JUDITH D. CASSEL, ESQUIRE

Partner, Hawke McKeon Sniscak LLP; Cannabis Law PA

Judith D. Cassel of Cannabis Law PA provides legal guidance to growers/processors, dispensaries, laboratories, physicians, certified medical education providers, ancillary businesses, and attorney bar associations navigating the regulatory landscape of medical marijuana.

Ms. Cassel has given multiple presentations on medical marijuana in Pennsylvania and Maryland including before the Lancaster Bar Association and the Widener Law and Government Institution. She has been a panelist on medical marijuana issues for WITF's SmartTalk Radio, the Opioid Epidemic: Law and Policy Program, Mother and Baby War on Opioids, and the Pennsylvania Bar Institute where she focused on how medical marijuana may alleviate the opioid crisis. Ms. Cassel has authored numerous articles on medical marijuana including most recently in *The Pennsylvania Lawyer* and *Marijuana Ventures*.

Ms. Cassel utilizes her law degree in conjunction with her MBA and years of corporate experience in assisting medical marijuana clients with: entity formation, financing, contract negotiations, sales and leasing transactions, and litigation. In her regulatory practice, Ms. Cassel has represented clients in applications, investigations, and litigation before state courts and administrative agencies. Ms. Cassel has most recently taken on pro bono clients in the area of Section 8 Housing.

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ROBERT J. DURKIN, ESQUIRE, M.S., R.Ph

Deputy Director Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA)

Bob Durkin is the Deputy Director of the Office of Dietary Supplement Programs (ODSP) in FDA's Center for Food Safety and Applied Nutrition (CFSAN). He has been in this role since July, 2016; prior to this serving as the first acting Office Director of ODSP.

Before joining ODSP, he served as Acting Director of the Food Defense and Emergency Coordination Staff (FDECS) at CFSAN. Bob joined the FDA in 2008 as a consumer safety officer with the Center for Drug Evaluation & Research's (CDER) - Office of Compliance where he worked on regulatory actions with respect to misbranded and unapproved new drugs, including compounded drugs, fraudulent drugs, marketed unapproved drugs, and over-the-counter drugs.

Prior to joining FDA, he served as a Commissioned Officer in the US Army where he completed a residency in Nuclear Pharmacy Practice at Walter Reed Army Medical Center and obtained status as Board Certified Nuclear Pharmacist.

Bob received his pharmacy degree from Philadelphia College of Pharmacy and Science, his master's degree in cell-molecular-biology from the University of Hawaii at Manoa, and his law degree from Widener University. He is licensed to practice pharmacy in Pennsylvania and Maryland and is a member of the Pennsylvania Bar.

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CHARLENE FULLMER, ESQUIRE

Deputy Chief for Affirmative Litigation, Civil Division,
United States Attorney's Office, Eastern District of Pennsylvania

Assistant United States Attorney **Charlene Keller Fullmer** is the Deputy Chief for Affirmative Litigation in the Civil Division of the United States Attorney's Office in the Eastern District of Pennsylvania, where she supervises and prosecutes health care and affirmative fraud matters. In October 2010, Attorney General Eric Holder presented her with the Attorney General Award for Exceptional Service, the Department of Justice's highest commendation.

She is a 1993 graduate of Lehigh University, cum laude, and a 1996 graduate of Temple University School of Law, cum laude, where she served on the Law Review.

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STANLEY R. MILSTEIN, Ph.D.

Former Acting Deputy Director (retired), FDA Office of Cosmetics and Colors
Milstein & Milstein Associates

STANLEY R. MILSTEIN, Ph.D., retired as Acting Deputy Director in FDA's Office of Cosmetics and Colors at the FDA Center for Food Safety and Applied Nutrition (CFSAN) in Washington, D.C. in 2017. Prior to joining the Agency in 1991, Dr. Milstein held several senior scientific and regulatory affairs positions in the R&D Division of the Andrew Jergens Co. (now KAO USA), (Cincinnati, OH).

