Combiz Richard Abdolrahimi, Esq., J.D., LL.M.
Global Emerging Technology & Innovation Strategist
Senior Advisor Manager
Government & Public Services
Deloitte

Combiz Richard Abdolrahimi is a U.S. national security lawyer, a global emerging technology and innovation strategist at Deloitte, a former regulator and policymaker, and until recently, he served as a senior policy advisor at the U.S. Department of the Treasury. Combiz has 11 years of public and private sector experience and has worked with senior executives and world leaders from various industries on shaping the business, policy, legal, regulatory, and technology dimensions of Blockchain and distributed ledger technologies (DLT), artificial intelligence and machine learning, digital asset technologies and innovations including cryptocurrency and digital fiat currency, cybersecurity, RegTech, banking and financial services, payments, identity, privacy, risk management and compliance. He co-authored the first U.S. government primer on how Blockchain can enable innovation in government; the first U.S. government primer on how FinTech and emerging technologies can deliver more seamless, safe, efficient, and impactful experiences; and he has held leadership roles on professional boards and government working groups. He serves as Special Advisor & ExecSec to the Chairman of the Federal Identity Forum & Expo (FedID) – which is largest conference and expo run by the U.S. Federal Government focused on public-private outreach and collaboration-building with the worldwide identity community.

Combiz has served extensively in government since he was 19 years old; and has worked on national security, cybersecurity, technology and innovation initiatives, public policy and diplomacy, economic, legislative, regulatory and legal matters. He has also served in the U.S. Senate, The White House, and State Department, where he liaised with government officials and world leaders from over 90 countries and received commendations from Republican and Democratic leadership. Combiz is a recipient of the 2018 Rising Stars Award which recognizes the top 20 U.S. government IT's innovators and emerging leaders; a Fellow with the ALPS Leadership Program; a Fellow with Blockchain in Healthcare Global-IEEE; an editorial board member with Blockchain in Healthcare Today; and Deputy Chair of the American Council for Technology (ACT) and Industry Advisory Council (IAC) Blockchain Forum.

Born in Texas, the son of immigrants, Mr. Abdolrahimi's first job was working the cash register for his family's small business—at the age of 12. He is a graduate of UCLA; American University of Beirut; and Georgetown Law, receiving his B.A., J.D. and LL.M. in national security. Mr. Abdolrahimi speaks several languages critical to U.S. interests and aspires to follow in the footsteps of an American hero, Ambassador Col. Charles W. Hostler, USAF (ret.), and serve as a U.S. Ambassador.

Sheila Arquette is the Executive Director of the National Association of Specialty Pharmacy. She holds a Bachelor of Science degree in Pharmacy from the State University of New York at Buffalo School of Pharmacy. She has extensive practical and leadership experience in retail pharmacy, hospital pharmacy, long-term care consulting and dispensing, in addition to managed care, PBM operations and specialty pharmacy. She is a regular speaker and participant at national pharmacy conferences, roundtables and industry meetings. Sheila has recently been appointed to the University of Pittsburg's Master of Science in Pharmacy Business Administration (MSPBA) Executive Steering Board and serves as a clinical pharmacist consultant to HealthNow New York Inc. She is the host of the NASP Podcast on the Pharmacy Podcast Network.

Sheila was elected to the NASP Board of Directors and received the NASP Distinguished Service Award in September 2016. She also is a long- standing member of AMCP.

Prior joining NASP in February 2017, Sheila was the Director of Pharmacy Services at Independent Health.

Larissa C. Bergin
Partner
Jones Day

Larissa Bergin's practice addresses the antitrust concerns arising from M&A matters, joint ventures, federal investigations, and commercial practices. She has overseen the antitrust aspects of corporate M&A, including due diligence, risk-shift negotiations, Hart-Scott-Rodino (HSR) filings, Second Requests, investigational hearings, integration planning, and consent decrees with federal agencies. She works with clients in a variety of industries, including the technology, health care, retail, and pharmaceutical sectors. Many of Larissa's clients have international reach, and she has been involved in matters that require advocacy before governments throughout Asia, the EU, and North America.

Larissa also advises clients on corporate contracting and operational practices that can run afoul of the antitrust laws, including supplier agreements, information sharing, competitive benchmarking, and Robinson-Patman Act pricing matters.

At the start of her career, Larissa clerked at the U.S. Court of Federal Claims, where she addressed intellectual property, tax, and government contract issues, including Serco, Inc. v. United States (also referred to as the Alliant protest), a bid-protest case involving a $50 billion procurement for government-wide information technology and services.

Larissa is a member of the Antitrust Section of the American Bar Association and is secretary of the New York State Bar Association, Food, Drug, and Cosmetics Law Section. She is admitted in the New York, Connecticut, and District of Columbia bars.

Larissa has been quoted on MSNBC regarding how Obamacare has affected M&A activity and in Getting the Deal Through on generic drug approval.

