.

Professor Rutschman's work has been recognized by numerous institutions, including the American Society of Law, Medicine & Ethics, which named her a Health Law Scholar in 2018 and Bio Intellectual Property Scholar in 2017. In 2018, she was also

named a Wiet Life Sciences Law Scholar by the Beazley Institute for Health Law and Policy at Loyola University Chicago.

In 2022, the Boston Congress of Public Health selected her as one of the inaugural recipients of a 40 Under 40 Public Health Catalyst Award for her work on vaccine law and policy. Professor Rutschman's book, *Vaccines as Technology: Innovation, Barriers and the Public Health*, was published in 2022 by Cambridge University Press. Her legal scholarship has appeared or is forthcoming in the *UCLA Law Review*, *Emory Law Journal*, *Indiana Law Journal*, *UC Davis Law Review*, *Arizona Law Review*, *Yale Law Journal Forum*, *Harvard Public Health Review,* and *Vanderbilt Journal of Transnational Law*, among others. Her peer-reviewed work has appeared in *Nature Biotechnology*, *Vaccine, Emerging Infectious Diseases*, and the *American Journal of Infection Control*, among others. Her commentary pieces have been published by the *Health Affairs* blog, *Bill of Health*, *Saint Louis Post-Dispatch*, *Huffington Post*, and *The Conversation*, and republished in *Scientific American*, *Newsweek Japan*, and numerous United States newspapers.

Michael T. Siekman, a partner with Goodwin Procter LLP, focuses his practice on intellectual property matters, including patent prosecution, licensing and post-grant proceedings and litigation. Leveraging over twenty-five years of experience, Michael has built in-depth patent portfolios, particularly advising clients in the biotechnology and pharmaceutical industries.

Michael keeps clients' business goals in mind as he regularly provides legal counsel on litigation matters, including Hatch-Waxman matters, and post-grant solutions for biosimilars. He has successfully led matters before the Patent Trial and Appeal Board (PTAB) and the European Patent Office. His transactional practice involves licensing agreements, collaboration agreements, and IP-related aspects of mergers, acquisitions, IPOs, and other financing mechanisms.

Michael has extensive experience with biosimilars and has written and presented often on the topic. One of his biosimilar articles has been cited in three amicus briefs to the Supreme Court of the United States in two cases involving the PTAB.

Eva Temkin, a partner with Arnold & Porter Kaye Scholer LLP, works with pharmaceutical, biotechnology, and medical device companies on a wide array of issues related to product development, approval, and marketing. Drawing on nearly twenty years of practice, including almost a decade at the United States Food and Drug Administration (FDA), she works with clients to develop and execute regulatory, legislative, and litigation strategies. She also advises clients with respect

to the Inflation Reduction Act and other new and evolving mandates affecting FDA-regulated products.

Eva has counseled clients through formal and informal FDA dispute resolution proceedings, been the regulatory lead for numerous financial transactions, and served as lead FDA counsel on several complex litigation matters.

Rose Weeks is a senior research associate at the Johns Hopkins Bloomberg School of Public Health. Ms. Weeks received her MPH from Johns Hopkins Bloomberg School of Public Health, where she is an enrolled DrPH student in the Implementation Science Program, and her BA from Vassar College.

Ms. Weeks conducts qualitative and implementation science research to inform communications and advocacy strategies for vaccine access and behavioral health projects. She also serves as senior communications advisor for the Center for Indigenous Health, providing strategic advice on public engagement and advocacy strategies to scale up evidence-based practices across Indigenous communities.

Richard Wilder is a professor of practice at the University of New Hampshire Franklin Pierce School of Law, and a senior scholar at the O'Neill Institute for National and Global Health Law. Most recently, he served as general counsel and director of legal and business development at the Coalition for Epidemic Preparedness Innovations (CEPI). There, he directed the legal and business development affairs of CEPI during its initial start-up phase and through the first two years of the response to the COVID-19 pandemic.

He previously had a similar role in the global health program at the Bill & Melinda Gates Foundation. Prior to that, he led the intellectual property policy team at Microsoft Corporation, where he was responsible for defining and driving company-wide policy in all areas of intellectual property. Professor Wilder has spent years as a partner in a global law firm, where he specialized in international trade law and practiced in the field of global public health.

Jerry Williamson is a board-certified physician affiliated with the Loyola University Chicago School of Law. A licensed risk manager with over thirty years of experience in private practice and health-care management, Dr. Williamson has served as medical director for a third-party administrator, vice president of medical affairs for a 280-bed hospital, assistant medical director for a staff model HMO, and a private practice physician. He has served in a senior leadership role with Collier Health Services, a federally qualified health center in South Florida, including serving as the chief medical officer and director of the Biomedical Informatics Program.

Dr. Williamson is a frequent lecturer and consultant on health law topics and is a certified AHIMA trainer for ICD-10, and a consultant with the American Academy of

Professional Coders. He is a fellow of the American Academy of Pediatrics and a clinical assistant professor of pediatrics at Florida State University College of Medicine. At the college, he also serves as an affiliate of the Center for Innovative Collaboration in Medicine and Law. He is an affiliate member of the Health Law Division of the Florida Bar, as well as a certified mediator and formally trained arbitrator listed as a neutral with both the American Arbitration Association and American Health Lawyers.

Dr. Williamson formerly served as a Meaningful Use Clinician Champion to The Center for the Advancement of Health Information Technology, a Regional Extension Center in Florida. He is the 2012 recipient of the Heroes in Healthcare award from the *Naples Daily News* for administrative excellence in healthcare. He received his BA from Queens College, his MD from the Medical College of Pennsylvania, and his MJ from Loyola University Chicago.

Ha Kung Wong is a partner in Venable LLP, where he practices general intellectual property (IP) law with an emphasis on complex patent and trade secret litigation, as well as IP transactions and contract negotiations for mergers, acquisitions, vendor agreements, and collaborations in pharmaceuticals, biologics, chemistry, medical devices, digital health, and artificial intelligence. Ha Kung has litigated cases relating to proton pump inhibitors, antiepileptic drugs, antitussives, ADHD medications, injectable microspheres, RNAi products, antibiotics, and other pharmaceuticals. Ha Kung also has extensive experience with *inter partes* review, post-grant review, IP counseling, pre-suit investigations, licensing, and due diligence, including patent strength and freedom-to-operate analyses.

Ha Kung is a member of the New York Bar and is admitted to practice before various federal courts, including the Supreme Court of the United States. He received his JD, *cum laude,* from the University of Notre Dame Law School, a BS in chemistry with high distinction from the University of Illinois Urbana-Champaign, and a BS in biochemistry from the University of Illinois Urbana-Champaign.