FOLEY & LARDNER LLP

Nathan A. Beaver

Partner

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Nathan A. Beaver is a seasoned FDA attorney known for responsive, big-picture advice. He counsels food and drug manufacturers, distributors, and retailers as they navigate federal and state agency compliance and regulatory issues. Whether clients are looking to move products through the FDA approval process, dealing with advertising or regulatory compliance issues, concerned with regulations related to telemedicine, involved in an M&A transaction, or facing FDA emergencies such as product recalls or inspections, Nathan utilizes his deep understanding of the food and drug industry to help clients meet their long-term objectives.

A partner and food and drug lawyer with Foley & Lardner LLP, Nathan's practice focuses on the representation of companies whose products and activities are regulated by the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), U.S. Department of Agriculture (USDA) and Federal Trade Commission (FTC). He advises clients on regulatory issues affecting prescription and over-the-counter drug products (including animal drugs), medical devices, dietary supplements, cosmetics and foods. Nate also has significant experience in FDA compliance and enforcement issues including 483s, warning letters and consent decrees.

Nathan's FDA regulatory and compliance experience is valuable to health care and life sciences companies involved in mergers and acquisitions. He regularly advises clients in M&A transactions and IPOs, including due diligence and diligence assessments, negotiations of regulatory issues in asset and purchase agreements, including reps and warranties, and post-transaction licensure issues.

Nathan counsels' telemedicine and digital health companies on federal and state laws governing the prescription of controlled substances via telemedicine. He has advised on state medical and controlled substance licensure, federal DEA controlled substance registrations, as well as requirements to create a valid prescriber-patient relationship. Nathan has represented companies in the digital health space in complying with FDA requirements and determining when FDA jurisdiction is not present.

Nathan also advises clients on the marketing of industrial hemp and CBD in food and beverage products as well as other FDA regulated products including cosmetics. Nathan has advised retailers, manufacturers, and universities on compliance with the 2018 and 2014 Farm Bills relating to industrial hemp as well as state requirements for marketing hemp and CBD.

Co-chair of the firm's Food & Beverage Industry Team and its Health Care & Life Sciences Sector – Medical Devices, Nathan is a member of Foley's Government Solutions and FDA Practices and its Cannabis Industry Team.

Representative Experience

Enforcement Matters

- U.S. v. Kabco Pharmaceuticals, Inc. – 2:12-cv-03468-JFB-ETB (ED NY 2012). Successfully negotiated with FDA to permit the reopening of dietary supplement manufacturing company after consent decree shut down.
- U.S. v. Wholesome Soy Products, Inc. et al. – 1:15-cv-02974 (ND IL 2015). Represented client in negotiation of consent decree.
- U.S. v. American National Red Cross, – 1:93-CV-00949 (D.D.C. 2015). Successfully negotiated with FDA for the termination of a longtime consent decree
- U.S. v. Wa Heng Dou-Fu & Soy Sauce Corp., – 2:16-CV-01358 (ED CA 2016). Represented client in negotiation of consent decree.

Transactional Matters

- Represented Power Plant Partners in its regulatory diligence and investment in Bobbie's (2023)
- Represented Archimed in its regulatory diligence and acquisition of Prollenium Medical (2021)
- Represented Archimed in its regulatory diligence and acquisition of American Preclinical Services (2021)
- Represented Archimed in its regulatory diligence and acquisition of Clinlogix (2021)
- Represented Archimed in its regulatory diligence and acquisition of Syntactx (2020)
- Represented Archimed in its regulatory diligence and acquisition of NAMSA (2020)
- Represented Montagu Private Equity in its regulatory diligence and acquisition of the RTI Surgical OEM business (2019/2020)
- Represented a biotherapeutics company in diligence and prospectus drafting for IPO (2018)
- Represented a spinal device company in diligence and prospectus drafting for an IPO (2018)
- Represented purchaser in regulatory diligence and purchase of medical device contract manufacturer (2018)
- Represented a leading pharmaceutical laboratory in the acquisition of HemoSonics LLC, a company specialized in the development of innovative Point-of-Care testing solutions based in Charlottesville, VA (2017)
- Represented G&W Laboratories in divestiture acquisition of ANDAs from drug manufacturers Gavis Pharmaceutical LLC and Novel Laboratories (2016)

