FDLI
Food and Drug Law Institute

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Food and Drug Law Institute Announces Six New Board Members and Two Officers

Washington, DC – The Food and Drug Law Institute (FDLI) is pleased to announce the addition of six new members to its Board of Directors: Scott D. Danzis, Covington & Burling LLP, Neal Fortin, Michigan State University, Bryant M. Godfrey, Foley Hoag LLP, Jonathan A. Havens, Saul Ewing Arnstein & Lehr LLP, Beth G. Oliva, Fox Rothschild LLP, and Marta L. Villarraga, Exponent, Inc. They join ten other highly respected leaders in the food and drug law field in serving on the FDLI Board.

"We are very excited to welcome our colleagues to the FDLI Board of Directors and congratulate our newly appointed officers. As we celebrate FDLI's 75th anniversary this year, we will work together to ensure the organization continues and expands its role as the preeminent professional education/training resource for our members and as neutral convenor for all stakeholders in the food and drug legal and regulatory community," said Board Chair Freddy A. Jimenez, Senior Vice President and General Counsel, Celldex Therapeutics.

Scott D. Danzis is a partner in the law firm of Covington & Burling, LLP, where he chairs the firm's Medical Device Industry Group. He is a leading expert on the regulation of medical devices, including therapeutic devices, digital health, and diagnostics. Scott regularly helps clients navigate their most complex regulatory challenges, including strategies for premarket clearance/approval, postmarket compliance, and enforcement actions. He previously served in FDA's Office of the Chief Counsel where he was involved in a wide range of legal and regulatory matters, and for more than a decade has taught FDA law at the Georgetown University Law Center. He is a graduate of the University of Virginia School of Law where he was the Editor-in-Chief of the *Virginia Law Review*. Following law school, Scott clerked for the Honorable Chester J. Straub on the U.S. Court of Appeals for the Second Circuit. He also holds a Master's Degree from George Washington University and a Bachelor of Science from Cornell University.

Neal Fortin is the Director of the Institute for Food Laws & Regulations at Michigan State University, and Professor in the Department of Food Science and Human Nutrition. He is also an Adjunct Professor at the Michigan State University College of Law. Neal teaches the courses "United States Food Law," "International Food Law," and is the author of *Food Regulation: Law, Science, Policy, and Practice, 2nd ed.* Neal was the 2009 recipient of a Michigan State University Distinguished Faculty Award for his teaching in food safety. He served as a Commissioner for the Michigan Local Public Health Accreditation Program, the Advisory Council of the Michigan Community Health Leadership Institute, and the NSF Council of Public Health Consultants. Neal has been a curriculum advisor to the International Food Protection Training Institute and the University of Catalonia. He is an emeritus member of the Association of Food and Drug Officials, a member of the Institute of Food Technologists, and the State Bar of Michigan.

Bryant M. Godfrey is a partner in the Washington, D.C. office of Foley Hoag and is Co-Chair of the firm's Healthcare Department and FDA Practice Group. His experience encompasses a wide range of issues relating to advertising and promotion, labeling, scientific exchange, investigations of off-label marketing, product jurisdiction, medical product development and approval/clearance, post-marketing commitments and requirements, Current Good Manufacturing Practices (CGMPs), drug supply chain issues, medical device reporting, FDA warning letters and responses, dispute resolution, FDA inspections, recalls, administrative detention, import alerts and refusals, combination products, digital health, food and dietary supplements,

tobacco products, and cannabis-derived products. Bryant served in several senior positions at FDA, including as Senior Lead Regulatory Counsel for the Office of Prescription Drug Promotion, Senior Regulatory Counsel in the Office of Regulations in the Center for Tobacco Products, and Senior Counsel/Special Assistant to the Principal Deputy Commissioner.

Jonathan A. Havens is the Managing Partner of Saul Ewing LLP's Baltimore office and serves as co-chair of both the firm's Cannabis Law and Food, Beverage & Agribusiness Practices. Companies in the cannabis (both hemp and marijuana), life sciences, food and beverage, and cosmetics industries turn to Jonathan for advice on how to get and keep their products on the market. Since 2019, Chambers USA has recognized him as one of America's leading lawyers in cannabis law. In 2021, Law360 selected Jonathan as a cannabis law rising star, and he has been quoted by or authored pieces for The New York Times, The Los Angeles Times, Reuters, CNBC, WIRED, MarketWatch, Engadget, Law360, High Times Magazine, and Marijuana Business Daily, among others. Jonathan began his legal career as a regulatory counsel with the U.S. FDA, and prior to law school, he served as a legislative aide in both the U.S. Senate and U.S. House of Representatives.

Beth G. Oliva represents manufacturers, distributors, retailers, and trade associations in regulatory, litigation and legislative matters. She handles a wide range of regulatory issues before federal and state agencies, including the Food and Drug Administration, and routinely counsels tobacco industry clients regarding FDA compliance and premarket review requirements. Beth also has extensive experience with state and federal government affairs. In addition, Beth has significant experience working with scientific issues. She has worked with scientific and medical personnel in the U.S., Canada, Europe, and the Middle East. She has worked to identify and review relevant literature within different fields of medicine and science to advise product manufacturers on regulatory and duty-of-care issues. Further, Beth has worked with scientific consultants, expert witnesses, and scientific literature both to support regulatory submissions and to prepare defenses in domestic and international product liability litigation.

Marta L. Villarraga is a Principal in Biomedical Engineering & Sciences at Exponent, based in Philadelphia, PA. Her expertise focuses on the evaluation of medical device performance during the premarketing and postmarketing stages. Marta has evaluated orthopedic, spinal, plastic and reconstructive surgery, urology, urogynecology, general surgery, women's health, wearables and diagnostic medical devices. She has provided technical support for due diligence, regulatory submissions, regulatory compliance, risk management, postmarketing surveillance, product development, product liability, and intellectual property matters. As a Regulatory Affairs Certified (RAC-US) professional, Marta uses her knowledge of the U.S. FDA regulations to develop regulatory strategies for novel products, contribute to or prepare regulatory submissions, and to support identifying and justifying technical evaluations for pre-market assessments and postmarket compliance matters. Marta has a PhD in Biomedical Engineering from Tulane University.

In addition, FDLI announces the following Executive Committee changes: Vernessa T. Pollard, McDermott Will & Emery has been named Vice-Chair and Melanie Katrice Gross, Genetech Inc. has been named Treasurer. Also serving on the Executive Committee are Chair, Freddy A. Jimenez, Celldex Therapeutics, Inc.; Secretary and General Counsel, Amy Norris, Clif Bar & Company; and Christine M. Simmon, President and CEO, FDLI.

FDLI thanks the five outgoing members of the Board of Directors: Frederick R. Ball, Duane Morris LLP; Dean R. Cirotta, EAS Consulting Group; Daniel A. Kracov, Arnold & Porter LLP; Cynthia Schnedar, Greenleaf Health, an Eliquent Life Sciences Company; Rachel Turow, Walmart. Each made invaluable contributions to FDLI and the broader food and drug law community through their Board service.

The Food and Drug Law Institute (FDLI) is a nonprofit membership organization that offers education, training, publications, and professional networking opportunities in the field of food and drug law. As a neutral convener, FDLI provides a venue for stakeholders to inform public policy, law, and regulation.