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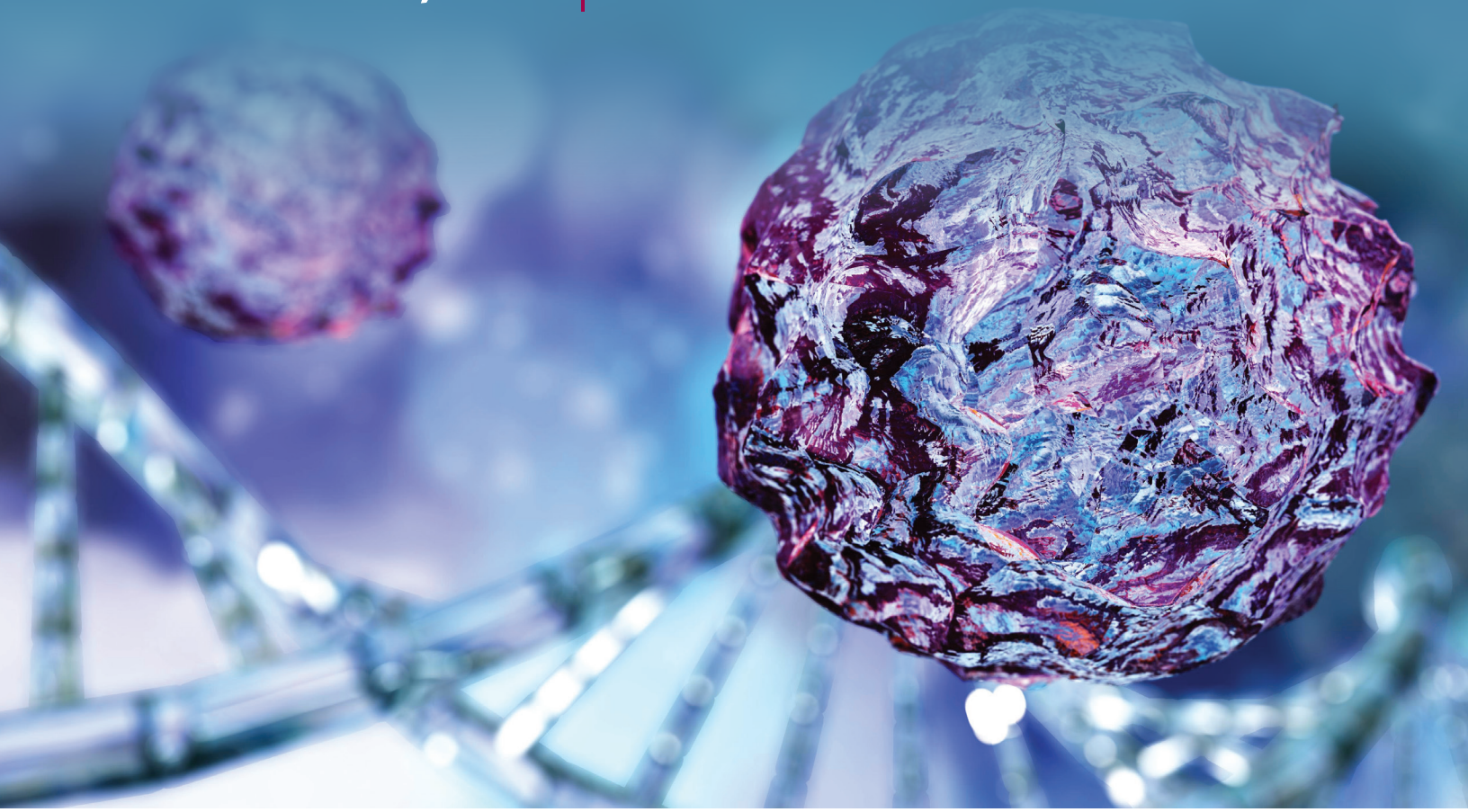
Regenerative Medicine:

Regulatory, Legal, and Compliance Challenges for Cell and Gene Therapies

June 8-9, 2021 | Virtual Event



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Regenerative Medicine: Regulatory, Legal, and Compliance Challenges for Cell and Gene Therapies

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Agenda

Tuesday, June 8

11:00–11:45 AM **Bonus Session: A Primer on Regenerative Medicine Science and Recent Breakthroughs**

This bonus session will provide an introduction to the science of cell and gene therapy. The panelists will also discuss recent therapeutic breakthroughs.

Heather C. Hatcher, Regulatory Scientist, Womble Bond Dickinson (US) LLP
Collin Stabler, Senior Associate, Exponent, Inc.
Moderated by **Barbara A. Binzak Blumenfeld**, Shareholder, Buchanan Ingersoll & Rooney PC

12:00–12:05 PM **FDLI Welcome and Introduction**
Amy Comstock Rick, President & CEO, FDLI

12:05–12:50 PM **Keynote Address**
Peter W. Marks, Director, Center for Biologics Evaluation and Research, FDA

1:05–1:50 PM **Updates on FDA's Comprehensive Regenerative Medicine Policy Framework**

During this session, speakers will examine FDA's Framework for supporting and expediting regenerative medicine product development, including the status of new and upcoming guidances. The panel will also discuss FDA's inter-Center coordination to advance regenerative medicine therapies.

Wilson W. Bryan, Director, Office of Tissues and Advanced Therapies, CBER, FDA
Lauren A. Miller, Senior Counsel, AbbVie
Moderated by **Joanne Hawana**, Member, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

2:05–2:50 PM **Global Regulatory Collaborations in Search of Cell and Gene Therapy Harmonization**

FDA and the European Medicines Agency have emphasized the need to internationally harmonize regulatory approaches for cell and gene therapy products in an effort to increase access to patients worldwide. The session will tour the landscape of international efforts to advance harmonization for these products. The session will also discuss revisions to the European Union's blood, tissue, and cell legislation, lessons learned during the approval of Advanced

Therapy Medical Products in the EU, and regulatory tools to facilitate development, approval, and access.