- Represented Auven Therapeutics in regulatory aspects of sale of Ocular Technologies Sarl including SecieraTM (OTX-101) to Sun Pharma (2016)
- Representation of a leading food manufacturer in regulatory aspects of acquisition of Corn Fields, Inc. (2016)
- Representation of a Fortune Global 500 health care distribution company in regulatory aspects of acquisition of the Harvard Drug Group (2015)

Awards and Recognition

- The Best Lawyers in America©
  - Food and Beverage Law (2015-2024)
  - FDA Law (2018-2023)
- Best Lawyers® "Lawyer of the Year," Washington, D.C. – Food and Beverage and FDA Law (2021)
- BTI Client Service All-Star (2012)
- The Legal 500 – Health Care and Life Sciences (2015)

Affiliations

- American Telemedicine Association Home Testing Special Interest Group (SIG) – Member
- FDLI Committee Member (Webinar Committee) (2020-2023)

Presentations and Publications

Nathan is a frequent speaker at Food and Drug Law Institute events and the author or co-author of many published articles.

- Co-author, "GLP-1 Drugs: Brand Companies Push FDA to Limit Compounding," Health Care Law Today (December 2, 2024)
- Co-presenter, "GLP-1 Drugs: What's Next after FDA's Resolution of Drug Shortages," Foley & Lardner Webinar (December 4, 2024)
- Co-author, "GLP-1 Drugs: FDA Sued Over Removing Tirzepatide from the Drug Shortage List," Health Care Law Today (October 23, 2024)
- Co-author, "GLP-1 Drugs: FDA Removes Lilly's Zepbound® and Mounjaro® (tirzepatide injection) from its Drug Shortage List," Health Care Law Today (October 7, 2024)
- Co-presenter, "Top Compliance Considerations when Commercializing in the U.S.," Foley & Lardner Webinar (October 17, 2024)
- Co-author, "Artificial Intelligence in Health Care: Key Considerations for Oncology," Health Care Law Today (September 25, 2024)
- Co-author, "FDA: The Effects of *Loper* on the Regulatory Agenda," Health Care Law Today (August 1, 2024)
- Co-author, "LDTs: FDA Rolls Out a Phased Implementation for New Regulatory Requirements," Health Care Law Today (May 20, 2024)