Dr. Milstein is a Fellow of the Society of Cosmetic Chemists (SCC) and has served the SCC over the past 40 years as Chapter Chair of the "Ohio Valley" and "Mid-Atlantic" Chapters, as regional Area II and Area IV Director, and as President of the National Society (1992). He is also a 50+ Year Member of the American Chemical Society (ACS).

Dr. Milstein He has held visiting faculty appointments in general and organic chemistry in the Departments of Chemistry at Adelphi University (Garden City, NY) and the University of Cincinnati, respectively. He recently joined the faculty of the UC College of Pharmacy as Adjunct Professor, Cosmetic Science.

Dr. Milstein has addressed Cosmetic Industry Trade Association (CTFA/PCPC, ICMAD) audiences and has given presentations to foreign regulatory delegations to FDA-CFSAN and in FDA Office of Regulatory Affairs University (ORA U) courses on *Import Operations and Entry Review* (2005-2017. He is currently a member of the FDA Alumni Association (FDAAA) Activities Committee.

Dr. Milstein has published in the peer review literature of organic and medicinal chemistry, is principal co-author of two chapters on cosmetic regulation in the *Handbook of Cosmetic Science and Technology* (Marcel Dekker/ Taylor-Francis, 2001, 2006) and co-author of a chapter on the

analysis and regulatory aspects of color additives in cosmetics in *Analysis of Cosmetic Products* (Elsevier, 2007, 2018). Most recently, he has published a 3-part "blog" for SCC ("*Following the Yellow Brick Road: Introducing the QSAR Paradigm to the Cosmetic Sector*") (2019). (See, https://www.scconline.org/yellow-brick-road-p1/; p2. May 2019)

Dr. Milstein holds a B.S. degree in Biology from Rensselaer Polytechnic Institute (RPI), an M.S. degree in Pharmaceutical Sciences (Cosmetic Science) from the University of Cincinnati College of Pharmacy, and a Ph.D. in Organic Chemistry from Adelphi University (Garden City, NY). He also completed two post-doctoral research fellowships in medicinal chemistry and QSAR at Pomona College (Claremont, CA) and at the University of Cincinnati College of Pharmacy (Cincinnati, OH).

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MATTHEW R. NOONAN, JD

Compliance Officer, U.S. Food & Drug Administration,
Office of Regulatory Affairs, Human and Animal Food Division East 2

Matthew Noonan is a Compliance Officer with FDA. He follows up on potentially violative establishment inspections and pursues voluntary correction or court/administrative action as appropriate. Matt also develops and presents agency training and industry presentations, and fields industry inquiries. Matt was previously an FDA Investigator in the food, drug, and bioresearch monitoring program areas. In this capacity he performed complex inspections and provided expertise. Matt has extensive experience in the HACCP, Acidified Food, Low Acid Canned Food, Sanitation, Food Defense, and Dietary Supplement program areas. He is a member of the ORA Instructor Cadre for Preventive Controls for Human Food and the ORA Seafood Certification Board.

Matt graduated cum laude from St. Joseph's University (Philadelphia, PA) with a BS in Chemistry and a Minor in Secondary Education, and from The George Washington University Law School (Washington, DC) with a JD. He is an Assistant Professor in the Temple University School of Pharmacy, Regulatory Affairs and Quality Assurance Graduate Program.

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HOOMAN NOORCHASHM, M.D.

Cardiac Surgeon turned Patient Advocate, Philadelphia, PA

Dr. Hooman Noorchashm is a cardiothoracic surgeon in Philadelphia, Pennsylvania. He trained at Hospital of University of Pennsylvania and Harvard Medical School's Brigham and Women's Hospital. Dr. Noorchashm is a devoted patient advocate, author, speaker and father of six children.

Dr. Noorchashm met his wife, Amy Reed, in Medical School at the University of Pennsylvania. Amy was an anesthesiologist and surgical intensive care physician.