Joan Wilmarth Blair, Senior Advisor for International Affairs, CBER, FDA
Victoria Palmi Reig, Senior Product Lead, Office of Advanced Therapies and Therapies for Immune and Inflammatory Diseases, European Medicines Agency
Moderated by **Cristiana Spontoni**, Partner, Jones Day

2:50–3:20 PM **Break**

3:20–4:20 PM **Gene Therapy Clinical Development Considerations**
This panel will explore issues associated with the clinical development of gene therapies, including design challenges, good clinical practice considerations, and use of real-world evidence in accelerated approvals. Speakers will also discuss the Bespoke Gene Therapy Consortium, a public/private partnership intended to provide a standardized and efficient approach for development and delivery of "bespoke," or individualized, gene therapies for patients with rare genetic diseases.

Mantej (Nimi) Chhina, Senior Director & Head, Global Regulatory Policy, BioMarin Pharmaceutical Inc.
Ilan Irony, Deputy Director, Division of Clinical Evaluation and Pharmacology/Toxicology, CBER, FDA
Gopa Raychaudhuri, Senior Scientist, Office of the Center Director, CBER, FDA
Moderated by **Michael N. Druckman**, Partner, Hogan Lovells US LLP

4:35–5:20 PM **Standardization of Regenerative Therapies**
Section 3036 of the 21st Century Cures Act requires FDA to work with other stakeholders to coordinate and prioritize the drafting of standards and consensus definitions to support the development, evaluation, and review of regenerative medicine therapies. Since 2017, FDA has been working with the Nexight Group and the Standards Coordinating Body to coordinate the development of regenerative medicine standards. This session will discuss the status of this work, why standards are important in this field, and what standards are currently in place.

Judy Arcidiacono, Regulatory Affairs Specialist, Office of Tissues and Advanced Therapies, CBER, FDA
Fouad Atouf, Vice President, Global Biologics, U.S. Pharmacopeia
Robert Shaw, Executive Director, Standards Coordinating Body
Moderated by **Deborah L. Livornese**, Director, Hyman, Phelps & McNamara, PC

Wednesday, June 9

12:00–12:05 PM **FDLI Welcome**

Laura A. Brown, Director, Educational Programs, FDLI

12:05–12:50 PM **Featured Speaker**
Bruce Levine, Barbara and Edward Netter Professor in Cancer Gene Therapy, University of Pennsylvania

1:05–2:05 PM **Regulation of Gene and Cell Therapy Manufacturing**
This session will discuss regulatory challenges associated with manufacturing of gene and cell therapies. Speakers will discuss similarities and differences in the manufacturing of cell versus gene therapies, use of advanced manufacturing technologies, and good manufacturing and tissue practice considerations. Legal issues associated with commercial supply chain agreements and inspections and supply chain disruptions during COVID-19 will also be discussed.

Mo Heidaran, Vice President, Technical, Parexel International
Lawrence Starke, Global Regulatory Affairs (CMC) Policy and Intelligence, Cell & Gene Therapy, Novartis Pharmaceutical Corporation
Moderated by **Kathleen M. Sanzo**, Partner, Morgan, Lewis & Bockius LLP

2:05–2:35 PM **Break**

2:35–3:20 PM **Ensuring Regenerative Therapy Product Compliance with FDA**
Due to their innovative and complex technology, regenerative medicine products can have unique considerations that can result in compliance issues. The panel will explore ways product sponsors can work with the agency on an informal basis at various stages of the approval process to ensure compliance. This session will also discuss recent compliance and enforcement trends.

Allison Fulton, Partner, Sheppard Mullin Richter & Hampton LLP
Melissa Mendoza, Deputy Director, Office of Compliance and Biologics Quality, CBER, FDA
Moderated by **Kalah Auchincloss**, SVP and Deputy General Counsel, Greenleaf Health, Inc.

3:35–4:20 PM **Gene and Cell Therapy Coverage, Reimbursement, and Pricing**
This session will explore challenges in providing access to expensive but highly beneficial regenerative therapies and best practices for aligning goals between manufacturers and payors to minimize coverage issues. Speakers will also explain how FDA and payors, including the Centers for Medicare and Medicaid Services, work together to expedite patient access to these lifesaving therapies.

Rochelle Fink, Senior Health Science Project Manager, CDRH, FDA
Michael Werner, Partner, Holland & Knight LLP
Moderated by **Catherine A. Brandon**, Partner, Arnold & Porter LLP

4:20 PM **Closing Remarks and Adjournment**

Regenerative Medicine
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Speaker Biographies

JUDY ARCIDIACONO has 30 years of experience at FDA. For the first 18 years of her career at FDA she served as a research/reviewer. In this role she performed research on the human immunological response to xenotransplantation products and reviewed clinical trial applications for NK cell and T cell therapies and xenotransplantation products. Ms. Arcidiacono is currently working in the Immediate Office of the Director, OTAT, where she is responsible for developing regulatory policy with respect to international harmonization efforts including standards development, and collaborations with global regulatory authorities in the area of regenerative medicine therapies. As an expert in standards development, she represents FDA in ISO Technical Committee 276, Biotechnology, the American Society for Testing Materials (ASTM) F04 Committee on Medical and Surgical Materials and Devices, Tissue Engineering Medical Products, and the Parenteral Drug Association Standards Development Organization. She serves as the secretariat for the International Pharmaceutical Regulators Programme (IPRP), Cell Therapy Working Group and Gene Therapy Working Group. Judith represents FDA as a Subject Matter Expert in regenerative medicine policy for the Asia Pacific Economic Cooperation Regulatory Harmonization Steering Committee Priority Work Area for Advanced Therapies. She is also a faculty member for the Northeastern University Center of Excellence for Advanced Therapies and Duke Medical School at the National University of Singapore Center ofr Regulatory Excellence.