Sharon Blinkoff

Sharon Blinkoff represents manufacturers, marketers, and distributors of cosmetics, dietary supplements, over the counter drugs, and medical devices as well as beauty appliances and other consumer products and luxury goods. She regularly advises clients on compliance with the laws enforced by the FDA, CPSC, and the FTC, and obtaining FDA registrations and 510k premarket clearances.

For many years Sharon has played a leadership role in the Cosmetics and Personal Care Industry serving on the Board of Directors and as Corporate Secretary for the Independent Cosmetic Manufacturers and Distributors (ICMAD) Trade Association. Sharon, on behalf of ICMAD, has served as part of the industry negotiating team that met with representatives of the US FDA to develop a framework for new Cosmetic legislation. She has also been an active participant on behalf of the industry, by submitting comments on FDA's proposed changes to the OTC Monograph proceedings and the proposal to require IND's for cosmetic testing, as well as other regulatory proceedings both state and federal that impact on the Cosmetic and Personal Care industry.

Having served as Division and Regulatory Counsel for Bristol-Myers Squibb/Fortis Clairol Division, as well as Senior Counsel for Revlon, Sharon brings considerable experience in representing regulated businesses on a broad range of regulatory and business matters. She also served as General Counsel to Ethan Allen Inc. and was part of the management group that restructured the company and took it public. With her broad regulatory experience and business background, She brings considerable knowledge and expertise to the challenges faced by her clients. Having spent her early career as a patent attorney for the National Institutes of Health, Sharon also brings a keen understanding of the technical side of the regulatory process and the interplay between regulatory issues and IP assets and how they relate to the client's business strategy.

Sharon has successfully defended clients in regulatory proceedings before the FDA and the FTC, and has instituted and defended clients in advertising challenges before the NAD, ERSP and the FTC as well as in Lanham Act litigations. She has also assisted in the structuring business transactions involving regulated products and industries, including corporate acquisitions and divestitures, public offerings, joint venture and distribution agreements.

Professional Affiliations and Recognitions

- Member, Bar Association of the City of New York
- Member, New York State Bar Association FDA section

- Member, American Bar Association Consumer Protection Section
- Member, the Society of Cosmetic Chemists
- Member, Board of Directors and Corporate Secretary of the Independent Cosmetic Manufacturers and Distributors Association

THOMAS COHN is Director and Senior Counsel, Sales & Marketing at New Avon LLC in New York City. Mr. Cohn graduated from Yale College and Boston University School of Law, and he was admitted to the New York State Bar in 1999.

Mr. Cohn has overall responsibility for providing legal advice regarding Avon's marketing, advertising and social media; promotions, sweepstakes and contests; sales, merchandising and pricing. In addition, he works closely with marketing colleagues and is responsible for claim substantiation and challenges, product labeling review, promotions/sweepstakes/contests, contract drafting and advertising review, including TV, print, brochure, and online/digital marketing. He also advises on product innovation, pricing and other merchandising matters, as well as ensuring compliance with regulatory requirements, including the FTC, FDA and other federal and state regulatory agencies.

Mr. Cohn also provides legal support in the area of intellectual property, including managing trademarks, such as clearance, prosecution, registration, portfolio management, as well as licensing for the product lines and advising on day-to-day trademark matters, domain names, copyrights, rights of publicity, and patents, as needed. He also works with the sales and commercial teams, including advising on regulatory issues, such as FTC/state law compliance regarding multi-level marketing, earnings opportunity, and incentive programs.

Mr. Cohn coordinates Avon's governmental affairs, working with national trade associations such as ICMAD, DSA and CRN, and serves on the task force creating DSA's new self-regulatory program with the Council of Better Business Bureaus. He is a former Northeast Regional Director of the Federal Trade Commission. Mr. Cohn is also a regular speaker and commentator at consumer law seminars and conferences.

Colleen Heisey
Partner
Jones Day

Colleen Heisey's practice focuses on food and drug law with a particular emphasis on product promotion and advertising, compliance counseling, good manufacturing practice requirements, product recalls, FDA inspection, competitor issues, and enforcement actions. She has advised on issues surrounding the regulation of drug, biological, food, dietary supplement, medical device, and cosmetic products by the FDA, USDA, and other federal and state agencies.

Colleen has substantial experience with regulatory oversight and compliance assessment for due diligence audits of drug, medical device, and food companies, including those related to product safety, product labeling, product marketing and advertising, and consumer complaints. She regularly provides legal support for pharmaceutical and device advertising and promotional activities, sales and marketing, and development of practitioner-oriented and direct-to-consumer print and broadcast advertising. Colleen has conducted audits and inspections of pharmaceutical and medical device company policies, procedures, and programs, including drug sampling, adverse event reporting, medical information management, and unsolicited requests. She has advised clients regarding matters related to the False Claims Act and Anti-Kickback Statute, reviewed and commented on strength of clinical trial designs in drug and device development and as potential support of product marketing, and has assessed proposed brand names for drug products in development for potential claims and product confusion, including appraisal of drug name similarity reports by third-party vendors. She has worked with regulated industry to develop and implement comprehensive regulatory compliance programs.