- Co-author, “FDA Continues to Take Stance That it Will Not Issue CBD Rules,” Health Care Law Today (April 24, 2024)
- Co-presenter, “FDA Breakthrough Designation: ROI and Considerations With Shifts in Coverage,” Life Science Intelligence’s USA 2024 Emerging Medtech Summit (March 20, 2024)
- Co-author, “FDA Issues New Warning Regarding Compounded Ketamine,” Health Care Law Today (October 26, 2023)
- Co-author, “DEA Extends Telemedicine Flexibilities for Prescribing of Controlled Medications: Second Time is the Charm,” Health Care Law Today (October 9, 2023)
- Co-author, “DTC Promotional Labeling and Advertisements: Quantitative Efficacy Wins Over FDA in Final Guidance on Presenting Risk Information,” Health Care Law Today (September 11, 2023)
- Co-author, “DEA Special Registration for Controlled Substance Prescribing via Telemedicine without an In-Person Medical Evaluation,” Alliance for Connected Care (March 24, 2023)
- Co-author, “FDA Drafts Public Health Emergency Transition Plan: What Device Manufacturers Need to Know” (January 6, 2022)
- Co-author, “DEA Extends Telemedicine Flexibilities for Prescribing of Controlled Medications,” Health Care Law Today (May 10, 2023)
- Co-author, “FDA’s New Guidance Proposes Flexible Use of AI in Medical Devices,” Health Care Law Today (May 10, 2023)
- Co-author, “COVID-19 Related Medical Devices: FDA Finalizes Transition Plan Guidance”, Health Care Law Today, April 2023
- Co-presenter, “Sunshine Act and State Sunshine Act Requirements”, ACC Online Education, August 2020
- Co-author, “COVID-19 Food & Beverage Regulatory Updates”, Coronavirus Resource Center: Back to Business, July 2020
- Co-author, “COVID-19: FDA Issues Template for Over-the-Counter At-Home Testing”, Coronavirus Resource Center: Back to Business, July 2020
- Co-author, “FDA Increases Scrutiny of COVID-19 Serology Tests: What Commercial Manufacturers Need to Know”, Coronavirus Resource Center: Back to Business, May 2020
- Co-author, “COVID-19: FDA Issues Guidance for Ventilator and Respirator Manufacturers”, Coronavirus Resource Center: Back to Business, May 2020
- Co-author, “Food Safety and the Coronavirus – Latest Updates from FDA”, Coronavirus Resource Center: Back to Business, March 2020
- Co-presenter, “Responding to COVID-19 – Rapid Development and Launch Strategies for Diagnostics, Vaccines, and Therapeutics in a Global Pandemic”, Foley webinar, March 2020
- Co-author, “What’s in a Name? The Plant-Based Foods Labeling Debate”, Foley.com, October 2019
- Co-author, “Your Next Hamburger Could Be “Slaughter-Free”, Foley.com, June 2019
- Presenter, “Top 15 Mistakes a Life Sciences Start-Up Makes,” Maryland Tech Council Roundtable, May 7, 2019
- “Agricultural Bioengineering and Food Manufacturing: Navigating the Regulatory Terrain,” FoodOnline (2018)

- Panelist, “M&A Disruption in the Food & Beverage Sector – A Regulatory Guide to Navigating M&A Due Diligence & Pre-Screening,” FoodBev Exchange Conference (2018)
- Panelist, “Immunotherapy at the Crossroads: Will Shifting Patent and Regulatory Trends Help or Hurt,” (2018)
- Panelist, “Collaborating With the FDA: What Has Worked and What Hasn’t?,” The 5th Annual Business of Personalized Medicine Summit (2018)
- “FDA Marketing Exclusivity Periods Limited to Same Active Moiety,” PharmaPatents, September 7, 2017
- “Seven Key Questions in Understanding the Current Regulatory State of HCT/Ps,” Personalized Medicine Bulletin, March 20, 2017
- “Can FDA Implement the BPCIA as the CAFC Suggested,?” PharmaPatents, July 21, 2016.
- “Ten Things That Health Care Lawyers Should be Thinking About,” Association of Corporate Counsel, December 16, 2014
- Book Chapter: “Recent Developments in Food and Drug Law,” “Natural” Claims: The Current Legal and Regulatory Landscape, Aspatore Publishing, 2013
- “Trends in ‘All Natural’ Class Actions,” Law360, November 2011
- “Certifying to Medical Necessity Under FDA,” Law360, April 2011
- “New Legal Pathway for Biosimilars Creates Opportunities and Challenges for Biological Manufacturers – A Guide to the Legislation,” Bloomberg Law Reports, August 2010
- “The FDA Stance on High-Fructose Corn Syrup,” Law360, October 2009
- “The Future of Drug and Biologics Approvals: Will Congressional Legislation Change the Landscape of Hatch-Waxman,” BNA Health Care Policy Report, September 2002
- “Fundamentals of Law and Regulation: An in-depth look at the 1997 Food and Drug Administration Modernization Act of 1997”

Sectors

- Cannabis
- Fashion, Apparel & Beauty
- Food & Beverage
- Food Regulatory Compliance
- Health Care & Life Sciences
- Pharmaceuticals
- Telemedicine & Digital Health

Practice Areas

- Corporate
- FDA Regulatory
- Government Solutions

Education

- Georgetown University Law Center (J.D., 1997)
- University of Arizona (B.A., cum laude, 1994)

Admissions

- District of Columbia