FOUAD ATOUF is Vice President, Global Biologics, for USP. He leads all scientific activities related to the development and maintenance of documentary and reference standards for biologics and advanced therapies and oversees the biologics laboratories in USP–US and USP–India. Dr. Atouf has been at USP for over 15 years and served in a variety of scientific leadership roles including being the regional champion for the Middle East and North Africa Region, where he helped facilitate, programs designed to enhance the understanding of the role of regulations and standards in the registration of medicinal products. Dr. Atouf has strong background and experience in the development and standardization for cellular and tissue-based products. Prior to joining USP in 2006, his research at the US National Institutes of Health focused on developing methods for the in vitro generation of cell-based therapies for diabetes. Dr. Atouf is the author of numerous publications in peer-reviewed journals and a frequent speaker at national and international scientific conferences. Dr. Atouf earned his Master's degree in Biochemistry and his PhD in Cell Biology from the Pierre & Marie Curie University, Paris, France.

KALAH AUCHINCLOSS is Executive Vice President, Regulatory Compliance and Deputy General Counsel at Greenleaf Health, Inc., where she advises clients on compliance, policy and regulatory issues. She has more than 15 years of food and drug legal, policy, and regulatory experience at FDA, on Capitol Hill, and in the private sector. Ms. Auchincloss spent six years at FDA, including as Deputy Chief of Staff for two FDA Commissioners. She has also served in FDA's Center for Drug Evaluation and Research (CDER) as a regulatory counsel in the Office of Regulatory Policy, and as Director of CDER's Office of Unapproved Drugs and Labeling Compliance in the Office of Compliance, leading a team of more than 50 staff working on pharmacy compounding, unapproved drugs, over-the-counter drugs, and other enforcement issues. Before joining FDA, Ms. Auchincloss was an associate at the law firm Foley Hoag LLP, in the firm's health care practice group. She holds a BA with honors from Williams College, a JD with honors from Georgetown University Law Center, and an MPH from Harvard University.

BARBARA A. BINZAK BLUMENFELD, a Shareholder at Buchanan Ingersoll & Rooney PC, helps clients make and execute on strategic decisions about FDA-regulated product approvals. She leverages her unique background, integrating science and biomedical ethics into her legal practice to create true value for her clients. For example, Barbara works closely with Buchanan's IP attorneys to create a holistic IP/FDA strategy that takes into account the company's patent portfolio, FDA Orange Book listings, and FDA-granted regulatory exclusivity. Barbara assists clients with FDA regulatory matters arising before, during, and after product approval and marketing. She has worked with clients on virtually all types of FDA-regulated products, including biologics, drugs (human and veterinary), regenerative medicine (cell and gene therapies), medical devices, foods (human and veterinary), and combination products.

JOAN WILMARTH BLAIR is the Senior Advisor for International Affairs to the Director/Deputy Director, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). As International Affairs Advisor, Ms. Blair is responsible for providing policy recommendations and guidance to the Center's leadership regarding international issues which affect the products and firms regulated by the Center and serves as CBER's primary point of engagement with the Agency on all international matters. She liaises with other US government agencies, international organizations, and representatives of foreign governments, and supervises the International Team of three staff members in the Immediate Office of the Director/CBER. Ms. Blair began her career in FDA in 1994. She earned her AB in Anthropology and Hispanic Studies from Bryn Mawr College and her MA in International Affairs from the School of Advanced International

Studies of Johns Hopkins University in the fields of Latin America, International Law and International Economics.

CATHERINE A. BRANDON is a partner at Arnold & Porter LLP where she focuses on the intersection of healthcare law and policy. Ms. Brandon counsels life sciences companies, healthcare providers, and related trade and specialty societies on healthcare regulatory, compliance and enforcement matters, as well as public policy issues. Ms. Brandon's work includes advising pharmaceutical companies and healthcare providers on matters related to healthcare fraud and abuse compliance, including anti-kickback laws and the "Stark" physician self-referral law; Medicare and Medicaid reimbursement and related policies; the Patient Protection and Affordable Care Act; and other regulatory and legislative initiatives affecting the life sciences and healthcare industries. Ms. Brandon has particular experience advising clients on patient support initiatives, contractual arrangements, value-based arrangements and reimbursement, and industry collaborations, including with respect to gene therapies and personalized medicine.

WILSON W. BRYAN is a neurologist who graduated from the University of Chicago Pritzker School of Medicine. Dr. Bryan served on the neurology faculty of the University of Texas Southwestern Medical School for 13 years. He has been an investigator on clinical trials in cerebrovascular disease and neuromuscular disorders, particularly amyotrophic lateral sclerosis. Dr. Bryan joined the United States Food and Drug Administration (FDA) in 2000, and now serves as Director of the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER).

MANTEJ (NIMI) CHHINA is Senior Director in BioMarin's Strategy, Scientific Collaborations and Policy (SSCP) function. She joined BioMarin Pharmaceutical Inc. in 2017 as Director of Regulatory Policy & FDA Engagement. In her current role, she heads their Global R&D and Regulatory Policy team, and provides strategic advice to global development programs, including gene therapy development, and commercial programs for lifecycle management. Before joining BioMarin, Nimi worked at the Office of Medical Policy in FDA's Center for Drug Evaluation and Research (CDER). She is a seasoned R&D and regulatory policy expert with strong understanding of FDA, EMA, ICH, and other global laws, regulations, policies, and guidances for development, review, and regulation of medical products. She also has extensive biotechnological, translational, and clinical research experience. She got her BS (Honors School) and MS (Honors School) in human genetics from Guru Nanak Dev University in India. She undertook graduate studies in biomedical genetics at University of Rochester, NY. She got her PhD in biotechnology and functional genomics from George Mason University, VA; and her JD

from UDC David A. Clark School of Law, DC. She has the Regulatory Affairs Certification (RAC) and certificate in legislative studies from the Government Affairs Institute at Georgetown University.

