Rebecca Jones McKnight

Partner

rebecca.mcknight@dlapiper.com

Austin
T: +1 512 457 7225
F: +1 512 721 2225
M: +1 512 968 7217

Washington, DC
T: +1 512 457 7225
F: +1 512 721 2225

Becca McKnight advises clients who develop, make and distribute FDA-regulated products and who play a part in the investigation and delivery of healthcare products and services.

She provides strategic regulatory counseling to help clients commercialize products and services and establish and maintain compliant operations. She has extensive experience in developing policies and procedures for FDA and health care compliance; conducting proactive reviews, risk assessments and internal compliance investigations; and correcting and remediating non-compliance.

Her FDA experience spans a wide range of products, with an emphasis on medical device, pharmaceutical and biological drug regulation and compliance.

Her work has also focused on potential compliance matters, under the Anti-Kickback Statute, Sunshine Act and other laws, raised by relationships between physicians and industry, including those arising in the context of clinical research; product development; and product sales, purchasing and promotion.

She provides advice on the intersection of clinical trial and healthcare law with "big data" business models, addressing regulatory and compliance considerations for the collection, sharing and use of patient and product information.

- International Trade, Regulatory and Government Affairs
- FDA
- Corporate
- Intellectual Property and Technology
- Litigation, Arbitration and Investigations
- Product Liability, Mass Torts and Product Stewardship

- Healthcare
- Life Sciences

Her advice is frequently sought in connection with a variety of corporate transactions involving FDA-regulated products and companies; from commercial agreements, to M&A transactions, to private company financings, to IPOs and follow-on offerings.

Becca assists clients with matters, including:

- Analyzing pharmaceutical, biologic, and medical device company policies, practices and documentation to assess areas of vulnerability under relevant regulatory standards and recommending methods to strengthen compliance efforts
- Tracking and evaluating emerging regulatory requirements with potential impact on FDA-regulated companies and developing

strategies for compliance

- Liaising and collaborating with counsel in Europe, Asia and Latin America to provide coordinated regulatory advice and strategic assistance to global pharmaceutical and medical device companies
- Advising on the federal Drug Supply Chain Security Act, and on state-level licensure and compliance requirements for manufacturers, distributors, pharmacies, laboratories and compounders
- Conducting internal investigations and assessments of regulated companies and entities in the areas of product promotion, adverse event reporting, notifications and filings triggered by product changes, data integrity, Good Manufacturing Practices, Good Clinical Practice and fraud and abuse
- Providing strategic guidance and advocacy on the Freedom of Information Act and its application by FDA and HHS-OIG
- Reviewing labeling, advertising, promotional materials and product claims for FDA-regulated products
- Developing strategy and providing advocacy and legal guidance for medical device manufacturers with innovative technologies throughout product development and the clearance/approval process
- Advising clients in the medical technology space, including developers of a variety of apps and algorithms, in light of FDA's evolving regulatory approach
- Conducting due diligence on FDA-regulated companies and products
- Providing guidance on Good Clinical Practice issues arising in pharmaceutical and medical device clinical trials
- Assisting in the negotiation of Corporate Integrity Agreements
- Advising companies on clinical trial registry and results database requirements and assisting with development of internal policies to facilitate compliance
- Advising FDA-regulated entities on registration and listing, adverse event and medical device reporting, recall procedures, FDA import/export issues, Quality System/GMP requirements and promotion and advertising
- Responding to 483 Inspectional Observations and Warning Letters
- Advising life sciences companies on regulatory and contract issues raised by a variety of partnerships, collaborations and outsourcing relationships
- Preparing Quality Agreements for pharmaceutical and medical device companies and providing advice on GMP compliance, vendor oversight and supply chain risk
- Advising companies on FDA regulation of radiation-emitting products (medical and non-medical)
- Providing regulatory counsel and strategic litigation assistance for pharmaceutical companies, as relevant to cases involving failure to warn claims, and addressing allegations related to reporting of adverse events and clinical data and promotional practices
- Assisting companies in assessing litigation risks in connection with FDA-regulated products
- Advising on cross-border issues such as importing research animals, importing animal-derived research materials and import/export of investigational products
- Providing guidance on the World Health Organization prequalification process, and implications for product procurement and sale
- Advising on CLIA issues and Laboratory Developed Tests, and the interplay of CMS and FDA oversight of testing and diagnostics

CREDENTIALS

Admissions

- District of Columbia
- New York
- Texas

Recognitions

In 2021 Becca was named to The American Lawyer's inaugural list of South Trailblazers. The list recognizes professionals in the South "who have moved the needle in the legal industry."

