



## Seth A. Mailhot

### PARTNER

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### OVERVIEW

With an education in chemical engineering and a prior career at the U.S. Food and Drug Administration, Seth brings clients rare regulatory insight on food, medical device and drug matters.

As Leader of the firm's FDA group, Seth handles a broad array of matters involving FDA-regulated products and services including food, medical devices, pharmaceuticals, biotechnology, tobacco, radiation-emitting electronic products and cosmetics. He assists clients in premarket strategies, advises on postmarket compliance, handles enforcement matters – including those before the U.S. Department of Justice – and drafts and negotiates corporate transactions.

Seth began his career as a chemical engineer for more than a decade at the FDA, conducting regulatory research, performing inspections of regulated industry and serving as a compliance officer, followed by nearly 15 years in private practice. Clients appreciate his multidisciplinary experience when faced with highly technical regulatory issues.

Among other clients, Seth counsels food producers, importers, restaurants, trade groups, farms, and manufacturers of food packaging materials and food additives as well as manufacturers of medical devices and pharmaceuticals. FDA compliance issues such as GMP, FSMA, GRAS, LACF; California State matters including Proposition 65, CLRA, FAL and UCL; premarket submission for medical devices [510(k) and PMA] and drugs (NDA and ANDA) are just a few of the matters he assist clients with for optimal solutions.

### Industries

Food Systems  
Healthcare  
Life Sciences

### Services

Animal Health & Production  
Cannabis  
Companion Animal Health  
COVID-19 Research and Laboratory Testing  
FDA Regulatory  
Food Safety & Regulation  
Functional Foods & Beverages  
Generic Drug / ANDA Litigation  
PFAS  
Product Safety  
Proposition 65  
Psychedelics & Emerging Therapies  
Public Policy, Regulatory, & Government Affairs

He also explores emerging markets, such as electronic nicotine delivery systems (ENDS) and industrial hemp and cannabidiol, identifying potential regulatory issues in order to guide clients in developing business and marketing strategies.

## Experience

### CALIFORNIA STATE MATTERS

- Regularly advise clients on compliance and litigation involving Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), which requires labeling of products containing "chemicals known to the State of California to cause cancer and birth defects or other reproductive harm."
- Develop Proposition 65 arguments for clients regarding preemption, threshold limits, safe harbor warning labels, testing and control of trace contaminants, and estimation of daily exposure.
- Routinely defend clients in claims under California's consumer protection and competition laws: Consumer Legal Remedies Act (CLRA), False Advertising Law (FAL) and Unfair Competition Law (UCL).

### FDA COMPLIANCE ISSUES

- Advise clients on drug and medical device good manufacturing practice (GMP) requirements.
- Counsel clients on food safety regulations under Food Safety Modernization Act (FSMA).
- Advise clients on low acid canned food (LACF) process registration.
- Assist clients in managing generally recognized as safe (GRAS) self-certification panels.
- Assist with software design controls of medical software and health IT products (including mobile medical devices).
- Conduct audits of process validation studies and food safety plans.

### HEALTHCARE

- Develop premarket regulatory strategies for drugs and medical devices.

## Experience

- Prepare and prosecute premarket submissions for medical devices [510(k) and PMA] and drugs (NDA and ANDA).
- Advise clients on adverse event reporting requirements.
- Assist clients with digital health software matters, including requirements for design controls, mobile medical apps, exemptions for medical software, and compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.
- Handle pharmaceutical lifecycle management and Hatch-Waxman regulatory matters.

## CRISIS MANAGEMENT

- Guided coronavirus planning for global certification association operating within organic food sector.
- Navigated COVID-19 strategy for regional retail convenience stores, with fast-changing local, state and federal statutes across 16 states.
- Counseled international packaging company amid COVID-19 pandemic on immunity from liability while supplying personal protective equipment (PPE) under the Public Readiness and Emergency Preparedness (PREP) Act.
- Handle complex food recall solutions for client including FDA communications, dispute with supplier that provided recalled product and claims/dispute with insurer.
- Amid COVID-19 pandemic, assisted various companies with sourcing and importing much-needed personal protective equipment (PPE), hand sanitizers and ventilators from foreign countries into the United States.

## GOVERNMENT EXPERIENCE

- Worked on research projects and sample testing for medical devices and radiation-emitting electronic products (e.g., microwave ovens and lasers).

## Experience

- Represented FDA on national standards organizations.
- Conducted regulatory inspections of foreign and domestic manufacturers, including extensive trips to China, Korea and Thailand.
- Worked as compliance officer preparing administrative and judicial enforcement actions on long-term assignment with Health Care Fraud Task Force of U.S. Attorney's Office for the District of Massachusetts concerning criminal violations of the Federal Food, Drug and Cosmetic Act.

### OTHER REPRESENTATIVE EXPERIENCE

- Review food, supplement, drug, device and cosmetic labeling.
- Claim substantiation for product promotional and advertising campaigns.
- Handle import holds of FDA regulated products.
- Assist clients with registration and listing of FDA-regulated facilities and businesses.
- Due diligence, drafting and negotiation of agreements involving FDA-regulated businesses, products and services.
- Manage patent term extension applications for products approved by the FDA, and state registration and licensing of drug distributors and manufacturers.

## Education

- J.D., New England Law
  - *summa cum laude*
  - Valedictorian
- B.S., University of Massachusetts

## Admissions

- U.S. Patent and Trademark Office
- Massachusetts
- District of Columbia
- California

## Community Leadership

Catholic University of America, Columbus School of Law, Lecturer, 2012-Present