MICHAEL N. DRUCKMAN is a partner at Hogan Lovells US LLP where he leverages his prior experience at the FDA – and what he has learned since then while extricating companies from regulatory problems – to anticipate and prevent life science clients from getting into trouble in the first place. Mike understands the business challenges that companies face in a highly regulated environment. He actively works with other Hogan Lovells lawyers experienced with government reimbursement, anti-kickback limits, product liability, and a full range of other regulatory areas to craft approaches that will maximize clients' opportunities and minimize their risks. Mike chairs the firm's Cell, Tissue, and Gene Therapies Working Group, a cross-disciplinary team that advises companies in this emerging space on the evolving regulatory and business challenges they face. Mike and the team work closely with companies developing stem cells, cord blood, placental tissues, gene therapies, proteins, and other cellular products to help people with serious health problems. Mike also advises companies with a full range of regulatory challenges involved in investigating new drugs, biologics, and combination products, obtaining FDA approval for those products, and in promoting, selling, and distributing them. His experience also includes the Drug Supply Chain Security Act, pharmacy compounding, expanded access/compassionate use clinical trials, orphan drug exclusivity, and precision medicine and companion diagnostics. While in the FDA Office of the Chief Counsel, Mike also advised on medical countermeasures. He served on the FDA's Pandemic Influenza Planning and Preparedness Team, and helped draft guidance on pandemic and seasonal flu vaccines and a regulation on Strategic National Stockpile product labeling. In his years at the firm, Mike has advised on Emergency Use Authorizations, select agents and toxins and Dual Use Research of Concern (DURC), and various issues involving vaccines and other products.

ROCHELLE FINK is a Senior Health Science Specialist at FDA. In that capacity, she works on joint CMS-FDA efforts to accelerate the regulatory and coverage decision making process. This responsibility includes spending a portion of each week working in CMS's Coverage and Analysis Group (CAG) and the remainder of the week working at FDA's Center for Devices and Radiological Health (CDRH). Dr. Fink is involved in the FDA-CMS Parallel Review Program and CDRH's Pre-Submission Program. As a registered patent attorney, Dr. Fink works on CDRH's technology transfer and patent matters. Additionally, she establishes collaborations with CDRH and has been involved in the FDA-Medical Device Innovation Consortium (MDIC) effort. Prior to joining CDRH, Dr. Fink worked in CDER's Office of Regulatory Policy where her primary responsibilities included responding to citizen petitions. Dr. Fink received her undergraduate and medical degrees from Brown University and her law degree from the University of Pennsylvania Law School. She has worked as an associate at Paul, Weiss, Rifkind, Wharton & Garrison, LLP and Sidley Austin, LLP.

ALLISON FULTON is a partner in the Life Sciences and FDA Team in the Washington, DC office of Sheppard, Mullin, Richter & Hampton LLP. She advises life sciences companies, including pharmaceutical, medical device, dietary supplement, food and cosmetic companies, in matters relating to the development, manufacture and marketing of products regulated by the US Food and Drug Administration (FDA). Allison's areas of focus include assisting US and international companies with complying to pre-market and post-market FDA requirements, including marketing authorization, clinical trials, compliance with GxP, product promotion and labeling, recalls and other product safety issues. She regularly advises companies on preparing for FDA inspections, responding to FDA Form 483s and Warning Letters, remediating GMP and data integrity issues and handling adverse events and medical device reports (MDRs). Allison also provides regulatory advice during acquisitions of life science companies, and counsels clients on a variety of life science transactions, including supply agreements, quality agreements and product licenses. Allison is passionate about novel technologies and advises clients on product approval and clearance strategies for innovative products, including digital health technologies, precision medicine and combination products. She has led numerous internal investigations involving allegations of product tampering, non-compliance with GMP and off-label promotion. Allison acts as FDA counsel on civil litigation matters, such as false advertising and False Claims Act litigation. Prior to attending law school, Allison was a software engineer, specializing in software validation. She earned her law degree from the University of Texas School of Law, where she was the managing editor of the Texas Intellectual Property Law Journal. She received a BS degree in Industrial Engineering from Northwestern University.

HEATHER C. HATCHER is a Regulatory Scientist with Womble Bond Dickinson (US) LLP. Dr. Hatcher has an extensive background as a basic and clinical research scientist, as well as Regulatory Affairs, and her experience has enabled her to effectively guide clients through the complex regulatory landscape governed by the US Food and Drug Administration (FDA). She advises clients with respect to early regulatory strategy and product development and has worked with clients on virtually all types of FDA-regulated products, including biologics, drugs (human and veterinary), regenerative medicine (cell and gene therapies and biomaterials), medical devices, foods and dietary supplements (human and veterinary), and combination products. Dr. Hatcher's research career spans a number of fields including endocrinology, cancer biology and regenerative and translational medicine; and her research has been published in numerous peer-reviewed journals. She is a member of the firm's Life Sciences and Pharmaceuticals team and FDA Regulatory team.

JOANNE HAWANA is a Member of the law firm Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, practicing in the Health/FDA Group and based in the firm's Washington DC office. She counsels global clients on the business impact of new US federal and state actions related to drugs, biologics, cellular therapies, foods, and medical devices. Her counseling and compliance support work reaches into all aspects of FDA-regulated companies' operations, including determining regulatory status of novel products; pre-market and post-market compliance requirements; and enforcement-related matters. She also provides regulatory expertise to her colleagues in class action and other litigation involving FDA-regulated products, and she works with the Mintz Corporate & Securities Practice on transactions and offerings for companies regulated by the FDA. Joanne has a masters degree in molecular genetics from UMDNJ and a bachelors degree in biology from the College of William & Mary. She received her JD from the University of Maryland Francis King Cary School of Law in 2007. Joanne is currently a member of the FDLI Publications and Academic Programs Committee.