Colleen has written extensively on the food and drug industry.

MINTZ

Bethany J. Hills

Member / Chair, FDA Practice

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New York

https://www.linkedin.com/in/hillsbethany

EDUCATION

- State University of New York - Buffalo (MPH)
- State University of New York - Buffalo (JD, cum laude)
- State University of New York - Geneseo (BA, summa cum laude)

ADMISSIONS

- New York

Bethany is nationally recognized for her experience and insight on FDA matters and advises businesses on both pre- and post-market issues, including everything from FDA submissions and communications strategies to post-approval compliance. Bethany also helps international and US companies enter and navigate the US health care market. She's adept at helping clients identify technologies that are likely to complement the health care delivery system, clear FDA regulatory hurdles, *and* provide a healthy return on investment. She also has an exceptional understanding of health care reimbursement issues.

Bethany is Chair of the firm's FDA practice and leverages deep FDA regulatory experience and exceptional knowledge of the health care delivery system to help international and domestic health technology companies enter and navigate the US health care market. Bethany helps companies manage the full range of FDA regulation issues, from inspections and investigations through complex regulatory challenges affecting everything from product approvals and product labeling to collaborative research, supply, and distribution agreements. She focuses on mission critical strategic engagements, including all aspects of FDA communications. Her client engagements regularly span the full scope of pre-market and post-market issues, from devising unique regulatory strategies that are then implemented through FDA submissions and complex interactions with the FDA, including post-approval compliance and enforcement. Bethany's representative clients include medical device, drug, combination product, diagnostic, biologic and regenerative medicine, cosmetic, dietary supplement and food industry companies.

Through her extensive representation of health care provider businesses, she has developed an understanding of compliance issues and of the US health care reimbursement system that far surpasses that of most FDA lawyers. She uses her strengths in these areas to provide clients with insight on regulatory policy, reimbursement issues, and pricing to shape innovation, and helps them use that knowledge to develop viable value propositions within the constraints of the evolving health care delivery system. She advises clients on laws applying to referral relationships, clinical trial compliance, licensure, and security and privacy issues as well as on the ins and outs of government and third-party reimbursement. Clients rely on Bethany's practical guidance to help them invest and collaborate strategically, by identifying technologies that are likely to complement the health care delivery system, clear FDA regulatory hurdles, *and* provide a healthy return on investment.

Before joining Mintz, Bethany served as the co-leader of the FDA and medical technology services team in the New York office of another law firm. She works with academic centers to educate future business leaders on relevant health care regulatory issues, and is frequently invited to speak on issues concerning FDA regulations, health care reimbursement, and pricing.

Recognition & Awards

- Lexology and the ILO: Client Choice Award
- Included on the New York Super Lawyers Rising Star: Food & Drugs, Health Care, and Technology Transactions lists (2015 - 2018)
- Chambers USA: "Up-and-Coming" lawyer, New York Healthcare category (2012 ? 2014)
- American Bar Association and Bureau of National Affairs: Excellence in Health Law (2005)
- Recognized by The Legal 500 United States for Healthcare: Service Providers (2017)
- Environment and Society Institute, Lester Milbrath fellowship

Involvements

- Member, executive committee, Food, Drug, and Cosmetic Law Section, New York State Bar Association

- Member, Editorial Advisory Board, BNA Medical Devices Law & Industry Report
- Member, Regulatory Affairs Professional Society
- Member, American Health Lawyers Association
- Appointed Member, New York State Bar's Committee on Cannabis Law
- Executive committee, Kevin Guest House for Patient Families, Buffalo, NY (until 2012)
- Board of directors, MedTech (2014 ? 2015)
- Board of directors, NY Data Protection Review Board (2010 ? 2013)

Experience

- Provided strategic counsel to a start-up medical application company that has devised a method to detect mild cognitive impairment as a precursor to more significant cognitive diseases.
- Represent a national IVF clinic and management provider in drug delivery, pharmacy relationships, and delivery of care issues.
- Counseled a cosmetic company on its response to an FDA Warning Letter related to the use of drug claims to promote cosmetic products and assisted in the company's implementation of internal processes and procedures to avoid similar issues in the future.
- Assisted multiple pharmacy clients in determining whether to register with FDA as an Outsourcing Facility and advised them regarding the establishment of such operations.
- Advise innovative drug development client on regulatory strategy following Phase II clinical study data analysis.
- Advise a food manufacturing company on multiple product line contract manufacturing arrangements and negotiated supply and quality agreements.
- Analyzed the impact of proposed Medicare National Coverage Decision on an integrated FDA and reimbursement strategy for a next generation sequencing cancer test and drafted comments to CMS.
- Guided a medical device manufacturer through multiple FDA inspections and developed effective and sustainable corrective actions to address deficiencies and avoid focused FDA enforcement.
- Participated in marketing and labeling pre-launch team, working side by side with biological client team to craft marketing messages and product labeling for product launch.
- Provided legal and regulatory advice to consumer app software collecting symptoms and providing guidance on possible next steps, including commercial agreements and new feature development.
- Conducted a regulatory assessment and classification of software product used to support monitoring and management of patients with chronic obstructive pulmonary disorder.
- Advised on legal and regulatory issues surrounding market launch of a software solution to gather patient data from peripheral devices and coordinate a communication and management platform with their physician, including licensing arrangements, clinical study agreements, and quality and supply agreements.