In October, 2013, Amy, underwent surgery to remove uterine fibroids through a laparoscopic procedure. The surgery involved the use of a medical device known as the Power Morcellator.

Shortly thereafter it was discovered that Amy's fibroid was, in fact cancerous. The morcellation of the fibroid caused the cancer to spread throughout her abdomen, leading to Amy's untimely death in May of 2017.

Amy's diagnosis of leiomyosarcoma served as the beginning of Amy and Hooman's extensive research on power morcellation. As a result of their research, Hooman and Amy began a quest to educate companies, lawmakers, the medical community and the public about the dangers of power morcellation. They also lead, and Hooman continues to pursue regulatory reform efforts relating to FDA approved medical devices.

Hooman and I will present to you today in an interview/conversational format. We welcome interjection of questions throughout the presentation, so please feel free to raise your hand at any time and we will address your questions.

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ROSEANN B. TERMINI, B.S., M.Ed., J.D.

Food and Drug Law Legal Scholar; National Speaker, Teaches Online FDA Law Courses, Widener University Delaware Law School

Roseann B. Termini, B.S., Ed. M., J.D. has extensive experience in food, drug, medical devices, personal care, dietary supplement, tobacco and veterinary products regulation. Ms. Termini recently published a new comprehensive edition both in print and E-book formats of *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products* (2019). She published the new edition because of evolving law, novel cases and latest regulations, a full E-book that mirrors the print, as well as 12 stand-alone separate subject specific E-books. Professional considerations, ethical issues, enforcement, criminal corporate liability and politics are covered.
See: *www.fortipublications.com*

Other publications span a broad array of topics including the right-to-request investigational therapies, corporate criminal liability, accountability, the Foreign Corrupt Practices Act, health claims, dietary supplements, product classification, duty to warn, preemption, promotion, tobacco, stem cells, risk assessment, labelling, globalization and e-cigarettes. Her works have been cited in other publications.

Ms. Termini is a featured speaker at international and national conferences and webinars including the Central Atlantic Association of Food and Drug Law Officials, the Pennsylvania Bar Institute (PBI), FDANews, the Food and Drug Law Institute and the Society of Cosmetic Chemists. She was selected to present at the Center for Ethics and Rule of Law Opioid Conference, was the sole speaker at a national opioid webinar and has been interviewed about this crisis. Ms. Termini is the faculty conference director of the annual "*All Matters FDA*" symposium at Delaware Law School, Widener University that addresses topics such as Marijuana, E-cigarettes, Food Safety, Claims, Homeopathic remedies, the Opioid Crisis, Foreign Corrupt Practices Act, Biosimilars, Dietary Supplement regulation, and Corporate Accountability. Presentations have included: *Opioids, GMOs, Personal Care Products, Medical Devices, Criminal Enforcement, Who Really Regulates Your Pizza, Are "Smart Labels" Really Smart and Terminology such as Natural and Healthy.*

Her writing expertise led her to an appellate clerkship, position as sole corporate pharmaceutical counsel, regulatory affairs attorney and senior deputy attorney general at the Pennsylvania Office of Attorney General (OAG) where she prosecuted cases at the trial and appellate levels and spearheaded the implementation procedures for the Pennsylvania Plain Language Act. She was the first recipient of the "Plain English" Award by the Pennsylvania Bar Association. Who's Who recognized Ms. Termini's excellence in the field with the Lifetime Achievement Award.

Ms. Termini has been actively involved in committees of several professional associations for several years, including her service as Chair of a Food and Drug Law Institute Committee. She is Co-Chair of the Pennsylvania Bar Assn. Health Law Committee and Vice Chair of the Disability Rights Committee. She served on the President's Council at Immaculata University and as Vice Chancellor of the Justinian Association. Ms. Termini was appointed to the Board of the St. Thomas More Law Society and is a member of the Central Atlantic Association of Food and Drug Law Officials. Her publications are available for download on the SSRN Author page link below.

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