MO HEIDARAN joined PAREXEL International as Vice President of Technical in December of 2018. He has close to 9 years prior experience as a Biologist and as a Master Reviewer in OTAT, and as a facility reviewer and inspector in the Division of Manufacturing and Product Quality (DMPQ). During his tenure at OTAT, in addition to his review responsibilities, he also served as Acting Team Lead and Branch Chief briefly and as a DCGT representative to several FDA and CBER wide working groups and outside organizations such as USP. He has also been involved in various standard development activities, cell based product manufacturing initiatives and various compliance activities. Dr. Heidaran has a multidisciplinary academic and industrial background in basic and applied cell biology and innovative cell therapy and tissue engineering product development. He also has hands-on industrial experience in manufacturing of cell therapy and tissue engineering products for about 15 years in small and large size Biotech companies. Mo received his formal training at the National Cancer Institute where he served as a Senior Staff Scientist for about six years and three years as an IRTA fellow studying signal transduction by receptor tyrosine kinases. Dr. Heidaran holds a PhD in biochemistry from the University of South Carolina, and received his formal training at the National Cancer Institute. Prior to FDA, he served as R&D Director at both Celgene and Becton Dickinson. He has been an adhoc reviewer and member of editorial boards of several peer reviewed publications. He also holds 25 issued patents and 54 pending patents and his work has appeared in more than 50 scientific publications. He is currently member of ISCT Legal and Regulatory Affair Committee, and USP Bio5 Expert Committee.

ILAN IRONY is the Deputy Director in the Division of Clinical Evaluation and Pharmacology / Toxicology in the Office of Tissues and Advanced Therapies / CBER. After training at UCSF and NIH and years of practice in Internal Medicine and Endocrinology, Dr. Irony joined FDA CBER in 2000 as a clinical reviewer. He also worked in the Endocrine Division in CDER as a reviewer and team leader. In 2011, he returned to CBER as chief of the General Medicine Branch, and in 2017 became Deputy Director in the Division of Clinical Evaluation and Pharmacology / Toxicology in the Office of Tissues and Advanced Therapies. Over the course of his career at FDA, he has directly reviewed or supervised the review of many trials investigating drugs, biologics, devices and combination products intended for treatment of conditions in almost all areas of Medicine and, in particular, trials of cellular and gene therapies for rare diseases. Dr. Irony is board certified in Internal Medicine and Endocrinology.

BRUCE LEVINE, Barbara and Edward Netter Professor in Cancer Gene Therapy, is the Founding Director of the Clinical Cell and Vaccine Production Facility (CVPF) in the Department of Pathology and Laboratory Medicine and the Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania. He received a BA (Biology) from Penn and a PhD in Immunology and Infectious Diseases from Johns Hopkins. First-in-human adoptive immunotherapy trials include the first use of a lentiviral vector, the first infusions of gene edited cells, and the first use of lentivirally-modified cells to treat cancer. Dr. Levine has overseen the production, testing and release of 3,000 cellular products administered to >1,300 patients in clinical trials since 1996. He is co-inventor of the first FDA approved gene therapy (Kymriah), chimeric antigen receptor T cells for leukemia and lymphoma, licensed to Novartis. Dr. Levine is co-inventor on 28 issued US patents and co-author of >180 manuscripts and book chapters with a Google Scholar citation h-index of 92. He is a Co-Founder of Tmunity Therapeutics, a spinout of the University of Pennsylvania. Dr. Levine is a recipient of the William Osler Patient Oriented Research Award, the Wallace H. Coulter Award for Healthcare Innovation, the National Marrow Donor Program/Be The Match ONE Forum 2020 Dennis Confer Innovate Award, serves as President of the International Society for Cell and Gene Therapy, and serves on the Board of Directors of the Alliance for Regenerative Medicine. He has written for Scientific American and Wired and has been interviewed by the NY Times, Wall Street Journal, Washington Post, NPR, Time Magazine, National Geographic, Bloomberg, Forbes, BBC, and other international media outlets.

DEBORAH L. LIVORNESE is Director at Hyman, Phelps & McNamara, PC in Washington, DC. Ms. Livornese has extensive experience in a broad range of FDA regulatory issues. She assists pharmaceutical drug companies of all sizes on regulatory requirements and strategies related to obtaining FDA approval and other paths to market, as well as on post-marketing regulatory requirements. Ms. Livornese also assists clients in connection with commercial transactions and public offerings by conducting FDA regulatory due diligence on behalf of regulated companies and potential investors or purchasers. Prior to joining Hyman, Phelps & McNamara, Ms. Livornese spent seven years in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. As a Senior Regulatory Counsel at FDA, she was involved in a wide variety of policy issues in the areas of drug approvals and withdrawals, the regulation of unapproved and over-the-counter drugs, and opioid drugs, and user fee programs. Prior to joining FDA, Ms. Livornese was Of Counsel with an FDA boutique law firm in Washington DC where she advised drug companies on promotional activities for compliance with FDA, FTC and HHS requirements, and assisted clients in responding to investigational findings, warning letters, and inquiries from the FDA and other agencies.

PETER W. MARKS 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.

MELISSA MENDOZA is the Deputy Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research (CBER) at the US Food and Drug Administration (FDA). OCBQ is responsible for ensuring the quality of products regulated by CBER over their entire lifecycle, from pre-market review and inspection to post-market review, surveillance, inspection, outreach, and compliance. Before joining CBER, Melissa served for eight years in FDA's Office of the Chief Counsel where she was an Associate Chief Counsel for Enforcement.