Practices

- **Consumer Product Safety**
- **FDA Regulatory**
- **Clinical Trials & Research**
- **Health Care Compliance, Fraud & Abuse, and Regulatory Counseling**
- **Medicare, Medicaid & Commerical Coverage & Reimbursement**
- **Health Care Enforcement & Investigations**
- **Health Care Transactional Due Diligence**
- **Israel**

Industries

- **Health Care**
- **Life Sciences**
- **PBMs & Pharmacies**
- **Digital Health**
- **Laboratories**
- **Diagnostics**
- **Hospitals & Health Systems**
- **MedTech, Tools & Devices**
- **Biosimilars**
- **Artificial Intelligence**

News & Press

FDA Focus: What Mintz's Practice Chair Is Watching
October 2, 2018 | **Law360**

Device Experts: Expanded Special 510(k) Good For Software, Review Times
October 2, 2018 | **Inside Health Policy**

Twenty-Four Mintz Attorneys Named 2018 New York Super Lawyers and Rising Stars
September 19, 2018

Device Lawyer: Guidance Shows FDA OK With More Premarket Risk
September 6, 2018 | **Inside Health Policy**

Industry Attorneys: New Pre-Cert Model Vague On Requirement Details
June 21, 2018 | **Inside Health Policy**

Artificial intelligence is evolving fast. Can the FDA keep up?
May 25, 2018 | **STAT News**

Medical device recalls reach historic levels in 2018 with software as leading cause
May 9, 2018 | **FierceHealthcare**

Expanded 510(k) Option Doesn't Quell Industry Skepticism Over Pathway
April 20, 2018 | **Inside Health Policy**

FDA medical device proposal may skirt the law: legal experts
December 19, 2017 | **Reuters**

FDA proposal on health software provides no clarity on artificial intelligence
December 8, 2017 | **STAT News**

After a 6-year wait, FDA’s clinical decision support guidelines get a mixed reaction
December 7, 2017 | **FierceHealthcare**

Twenty-Seven Mintz Attorneys Named 2017 New York Super Lawyers and Rising Stars
September 20, 2017

Mintz Attorneys and Practice Areas Recognized By 2017 Legal 500 Guide
August 17, 2017

9 companies will play a huge role in shaping the FDA’s novel approach to digital health
August 2, 2017 | **FierceHealthcare**

FDA unveils precertification pilot program for digital health technology, maps out upcoming guidance
July 28, 2017 | **FierceHealthcare**

“Will a New FDA User Fee Discourage Medical Device Innovation?”
June 12, 2017

Trump’s Budget Would Add $313M to Medical Device User Fees, but Congress is Unlikely to Follow Through
May 25, 2017

3 Ways Trump’s FDA Nominee Could Reshape Digital Health
March 16, 2017

New FDA Enforcement Stats Show Shifting Targets
February 13, 2017

High Expectations During the Trump Administration
January 23, 2017 | **New York Law Journal**

21st Century Cures Act & Real World Evidence: Device Policy as Foundation
January 23, 2017

The FDA targeted DTC, video, unapproved drug promotion in 2016
January 18, 2017

Health Care Enforcement Review And 2017 Outlook: Part 1
January 13, 2017

Attorney: Combo Review Issues Signal Hurdles For FDA Intercenter Institutes
December 16, 2016 | **Inside Health Policy**

Cures Exempts Some Medical Software; More Clarity Needed, Attorneys Say
December 15, 2016 | **Inside Health Policy**

Senate passes landmark 21st Century Cures, sending legislation to Obama
December 7, 2016 | **STAT News**

Twenty-Eight Mintz Attorneys Named 2016 New York Super Lawyers and Rising Stars
September 21, 2016

Questions Of Culpability After 8th Circ. Egg Exec Decision
August 1, 2016

Akin Gump Health Leader Heads In-House, Plus More Lateral Moves
March 22, 2016

Movers & Shakers: Pamplona Recruits Pacala For Healthcare Investments
March 15, 2016

Mintz Bolsters Health Law Practice in New York with Addition of Bethany Hills and Benjamin Zegarelli
March 07, 2016

Events

//
Nov 1 2018
2018 Technology in Psychiatry Summit: Closing Gaps in Translation
De-Risking Digital Development: Innovations in Substance Use Disorder Treatment

Boston, MA

// SPEAKER
Oct 10 2018
Retail Industry Leaders Association (RILA) Retail Law Conference
Austin, Texas

// SPEAKER
Jul 18 2018
Rare Disease Symposium
Westchester Biotech Project

New York, NY

// MODERATOR
Jun 1 2018
6th Annual World Life Sciences Conference
International Bar Association

