

Sheppard Mullin Expands Life Sciences Team With FDA Regulatory Group

Group Brings Sophisticated FDA Regulatory Compliance Experience in Pharma, Biotech and Medical Device Sectors

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Sheppard, Mullin, Richter & Hampton LLP is pleased to announce that a five-person team, led by partner Scott S. Liebman, has joined the firm's Life Sciences and FDA Regulatory industry teams. Liebman was most recently a partner at Loeb & Loeb LLP where he chaired the firm's FDA Regulatory & Compliance practice and co-chaired its Life Sciences practice. Based in New York, Liebman will serve as co-leader of Sheppard Mullin's Life Sciences team, as well as the FDA Regulatory team. Also joining Liebman from Loeb & Loeb are partner Dominick P. DiSabatino (who will be based in Washington, D.C.), special counsel Eve Costopoulos, associate Alexandra Kitson, and regulatory and compliance specialist Jeremiah Miah (all of whom will be based in New York).

"Adding leading and sophisticated practitioners like Scott, Dom, Eve, Alex and Jeremiah is part of our strategic drive to augment the firm's life sciences capabilities," said Sheppard Mullin chair Luca Salvi. "This group's deep understanding of the FDA will be incredibly valuable to our pharmaceutical, biotech, medical device and cosmetics clients. We're thrilled to add them to our life sciences and FDA regulatory practices."

"Sheppard Mullin is a natural and strategic fit for my clients and team. The firm's vision, growth and energy align perfectly with my practice," said Liebman. "In so many ways, our team supplements Sheppard Mullin's already strong life sciences and FDA regulatory practices and works synergistically with other practices throughout the firm. All around, we are very excited to be here."

The addition of Liebman and his team follows on the recent Life Sciences team hires that include partner Martin Bruehs and his team, including special counsel Rajesh Noronha and Gary Mangels, Ph.D., and associates James Turner, Ph.D. and Ying-Hua (Betty) Sun, M.S. in Washington, D.C.; and partner Jing Liu, Ph.D. and her team, including associates Paul Chang, Ph.D. and Marc Chatenay-Lapointe, Ph.D. in Del Mar.

Allison Fulton, co-leader of Sheppard Mullin's Life Sciences and FDA Regulatory teams, added, "Scott and his team's proven ability to help clients resolve FDA challenges and effectively navigate the increasingly complex regulatory environment will be an enormous asset to our national and international life sciences clients. The group's broad technical knowledge combined with their creative problem-solving make them an ideal fit for our collaborative culture."

Liebman focuses on complex FDA regulatory, compliance and legal matters affecting global pharmaceutical, biotechnology, medical device and cosmetic manufacturers. He counsels clients on federal and state requirements and develops legal and regulatory strategies to help commercialize their products. Liebman

supports clients through sophisticated product launches; implements corporate integrity agreements; develops comprehensive training and compliance programs; and handles anti-kickback, sampling and off-label investigations. He works with small life sciences organizations launching their first product to Fortune 500 companies in the pharmaceutical and medical products/equipment industries. Liebman received his B.A., *with high honors*, from Lehigh University and his J.D. from Seton Hall University Law School.

DiSabatino focuses on complex FDA and healthcare regulatory, compliance and legal matters in the life sciences industry. Drawing from in-house secondments with clients of various growth stages, DiSabatino offers clients a deep knowledge of advertising and promotion of FDA-regulated products, organizational OIG compliance programs, labeling review and approval strategies, managed markets and payer interactions and privacy/data security concerns. He also advises on matters regarding commercial contracting and supply chain logistics, clinical trial agreements, federal transparency obligations and interactions with FDA such as post-market adverse event and product complaint reporting, facility inspections and Form 483s. DiSabatino received his B.S. from Bucknell University and his J.D., *with honors*, from George Washington University Law School.

Costopoulos focuses on managing complex legal, compliance and ethics issues in the life sciences industry. She has held senior executive positions at several life sciences companies and has extensive experience developing, implementing and managing compliance activities, including corporate internal audit programs. She has significant experience in key risk areas facing life sciences companies, including fraud and abuse, FDA regulatory and commercial transactions. She received her B.A. from Rutgers University and her J.D. from Seton Hall University School of Law, where she was associate editor of the *Seton Hall Law Review*.

Kitson advises clients in the pharmaceutical and medical device industries on FDA regulatory and compliance issues, as well as compliance issues at the state level and regulatory due diligence in transactions. She also has experience counseling clients on state licensure issues, advertising and promotion, transparency reporting, state and federal fraud and abuse issues, and pharmaceutical sampling programs. Prior to practicing law, Kitson was a Legislative Assistant for Congressman Dave Loebsack (Ret.) of Iowa. She received her B.A. from Cornell College and J.D. from Cornell Law School.

Miah focuses his practice on life sciences compliance and regulatory issues relating to marketing and commercial interactions with healthcare professionals. He supports life sciences companies to ensure compliance with standard operating procedures, state and federal laws and industry guidelines. Miah also has extensive experience advising clients with on federal and state transparency disclosure requirements ("Sunshine Act") including project management, preparation and submission of applicable disclosure projects and reports. He received his B.A. from Binghamton University.

About Sheppard Mullin's Life Sciences Industry Team

Sheppard Mullin's Life Sciences industry team helps promising startups, publicly held multinational corporations, research institutions and investors protect and leverage intellectual property; raise and deploy capital; structure mergers, acquisitions, strategic alliances, joint ventures, spin-offs; and navigate complex regulatory issues. We also work with our life sciences clients as they access the capital markets through initial public offerings or private placements and consult with them on corporate governance and SEC compliance issues. In an industry where partnerships and collaborations are on the rise and there is pressure to produce results, we work hand-in-hand with our clients in their drive for success and profitability.

About Sheppard Mullin's FDA Regulatory Team

Sheppard Mullin attorneys counsel clients whose activities are regulated by the U.S. Food and Drug Administration (FDA). We represent companies across an array of industries—pharmaceutical, biologic, biotechnology, medical devices and digital health, food and beverage, dietary supplements, and cosmetics—on matters spanning the entire product lifecycle, from concept to commercialization. We bring an innovative and business-oriented approach to resolving complex legal and regulatory issues that complements our clients' cutting-edge technologies and novel products. Our attorneys also provide advice on comprehensive compliance programs and risk management strategies, advertising and promotional rules, product labeling, FDA exclusivity, industry guidances, licensing transactions, and regulatory enforcement actions, including DOJ investigations and corporate integrity agreements.

Attorneys

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Practice Areas

FDA Regulatory

Intellectual Property

Industries

Life Sciences