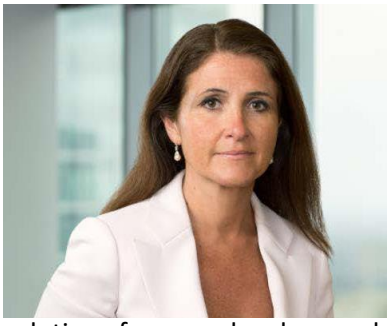
LAUREN A. MILLER is Senior Counsel at AbbVie where she works in the brand legal group providing legal support for US oncology commercialized and pipeline products. At AbbVie, Ms. Miller provides legal counsel on a broad range of issues arising under FDA regulations, False Claims Act, Anti-Kickback Statute, OIG guidance, the PhRMA Code. Prior to her current role Ms. Miller served as Corporate Counsel at Otsuka America Pharmaceutical Inc., ("Otsuka"). At Otsuka, she provided legal support to U.S. business teams and medical affairs. Additionally, she also served as the lead legal reviewer for the company's Nephrology portfolio advising business teams on all aspects of promotional activities. Ms. Miller also reviewed and negotiated complex commercial agreements, research agreements, and other corporate agreements. Previously, Ms. Miller served as Regulatory Counsel in FDA's Office of Prescription Drug Promotion ("OPDP") where she counseled and advised OPDP on: procedures and methods related to implementing and applying regulations under the Federal Food, Drug and Cosmetic Act ("FD&C Act"), policy statements, and guidance documents for purposes of carrying out OPDP's regulatory mission. During her time at FDA she worked to provide guidance on the compassionate use of investigational new drug aimed at combating the Ebola virus. Prior to joining OPDP, Ms. Miller worked as an associate at Arnold & Porter, LLP in the firm's FDA and Healthcare practice group providing counseling on regulatory and public policy issues for clients in the drug, food, tobacco, medical device and healthcare sectors. Ms. Miller received her BA from the University of Michigan and her JD, cum laude, from Howard University School of Law.

GOPA RAYCHAUDHURI is a Senior Scientist in the Office of the Director at the Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration. Dr. Raychaudhuri is CBER's liaison to the World Health Organization (WHO) and in this role, she provides strategic direction and oversees CBER's scientific collaborations with the WHO. Additionally, she leads and manages CBER's Individualized Therapeutics Program. Dr. Raychaudhuri received her Bachelor of Science and Master of Science degrees in Biochemistry from the University of Toronto and received a PhD in Microbiology from the University of Virginia. She did her post-doctoral training at the National Institute for Allergy and Infectious Diseases (NIAID) at the National Institutes of Health where her research focused on development of a live, attenuated vaccine for hepatitis A. After her post-doctoral training, Dr. Raychaudhuri joined the Office of Vaccines Research and Review in FDA/CBER as a scientific reviewer. Since 2010, she has been in her current position in the Office of the Director advancing strategic programs to implement CBER priorities. Dr. Raychaudhuri has a long-standing interest in development and access to essential medical products that promote national and global public health.

VICTORIA PALMI REIG is currently Product Lead of Advanced Therapies in the European Medicines Agency (EMA); she supports the benefit/risk evaluation and leads early access initiatives. She has previously worked as Product Lead in the Immunology, CNS and Endocrinology office, also at EMA. She has a degree in pharmacy from the University of Valencia (Spain) and René Descartes-Paris (France). Additional qualifications include Methodology of Clinical Trials and European Regulatory affairs.

KATHLEEN M. SANZO is a partner at Morgan, Lewis & Bockius LLP. As the FDA practice leader, Kathleen represents clients in the pharmaceuticals and biotechnology, food and dietary supplements, consumer products, consumer protection safety, advertising, cosmetics, drugs, and medical industries. Kathleen advises companies on regulatory pathway strategies, appropriate responses to FDA protocols and complete response letters, dispute resolution, responding to Current Good Manufacturing Practice (cGMP) issues, including 483s and Warning Letters, as well as day to day counseling on marketing and promotion launch and other communications, including responses to FDA Untitled and Warning Letters; and similar advice and counsel on food, dietary supplements, and cosmetic products, including various notices and registrations to FDA; recalls and other crisis management; and counseling on product testing, Section 15(b) notices and penalty investigations, as well as product recalls. A frequent author and co-author on publications related to FDA matters, Kathleen regularly speaks on these issues at industry events. Industry and legal groups have praised her work: Legal Media Group Life Sciences named her the “US Regulatory Attorney of the Year,” “FDA Pharmaceutical Industry Lawyer of the Year,” and a “Life Sciences Star.” Chambers USA have listed her in “America’s Leading Lawyers for Business.” She serves as vice-chair of the Consumer Product Regulation Committee of the American Bar Association Section of Administrative Law and Regulatory Practice. Kathleen is also a member of FDLI’s 2021 Medical Products Committee.

ROBERT SHAW is the Executive Director of the Standards Coordinating Body for Regenerative Medicine. Bob has over 30 years of international management experience in the biopharmaceutical and cell therapy areas in both small, upstart organizations and large mature corporations. Most recently with Cell One Partners Inc. Bob's primary focus was on strategy, commercial development and operations' excellence. Previously with Thermo Fisher Scientific, he had responsibilities for their Technical Services Organization, their Cell Culture and Cell Therapy business, and initially product management for the BioProduction Division following the acquisition of Life Technologies. Bob brings a passion for change management, and for development of strategies that can be used to implement effective and efficient tactical processes for commercial development and marketing. He thrives on creating sustainable and scalable models for growth and organization development.Prior to Thermo Fisher Scientific, Bob had senior positions at Progenitor Cell Therapy, Millipore (now MilliporeSigma), Wyeth Pharmaceuticals (now Pfizer), Univax Biologics (NABI), and Sanofi-Pasteur. Bob's other activities have included Board membership at Ossify Biologics, the Alliance for Regenerative Medicine, Westford Education Foundation, the Parenteral Drug Foundation, and he was founder and Co-Chair of the Process Development Committee at the Massachusetts Biotechnology Council.



CRISTIANA SPONTONI is internationally recognized as a leader in life sciences, including biotechnology, pharmaceuticals, medical devices, food and cosmetics, as well as in general EU product and industries regulation. She is also actively involved in the shaping and interpretation of EU legislation affecting many different regulated industries and has successfully represented clients in legislative challenges based on EU law. Cristiana frequently coordinates large international assignments and provides comprehensive one-stop-shop solutions for cross-border regulatory issues affecting clients' operations. She has coordinated projects in more than 80 countries worldwide. Cristiana advises clients from the pre-market phase, including clinical trials and pre-market authorizations, to post-market issues, including product liability, marketing/advertising, distribution, and compliance (including sector-specific antibribery and data privacy). Cristiana handles safety and compliance issues for a large variety of clients both in the life sciences and consumer products sectors, including in regards to product regulation, crisis management (e.g., recalls), regulatory enforcement and media attacks, as well as in marketing/advertising/claims and associated substantiation matters. Cristiana frequently speaks at and chairs major international conferences. She is recognized in the leading lawyer directories including Chambers, Legal 500, Best Lawyers, and International Who's Who and has received several important awards, including "Life Sciences Lawyer of the Year"(Corporate LiveWire 2018 Global Awards) and the ILO Client Choice Award for EU-wide Healthcare & Life Sciences. She has been named a "Star" by LMG Life Sciences and Acritas.