InterContinental Boston 510 Atlantic Avenue Boston, MA 02210

// MODERATOR
Mar 29 2018
Risks and Rewards of Accelerated FDA Pathways
Mintz Levin

Boston, MA

// PANELIST
Mar 11 2018
BPIP 6th Annual Conference
Best Practices in Intellectual Property

Sheraton Tel Aviv Tel Aviv, Israel

// SPEAKER
Feb 15 2018
Part III: The Impact of Cures on the FDA
Webinar

// MODERATOR
Feb 7 2018
Conducting Multi-Jurisdictional Trials: Understanding Changes in the US and EU Part II
Webinar

// SPEAKER
Jan 24 2018
Part I - Multi-Jurisdictional Clinical Trials: Understanding Changes in the US and EU
Webinar

// MODERATOR
Nov 21 2017
IP Course: Medical Device Regulatory Lecture
New York, NY

// PANELIST
Nov 16 2017
Digital Health - Regulatory Process Panel
New York, NY

// MODERATOR
Nov 14 2017
IP Course: Therapeutics-focused Regulatory Lecture
New York, NY

// PANELIST
May 24 2017
ATA 2017

// PANELIST
May 11 2017
The NewYorkBIO 2017 Annual Conference
New York, NY

// FACULTY
Feb 10 2017
Trump's First 100 Days, Part IV: AMCs, Life Sciences, Pharma, and Medical Device Companies
AHLA

Webinar

// SPEAKER
Jan 26 2017
Food, Drug & Cosmetic Law Section Meeting
New York State Bar Association

New York, NY

// SPEAKER
Jan 24 2017
FDA in 2017: What to Expect?
New York, NY

// PANELIST
Jan 18 2017
Impact of the Cures Act on the Medical Device Industry
MassMEDIC

Webinar

// SPEAKER
Jan 12 2017

Part I: Introduction to the 21st Century Cures Act
Webinar

// SPEAKER
Nov 8 2016
Icahn School of Medicine at Mount Sinai Program
ISMMS

// SPEAKER
Oct 21 2016
Critical Path Life Sciences Accelerator Program
University at Buffalo Technology Incubator

// SPEAKER
Sep 29 2016
Medical Device Reimbursement 201 Workshop
AdvaMed

Washington, DC

// PANELIST
Sep 22 2016
Mobile Medical Applications: Navigating Regulatory, Profitability, and Patentability
Boston, MA

// PANELIST
Sep 19 2016
2016 RAPS Annual Meeting

Aaron L. Josephson

Senior Director
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Aaron is based in our Washington, DC office and is a Senior Director of ML Strategies. He advises clients on health care policy issues related to medical devices and pharmaceuticals.

Prior to joining ML Strategies, Aaron spent 10 years with the US Food and Drug Administration, most recently as a senior policy advisor in the Center for Devices and Radiological Health where he led legislative policy development activities related to all aspects of medical device regulation and oversight. He also apprised members of Congress and their staffs about FDA policies and programs and advised multiple FDA Commissioners and other senior officials on strategy and content for meetings with Congress, industry representatives, and other stakeholders. In addition to negotiating the reauthorization of the medical device user fee program (MDUFA), Aaron led FDA's implementation of key provisions of the 21st Century Cures Act and the FDA Reauthorization Act.

Earlier, Aaron was a budget analyst in the FDA's Center for Drug Evaluation and Research, where he developed the center's annual budget and provided information to the Congressional Budget Office (CBO) and congressional authorizers. He began his FDA career in the Center for Biologics Evaluation and Research as an information management specialist responsible for data analyses to support FDA policies and programs.

During his tenure with the FDA, Aaron won numerous agency awards, including the Lireka P. Joseph Award for Excellence in Public Health Communication or Education. He also received special recognition from multiple FDA Commissioners, including a June 2017 special citation for outstanding and sustained performance in the negotiation and reauthorization of MDUFA IV and an August 2016 award for contributions to the 21st Century Cures Act.

Aaron earned a master's certificate in project management from the George Washington University School of Business and is certified by the American Society for Quality as a quality improvement associate.

EDUCATION

- Johns Hopkins University (MS)
- University of Virginia (BA)

Ron Lanton III, Esq., has over 25 years of experience in government affairs at the municipal, state, and federal government levels, with 15 years dedicated to the healthcare sector. He is currently the executive director and head lobbyist at Frier Levitt Government Affairs, LLC and senior counsel at Frier Levitt. He frequently consults Wall Street firms on financial issues related to the healthcare sector.

Lanton is a featured industry speaker on issues such as pharmaceutical safety and healthcare cost containment, and he has authored numerous articles regarding pharmacy and healthcare law. He earned a B.A. from Miami University and a J.D. from The Ohio State University. He is also the chair of the Biologics Committee for the New York Bar Association.