In 2017 and 2018, Becca was named a Super Lawyers Rising Star in the area of Food and Drug law, in a joint project of Super Lawyers and Texas Monthly magazine.

She has served on the Food & Drug Law Institute (FDLI) Webinar Programs Committee, which advises FDLI in formulating and implementing webinars about law, regulation and policy affecting food and dietary supplements, tobacco and nicotine, and medical products.

She also previously served on FDLI Medical Devices Committee from May 2013 to May 2016.

Education

- J.D., University of Texas School of Law 2003
  with honors
- B.A., Wake Forest University 2000
  Phi Beta Kappa

Civic and Charitable

Becca has served as a member of the Texas Health Catalyst Advisory Panel, serving with other Austin-area life sciences leaders. Texas Health Catalyst is a program of the University of Texas Dell Medical School. Researchers submit proposals for projects that target a specific health need and have the potential to translate research into a value-based therapeutic, diagnostic, device or digital health product. Texas Health Catalyst consults with the Advisory Panel for assistance in the evaluation and decision-making process for potential seed funding grants.

Becca also serves on the Advisory Council of Divine Canines, a nonprofit organization that provides free therapy dog services to people of all ages facing various challenges, including mental illness, developmental differences, physical limitations, dementia and PTSD following military service. She previously served as a member of the board of directors from 2011 to 2016, including terms as Chair Elect and Chair of the Board.

Becca also supports a number of other health-related causes:

- Divine Canines Team, National Alliance on Mental Illness (NAMI) Walk, September 2015
- DLA Piper Team, Mamma Jamma Ride to Leave Breast Cancer Behind, October 2011
- DLA Piper Team, American Lung Association Fight for Air Climb, May 2011
- DLA Piper Team, Komen Race for the Cure, November 2010

INSIGHTS

Publications

[UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

COVID-19: As diagnostic companies and laboratories ask “how can I help?” FDA responds with unprecedented regulatory flexibility, seeking to achieve more rapid testing capacity in the US

18 March 2020
Options expand for life science, healthcare and other stakeholders.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

Offering healthcare solutions at consumers' fingertips? What you should know about FDA regulation of mobile medical apps

10 OCT 2013

- Co-Author, United States, "Explore compliance requirements for pharmaceutical companies engaging healthcare professionals around the world," *DLA Piper,* 2021
- Contributing Author, "EU Medical Device Regulation May Spur Litigation Uptick," *Law360,* May 14, 2021
- Life Sciences: Product Regulation and Liability in the USA, *The Lexology Navigator*, November 2018
- "Assessing Regulatory Responsibility When Reporting Postmarket Cybersecurity "Corrections" to the FDA," *Cybersecurity Law Report*, March 27, 2017
- "Amidst a rising tide of FDCA criminal enforcement, FDA cautions companies to remain mindful of CGMP data integrity," *Bloomberg*

BNA's Pharmaceutical Law & Industry Report, August 5, 2016

- "Amarin v. FDA: Predicting the Future of Off-Label Promotion," *Pharmaceutical Compliance Monitor*, October 12, 2015
- "Chapter 5: Manufacturing Regulations," *FDA Basics for the Drug and Medical Device Lawyer*, 2015
- "FDA and Medical Device Clinical Trials Around the Globe: In God We Trust, All Others Bring *GCP-Compliant Data*," *For The Defense*, July 2013
- "Don't fear the Sunshine (but wear your sunscreen)," *Compliance Today*, July 2013
- United States chapter, *Getting the Deal Through – Life Sciences*, 2011