COLLIN STABLER is a senior associate at Exponent. Dr. Stabler's expertise is medical device and drug delivery platform development for implantable cardiovascular devices, pulmonary therapies, and tissue engineered medical products. His experience includes design evaluation and mechanical behavior of nitinol-based cardiovascular implants (e.g., occluders, prosthetic heart valves), functional evaluation of balloon catheters and expandable stents, 3D-printing for biomedical purposes (e.g., bioprinting), tissue engineering and regenerative medicine, bioreactor design, in vivo disease modeling, and ex vivo microphysiologic assay development (e.g., organoids, microfluidic devices). Dr. Stabler is proficient in mechanical testing of medical devices and biomaterials, histological analyses, cell and molecular biology techniques, and has extensive experience working with animal models for disease and regeneration studies, as well as a multitude of microscopy and dry lab techniques. As a data scientist, he has expertise in handling large datasets, market and strategic analysis, and data visualization tools. Dr. Stabler's research has included the development of methods for manufacturing bioengineered lungs, bioreactor design for stem cell culture, disease modeling of acute respiratory distress syndrome and pulmonary fibrosis, and tissue engineering of lung, tracheal, and bone tissues. Dr. Stabler's experience provides him with the necessary skill sets for solving complex technical problems in the pharmaceutical and medical device industries, enabling companies to address patient needs more effectively and efficiently. Dr. Stabler has published a number of papers in the field of tissue engineering and regenerative medicine, and his research contributed to the founding of a medical device startup company. He maintains a broad presence in the industry through involvement in professional and entrepreneurial societies. His work has resulted in several academic awards from a government agency, private foundations, and publicly held companies.

LAWRENCE STARKE is currently head of Regulatory CMC Policy and Intelligence at Novartis Pharmaceuticals Corporation in East Hanover, NJ. Prior to assuming his currently role, Dr. Starke was RA-CMC Unit Head for Cell and Gene Therapy Products at Novartis and held positions of increasing responsibility within the biologic RA-CMC roles at Eli Lilly and Company and at Merck. Dr. Starke received his Ph.D. in Cell and Molecular Biology at Duke University in Durham, North Carolina and was a research associate at Baylor College of Medicine in Houston, Texas prior to his career in the pharmaceutical industry.

MICHAEL WERNER is a Washington, DC-based public policy and regulatory attorney and a co-leader of Holland & Knight's Healthcare & Life Sciences Team. Mr. Werner has almost three decades of healthcare law, lobbying, regulatory, and reimbursement experience in Washington. He focuses on issues affecting FDA-regulated entities, including biotechnology and pharmaceutical companies developing and manufacturing prescription and over-the-counter (OTC) drugs, biosimilars, cosmetics, dietary supplements, and digital-health technologies. His specific areas of knowledge include FDA regulations regarding product approval, marketing, and distribution; Medicare, Medicaid, and commercial insurance reimbursement; regulation and reimbursement of cell therapy, gene therapy, tissue engineering, and regenerative medicine products; the Physician Sunshine Act; human subject protection issues such as institutional review board (IRB) review and informed consent; as well as conflicts of interest and other bioethics issues arising from research and uses of new technologies. Mr. Werner is the co-founder and senior policy counsel of the Alliance for Regenerative Medicine, the leading global organization representing the cell therapy, gene therapy, tissue engineering, and regenerative medicine sector.

Regenerative Medicine: Regulatory, Legal, and Compliance Challenges for Cell and Gene Therapies
June 8-9, 2021
Attendee List