Janet B. Linn

Janet B. Linn is intellectual property litigator at Tarter Krinsky & Drogin, with more than 25 years' experience ligating patent, trademark, unfair competition, trade secret and copyright cases, as well as advising on patent prosecution, and providing patent validity and infringement opinions, in a broad range of technologies including pharmaceuticals, medical devices, consumer products and mechanical devices. She has extensive experience in pharmaceutical patent litigation, representing both branded and generic companies, and has acted as trial counsel in patent (Hatch-Waxman), trade secret and antitrust litigation involving pharmaceuticals with annual billion dollar sales.

Active in the profession, Ms. Linn is a member and former Chair of the Patents Committee of Association of the Bar of the City of New York, the current Vice Chair of the Food Drug & Cosmetic Section of the New York State Bar Association, a member of Women in Licensing, and a frequent author and lecturer on intellectual property issues

Brian Malkin

Brian is an attorney in Arent Fox's FDA, Intellectual Property, and Health Care Groups. Brian has more than 24 years of food and drug law practice and over 13 years of intellectual property law practice. In particular, his practice includes the interrelation between patent law and food and drug law. Brian's regulatory experience includes all types of FDA-regulated products: drugs (including animal drugs), biologics, medical devices, foods and dietary supplements, tobacco products, and cosmetics. Brian's intellectual property experience includes FDA and patent litigation for both innovator and generic companies. Brian began his legal career as a regulatory counsel at the U.S. Food and Drug Administration, where he worked for more than nine years in both the Office of the Commissioner and the Center for Drug Evaluation and Research. At FDA he focused on new product evaluations, compliance issues related to clinical investigations and intellectual property (e.g., patent term restoration), and Brian also was an agency liaison for the Institute of Medicine. Brian's work resulted in new product approvals as well as new industry guidance documents and policies, such as the animal efficacy rule for counter-terrorism products. Following several years of practice in an FDA law firm, Brian recognized an unmet need to understand both food and drug and intellectual property law for life cycle management and diligence, particularly concerning products affected by the Hatch-Waxman Act such as generic and 505(b)(2) new drug applications. As a result, Brian returned to university to obtain a Bachelor of Science degree in biochemistry. Prior to joining Arent Fox, Brian practiced for more than nine years at an intellectual property law firm, where he worked on a variety of new product evaluations, FDA and patent litigations, due diligence projects, patent prosecutions, and licensing and commercial transactions and has also led an FDA Group at an international law firm for nearly three years.

Lesley R. Maloney

Lesley R. Maloney, Pharm.D., is Head, U.S. Regulatory Policy for Roche Diagnostics. In that role, she is responsible for guiding Roche Diagnostics' regulatory policy efforts in the United States. In addition, she is also responsible for specific regulatory policy efforts related to digital health, including Roche's involvement in the FDA Software Precertification Pilot Program. Dr. Maloney joined Roche Diagnostics in 2017. Prior to joining Roche Diagnostics, she worked for the U.S. Food and Drug Administration in the Office of the Commissioner, where she served in various roles, including Deputy Chief of Staff, Senior Policy Advisor, and Deputy Associate Commissioner for External Affairs. While at the FDA, Dr. Maloney worked on such medical product policy issues as the 21st Century Cures Act legislation, improvements related to combination product oversight, and development of a new regulatory framework for over-the-counter medications. Dr. Maloney also has experience in the pharmaceutical industry, a quality improvement organization, and a national pharmacist association. Dr. Maloney holds a doctor of pharmacy degree from the University of Oklahoma and did an Executive Residency in Association Leadership and Management at the American Society of Health-Systems Pharmacists.

Victoria J. Maniatis graduated with a BA from the Pennsylvania State University in 1990, a J.D. from Hofstra University School of Law in 1993 and has been admitted to practice law in New York and New Jersey since 1994. During law School, Ms. Maniatis interned for two summers with the Middlesex County Prosecutor's office. Once admitted, she started practicing as a general negligence defense attorney, before transitioning into the field of Plaintiffs' Mass Tort in 1998 at Kreindler & Kreindler litigating Aviation disasters. Currently she is a partner at Sanders Phillips Grossman where she works on mass tort cases involving pharmaceuticals and medical devices, the field she has worked in for seventeen years. She is a frequent invited lecturer and moderator on a wide variety of pharmaceutical and mass tort cases including, Opioids, Trans Vaginal Mesh, Fosamax, Ortho Evra, Risperdal, Propecia, Avandia, Onglyza, as well as several medical devices. She has also published articles on pharmaceuticals and vaccines. She currently serves on her firm's Opioids Task Force educating lawyers and municipalities about the epidemic. Ms. Maniatis has been appointed by State and Federal Judges to serve as lead counsel and on Plaintiffs' steering committees. She currently acts as lead counsel in the New Jersey Propecia Multi County Litigation. She also serves on the Fosamax Femur PSC (DNJ), the Transvaginal Mesh MDL PSC's in the Bard, Boston Scientific, American Medical Systems and Ethicon cases (DWV), the Benicar MDL PSC (DNJ) as well as the Talcum Powder MDL PSC (DNJ). Vicki has also regularly performs common benefit work outside her PSC appointments.