Events

Previous

False advertising 101

15 September 2021 | 2:00 - 3:00 ET
Consumer Goods and Retail speaker series
Webinar

- Speaker, "Clinical Investigations: Sponsor/Investigator/IRB Responsibilities and Compliance Issues," Food & Drug Law Institute's Introduction to Medical Device Law and Regulation (November 16-18, 2021)
- Speaker, "False Advertising 101" (September 15, 2021)
- Instructor, "Informed Consent, Institutional Review Boards, and Protection of Human Subjects in Device Research," Food & Drug Law Institute Training Program for FDA Center for Devices and Radiological Health (February 23, 2018)
- Speaker, "Behind the Curtain at FDA and DOJ: Investigation and Prosecution of Quality Matters" (November 14, 2017)
- Panelist, "What Do You Need as a Life Sciences Company?," Austin Technology Council Annual Life Sciences Summit (October 21, 2015)
- Presenter and Panelist, "Compliance and Liability Issues: Latest Developments," FDLI Medical Device Conference (February 27, 2014)
- Presenter, "FDA Regulatory Process Primer: Understanding Regulatory Processes for Devices," American Conference Institute: Medical Device Patent Litigation Conference (January 31, 2011)
- Panelist, "Regulatory Matters Matter! A Commercialization Discussion for Biotechnology Entrepreneurs," Austin Technology Incubator – Biosciences and Rice Alliance symbiosis (January 25, 2011)
- Presenter, "FDA-Regulated Companies: Short-Term Decisions, Long-Term Consequences," Austin Technology Incubator - Biosciences (September 16, 2009)
- Presenter, "Developing a Relationship with FDA: Strategies for Communication," Austin Technology Incubator – Biosciences (March 11, 2009)

NEWS

Ardith Bronson, Isabel De Obaldia and Rebecca Jones McKnight named to The American Lawyer’s list of 2021 South Trailblazers

4 October 2021
DLA Piper is pleased to announce that Ardith Bronson, Irma Isabel De Obaldia and Rebecca Jones McKnight have been named to *The American Lawyer’s* inaugural list of South Trailblazers. The list recognizes professionals in the South “who have moved the needle in the legal industry.”

DLA Piper advises Kadmon Holdings in its acquisition by Sanofi

14 September 2021

DLA Piper is representing Kadmon Holdings, Inc. (NASDAQ: KDMN) in its pending acquisition by global biopharmaceutical company Sanofi S.A. (NASDAQ: SNY) for approximately US$1.9 billion.

DLA Piper advises underwriters of MaxCyte's upsized US IPO

30 July 2021
DLA Piper represented Cowen and Company, LLC, Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C., as underwriters in the initial US public offering of 13,500,000 shares of common stock of MaxCyte, Inc. (Nasdaq: MXCT) (LSE: MXCT, MXCN), a leading provider of cell-engineering platform technologies, at an initial offering price of US$13.00 per share.

DLA Piper advises Cowen and Company, William Blair & Company, BTIG and Stephens Inc. as underwriters of Alpha Teknova IPO

12 July 2021
DLA Piper represented Cowen and Company, LLC, William Blair & Company, L.L.C., BTIG, LLC and Stephens Inc. as underwriters in the US$110.4 million initial public offering of Alpha Teknova, Inc.

DLA Piper advises Akoya Biosciences in its US$151 million initial public offering

3 May 2021
DLA Piper represented Akoya Biosciences, Inc. (Nasdaq: AKYA) in its recent initial public offering of 7,567,000 shares of its common stock at a price of $20 per share, including the exercise of the underwriters' option to purchase 987,000 shares of common stock, less underwriting discounts and commissions.

DLA Piper advises Immunomedics in its US$483 million follow-on offering

15 May 2020
DLA Piper represented Immunomedics, Inc., a leading biopharmaceutical company in the area of antibody-drug conjugates, in its recent US$483 million follow-on offering of common stock.

MEDIA MENTIONS

- Quoted, "Pharmaceutical industry bristles under FDA draft guidance," *Compliance Week*, July 6, 2016
- Quoted, "When the FDA Knocks: A Food Safety Inspection Playbook," *Law 360,* August 5, 2014

PRO BONO

Becca has been recognized throughout her career for her commitment to pro bono service. Her work includes providing education and advice on FDA, health care, regulatory and administrative law issues to several nonprofit pro bono clients. She has also worked on

political asylum, human rights and civil rights issues.