First Name	Last Name	Job Title	Company Name	City and State
Cheri D.	Adams	Pharmacovigilance Specialist, and MSHS in Regulatory Affairs at GWU	University of Colorado	Parker, CO
Judith	Arcidiacono	Regulatory Affairs Specialist	FDA - CBER	
Fouad	Atouf	Senior Scientist	U.S. Pharmacopeia	Rockville, MD
Kalah	Auchincloss	Executive Vice President and Deputy General Counsel	Greenleaf Health, Inc.	Washington, DC
Eugene	Babcock	Associate Director, CMC Regulatory Affairs		Waltham, MA
Anthony	Baiamonte		Passage Bio Inc.	Southampton, PA
Julie	Batal	Vice President of Regulatory Labeling, Advertising and Promotion	bluebird bio, Inc.	Cambridge, MA
Jeannie	Baumann	Reporter	Bloomberg News	Washington, DC
Barbara A.	Binzak Blumenfeld	Shareholder	Buchanan Ingersoll & Rooney PC	Washington, DC
Joan Wilmarth	Blair	Senior Advisor for International Affairs	FDA - CBER	Rockville, MD
Mladen	Bozic	VP, Regulatory & Stakeholder Engagement	bluebird bio, Inc.	Boston, MA
Catherine A.	Brandon	Partner	Arnold & Porter LLP	Washington, DC
Laura	Brown	Director, Educational Programs	Food and Drug Law Institute (FDLI)	Washington, DC
Wilson W.	Bryan	Director, Office of Tissues and Advanced Therapies	FDA - CBER	Silver Spring, MD
Alexandria	Buettner	Intergovernmental Affairs Specialist	FDA - OC	Silver Spring, MD
Cathy L.	Burgess**	Partner	Alston & Bird LLP	Washington, DC
Coleen	Carney	Manager, Meetings	Food and Drug Law Institute (FDLI)	
Iris	Case	Student	Johns Hopkins University	
Mantej Nimi	Chhina*	Senior Director & Head, Global Regulatory Policy	BioMarin Pharmaceutical Inc.	Potomac, MD
Tom	Class	Vice President Regulatory Affairs	Translate Bio	Lexington, MA
James	Cooper	MD/PhD Candidate	University of Buffalo	Buffalo, NY
Amanda	Cowley	General Counsel & SVP, Legal Strategy and Insights	U.S. Pharmacopeia	Rockville, MD
Lesley	DeRenzo	Associate Director and Corporate Counsel	Vertex Pharmaceuticals, Inc.	Boston, MA
Nicholas	Drago	Associate Director Regulatory Policy & Intelligence	Bayer Healthcare Pharmaceuticals	Whippany, NJ
Michael N.	Druckman	Partner	Hogan Lovells US LLP	Washington, DC
Aaliyah	Eaves	Partner of Counsel	Dinsmore & Shohl LLP	Washington, DC
Joanne	Eglovitch	News Editor, RAPS Focus	Regulatory Affairs Professional Society (RAPS)	Rockville, MD
Robert J.	Falb	Director, U.S. Policy and Advocacy	Alliance for Regenerative Medicine	Bethesda, MD
Rochelle	Fink	Senior Health Science Project Manager	FDA - CDRH	Silver Spring, Marylanf
Kay	Fuller	President	No Account	Ann Arbor, MI
Allison	Fulton*	Partner	Sheppard Mullin Richter & Hampton LLP	Washington, DC
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Derrick	Gingery	Senior Writer	The Pink Sheet	Washington, DC
Bryant M.	Godfrey	Counsel	Arnold & Porter LLP	Washington, DC
Heather C.	Hatcher	Regulatory Scientist	Womble Bond Dickinson (US) LLP	Winston-Salem, NC
Joanne	Hawana	Member	Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.	Boston, MA
Mo	Heidaran	Vice President, Technical	Parexel International Corporation	
Krystal	Huntsman	CSR	Guest Checkout Account FDLI Store	Sandy, UT
Ilan	Irony	Deputy Director, Division of Clinical Evaluation and Pharmacology/Toxicology	FDA - CBER	
Joseph	Jimenez	Managing Director, Arches Consulting, LLC	Sole Practitioner	Miramar, FL
Kathleen	Johnson	Assistant General Counsel	Vertex Pharmaceuticals, Inc.	Weston, MA
Jane	Kalinina	Associate	Hogan Lovells US LLP	Washington, DC
Sheila M.	Kaplan	Correspondent	New York Times	Bethesda, MD
Sharon	Kime	Head of US Regulatory Intelligence	Genentech, Inc.	Pacifica, CA

Kasey Rebecca	Kime	Regulatory Manager/Student	Thermo Fisher Scientific	Christchurch, Canterbury
Audrey	Kusiak		US Department of Veterans Affairs	Washington, DC
Bruce L.	Levine	Barbara and Edward Netter Professor in Cancer Gene Therapy	University of Pennsylvania	
Jane Massey	Licata	Partner	Licata & Tyrrell P.C.	Marlton, NJ
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Peter W.	Marks	Director, Center for Biologics Evaluation and Research	FDA - CBER	Silver Spring, MD
Jean	McCue	Regulatory Counsel	FDA - CDER	Silver Spring, MD
David L.	McFarland	Editor	FDA Review	Camp Hill, PA
Melissa	Mendoza	Deputy Director, Office of Compliance and Biologics Quality	FDA - CBER	Silver Spring, MD
Karen	Midthun	Principal, Greenleaf Health	Greenleaf Health, Inc.	Washington, DC
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Kai	Mindick	Incoming FDA Group Associate	Cornell University	Binghamton, NY
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Grace	Moser	Reporter	Prevision Policy LLC	Washington, DC
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Matthew	Perrone	AP Health Writer	Associated Press	Washington, DC
Smruti	Phadnis	Marketing Manager	Agilent Technologies	Santa Clara, CA
Nathan	Poluga	Managing Editor	International Pharmaceutical Quality	Bethesda, MD
Gopa	Raychaudhuri	Scientific Reviewer	FDA - CBER	Rockville, MD
Victoria Palmi	Reig	Product Lead, Office of Therapies for Immune and Inflammatory Disease	European Medicines Agency	
Gary	Richard	VP, GXP Compliance	BioMarin Pharmaceutical Inc.	Novato, CA
Amy Comstock	Rick**	President and CEO	Food and Drug Law Institute (FDLI)	Washington, DC
Duncan	Ross	CEO	Kimera Labs Inc	Miramar, FL
Andrea L.	Ruth	Principal Consultant	No Account	Pacifica, CA
Priya	Sankar	Associate General Counsel	Passage Bio Inc.	Newtown Square, PA
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Melissa	Scales	Assistant Director, Educational Programs	Food and Drug Law Institute (FDLI)	Rockville, MD
Devon	Schulz	Associate	Covington & Burling LLP	San Francisco, CA
Robert	Shaw	Executive Director	Standards Coordinating Body	
Faraz	Siddiqui	Associate	Hyman, Phelps & McNamara, PC	Washington, DC
Erin	Skold	Legal Counsel	Mayo Clinic	Eau Claire, WI
Cristiana	Spontoni	Partner	Jones Day	Brussels,
Collin	Stabler	Senior Associate	Exponent, Inc.	Philadelphia, PA
Lawrence	Starke	Policy Lead, Regulatory Affairs (CMC), Cell & Gene Therapy	Novartis Pharmaceuticals Corporation	
Deborah	Tolomeo	Senior Director, External Collaborations and Global Compliance	Genentech, Inc.	Los Altos, CA
Kristin	Van Goor	Senior Director, Regulatory Policy & Intelligence	Vertex Pharmaceuticals, Inc.	Boston, MA
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Benjamin	Wolf	Senior Associate	Alston & Bird LLP	Washington, DC
Daniel	Zinn	Manager, Membership & Communications Analytics	Food and Drug Law Institute (FDLI)	Washington, DC

***Member, Conference Planning Committee**

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