Vicki performs all levels of bellwether trial case specific work up including, plaintiff, spouse and family member depositions, implanting, explanting, treating physicians, sales representative and expert depositions, for over 30 cases in several mass torts including TVM, Mirena and Propecia cases.

Vicki has taken part in researching, meeting, retaining, working with experts for depositions and all levels of preparation in several litigations she has worked on and can provide additional information in this regard (subject to strategy and attorney work product).

Vicki has participated in focus group/mock trial scenarios for medical malpractice, aviation disasters, and pharmaceutical cases. She has presented as counsel and witnesses for Plaintiff and defense in Mock trials, and focus groups.

Vicki has been recognized as a Top Attorney of the NY Metro Area and Top Woman Attorney in the NY Metro Area (2013 to date). She is an active participant in the American Association for Justice (AAJ), New Jersey Association for Justice and New York State Trial Lawyers Association (NYSTLA). Ms. Maniatis serves as a founding member of Mass Tort Med School, an annual medical seminar for Plaintiffs' attorneys that offers numerous physician speakers and cutting edge medical issues. She previously served as a committee co-chair for the Women En Mass group. Ms. Maniatis in an active runner and triathlete having completed Marathons, half iron and full Ironman races. She also serves as an Advisory Council Member to the Academy for Biotechnology of the Morris County Vocational School District & Mountain Lakes HS.

A Partner with Dalimonte Rueb LLP, Jennifer Orendi currently contributes several years of experience in law and science to serve individuals adversely affected by dangerous products, including pharmaceuticals and medical devices. Her background in neuroscience research, understanding of neurologic injuries, and laboratory experience prior to law school compliment her aptitude for helping to build cases based upon scientific data and analyses. Prior to law school, Ms. Orendi graduated with honors from Carnegie Mellon University, where she was awarded one of the first undergraduate fellowships by the National Institute of Mental Health (NIMH). She continued her research at laboratories at the University of Pittsburgh Medical Center (UPMC) and at the University of Wisconsin, and then attended Illinois Institute of Technology's Chicago-Kent College of Law, where she earned her Juris Doctor degree with a Certificate in Intellectual Property Law.

Ms. Orendi has managed and litigated hundreds of individual pharmaceutical and medical device product liability cases from intake to resolution and has contributed her passion for science and medicine to several Federal Multi District Litigations (MDLs), including Fen-Phen, Phenylpropanolamine Products, Zyprexa, Vioxx, Ortho Evra, and Pradaxa. She enjoys applying her knowledge of medical facts and prognoses toward the negotiation of claims to help the injured move forward. She is especially interested in legal issues regarding OTC and cosmetic products marketed and sold specifically to women and girls, and in injuries based in neurologic, endocrine and psychiatric manifestations.

Ms. Orendi leads Dalimonte Rueb's efforts on behalf of injured women in the Talc, Taxotere, and Mirena litigations, and was appointed to the Plaintiffs' Steering Committee in *In Re: Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II),* MDL No. 2767 (Southern District of New York). Before joining Dalimonte Rueb LLP, Ms. Orendi worked on behalf of injured individuals at a nationally-acclaimed law firm, and for a large law firm specializing in food and drug regulatory law, both in Washington, DC. Having completed the program at The Aveda Institute in Washington, DC, Ms. Orendi is also a licensed Cosmetologist.

Kelly Ryan

Kelly Ryan is Senior Director, State Advocacy at PhRMA and provides policy support for New York, Maine, Vermont, New Hampshire, Connecticut, and Rhode Island. Prior to joining PhRMA, Kelly served as Senior Associate General Counsel/Director of Regulatory Affairs at United Healthcare, where she provided regulatory counsel for commercial lines of business in the New York market, and was a Principal in Hinman Straub's Health Law and Government Relations practice groups. While at Hinman Straub, Kelly was a key member of PhRMA's New York team for several years and developed an expertise in a range of health and biotech issues through her representation of stakeholders including health insurers, medical schools and research facilities. She also previously served as legislative counsel to NY State Senator Martin Golden. Kelly is a graduate of Russell Sage College and the Ohio State University School of Law. She is a member of the New York State Bar.

Bruce S. Weintraub

Bruce S. Weintraub is Senior Corporate Counsel in the Legal Division at Pfizer Inc in New York, NY. He is a Core Negotiator for the Global IP Transactions Team at Pfizer Inc. This Team supports Worldwide Business Development, Worldwide Research & Development and Strategic Alliances at Pfizer Inc. Prior to this position, Mr. Weintraub managed patent licensing, R&D collaboration agreements, acquisitions and due diligence for the Pfizer Animal Health division. He graduated from Benjamin N. Cardozo School of Law and is admitted to practice in New York. Mr. Weintraub is a regular speaker and commentator at businessjseminars and conferences.

Howard A. Zucker, M.D., J.D.

Dr. Howard A. Zucker is Commissioner of Health for New York State. As the state's chief physician, Dr. Zucker leads initiatives to combat the opioids crisis, strengthen environmental health and end the AIDS epidemic in New York. Since his arrival at the helm of the NYS Department of Health, he has established a network of hospitals equipped to treat Ebola, implemented programs to address the threat of Zika and spearheaded efforts to combat antimicrobial resistance.

Dr. Zucker oversaw the launch of the state's medical marijuana program and continues to update the program to accommodate evolving needs. He also developed numerous campaigns to address major public health issues, including lead contamination, legionella and breast cancer screenings. His extensive review of scientific literature led the state to reject hydrofracking in its borders.

As Commissioner, Dr. Zucker presides over the state's Medicaid program, the New York State Public Health and Health Planning Council, and the Wadsworth Center, New York's premier public health lab. He also oversees the entire health care workforce, as well as health care facilities, including hospitals, long-term care and nursing homes.

In his previous role as first deputy commissioner, Dr. Zucker worked on the state Department of Health's preparedness and response initiatives in natural disasters and emergencies. He collaborated closely with the New York City Department of Health and Mental Hygiene and other health-related entities in the city.

A native of the Bronx, Dr. Zucker earned his M.D. from George Washington University School of Medicine at age 22, becoming one of America's youngest doctors. He is board-certified in six specialties/subspecialties and trained in pediatrics at Johns Hopkins Hospital, anesthesiology at the Hospital of the University of Pennsylvania, pediatric critical care medicine/pediatric anesthesiology at The Children's Hospital of Philadelphia, and pediatric cardiology at Children's Hospital Boston/Harvard Medical School.

Before joining the state Department of Health in September 2013, Dr. Zucker was a professor of clinical anesthesiology at Albert Einstein College of Medicine of Yeshiva University and pediatric cardiac anesthesiologist at Montefiore Medical Center in the Bronx. He was an adjunct professor at Georgetown University Law School, where he taught biosecurity law.

His vast experience in public policy began as a White House Fellow under then-Health and Human Services Secretary Tommy Thompson. Subsequently he became the Deputy Assistant Secretary of Health where he developed the nation's Medical Reserve Corps, which today is run by the U.S. Surgeon General and includes more than 200,000 volunteers across nearly 1000 programs. He also worked on the development of the initial SARS preparedness plan, the anthrax crisis, and the National Institutes of Health autism summit, and led a multidisciplinary team on the issue of tissue engineering/regenerative medicine. Dr. Zucker advanced his public policy experience while serving as an Institute of Politics Resident Fellow at Harvard Kennedy School and later as a Presidential Leadership Scholar.

Dr. Zucker is recognized internationally for his work to advance global health. As senior advisor in the Division of Global Health and Human Rights at Massachusetts General Hospital, he leads a team of experts in developing a community peace index, a research initiative aimed at identifying the effectiveness of peace intervention programs in countries impacted by war, political strife and economic instability.

Previously, he served as Assistant Director-General of the World Health Organization (WHO) in charge of the Health Technology & Pharmaceuticals cluster. In this capacity, Dr. Zucker was the highest ranked American at the WHO and spearheaded efforts to globally combat counterfeit medicines as well as address the interface between intellectual property rights, innovation and public health. He is also a member of the Council on Foreign Relations, Council for Emerging National Security Affairs, and was a "high-level expert" on public health for NATO.

While working on a public-private partnership with an educational technology company, he developed The Afghan Family Health Book, a health literacy project that has educated millions of women in Afghanistan. Dr. Zucker has traveled to China and Haiti on medical missions and spoken extensively throughout the United States on national health policy issues as well as internationally on global health challenges.

Dr. Zucker served as associate professor of clinical pediatrics and anesthesiology at Columbia University College of Physicians & Surgeons and pediatric director of the ICU at New York Presbyterian Hospital, where he launched the restructuring of the critical care complex both from a clinical care delivery standpoint as well as the physical environment. He has held academic appointments at Yale University School of Medicine and the National Institutes of Health, and as a research affiliate in the Center for Space Research at the Massachusetts Institute of Technology.

Dr. Zucker received his B.S. degree from McGill University. As a student at McGill, he helped design zero-gravity medical experiments that ultimately were conducted aboard several Space Shuttle missions. Today, he serves on the Board of Directors of the nongovernmental organization that oversees the U.S. National Lab on the International Space Station.

Dr. Zucker holds a J.D. from Fordham University Law School, a LL.M. from Columbia Law School and a postgraduate diploma from the London School of Hygiene and Tropical Medicine. He holds an honorary Doctor of Science from the Icahn School of Medicine at Mount Sinai and an honorary Doctor of Humane Letters from the Albany College of Pharmacy and Health Sciences. A former ABC World News' Person of the Week and Columbia University Pediatrics Teacher of the Year, Dr. Zucker has been listed in Best Doctors in America as well as Who's Who in the World. He is a member of the medical honor society, Alpha Omega Alpha, and the Bar of the U.S. Supreme Court.