

## Elise N. Paeffgen

Partner

202.239.3939

elise.paeffgen@alston.com

Washington, D.C. | The Atlantic Building, 950 F Street, NW | Washington, DC 20004-1404



Elise Paeffgen’s practice is centered at the intersection of EPA, FDA, and DEA regulation. Elise works with manufacturers, importers, and forward and reverse distributors to effectively navigate EPA, FDA, and DEA regulations and minimize enforcement risks. She provides counsel to FDA-regulated clients, such as pharmaceutical, medical device, and cosmetic manufacturers, on issues ranging from marketing claims to the management of hazardous waste pharmaceuticals. On environmental compliance and enforcement matters, Elise represents health care facilities and domestic and international companies in the consumer product, chemical, pesticide (antimicrobial), automotive, construction equipment, renewable fuel, and oil and gas industries.

In addition to a J.D., magna cum laude, from Vermont Law School, Elise earned a master of environmental management from the Yale School of the Environment, with concentrations in climate change and corporate environmental management. During her joint degree program, Elise worked for the U.S. EPA Office of Enforcement and Compliance Assurance. Elise received a B.A. in environmental studies and politics from Oberlin College, and was awarded high honors.

Elise has been named a *Super Lawyers* “Rising Star” each year since 2014. In 2021, Elise was recognized by client counsel in Acritas Stars for outstanding service.

### ***Representative Experience***

#### ***Pharmaceutical, Medical Device, Antimicrobial, and Consumer Product Manufacturing, Labeling, Distribution, and Disposal***

- Counseling pharmaceutical manufacturers, logistics providers, and forward and reverse distributors on pharmaceutical waste characterization, management, transportation, and disposal; the EPA’s Management Standards for Hazardous Waste Pharmaceuticals; DEA Disposal Act compliance; and federal and state licensure matters.
- Advising health care facilities on pharmaceutical and medical/infectious waste management.
- Providing EPA and FDA counsel as companies develop and market antimicrobial consumer products, coatings, treated textiles, medical devices, air filters and purifiers, disinfectants and sanitizers.
- Providing label compliance and import advice to manufacturers, private labelers, and distributors of disinfectant and antiseptic wipes.
- Counseling consumer products companies on the development of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) exempt treated articles and minimum risk pesticides.
- Providing strategic advice on cosmetic and consumer product development, marketing, and acquisitions, including compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA), Fair Packaging and Labeling Act (FPLA), Proposition 65, FTC Green Guides, organic standards, and country of origin labeling.

- Assisting in developing and implementing CBD and cannabis management and disposal policies and procedures.
- Providing strategic advice to drug manufacturers on compliance with pharmaceutical take-back ordinances.
- Spent more than 100 days inside pharmaceutical API, intermediate, and finished drug product manufacturing facilities in the U.S. and Europe managing FDA inspections, counseling on good manufacturing practices (GMP), and implementing significant remedial actions.

## ***Environmental Compliance Counseling***

- Conducting environmental and FDA regulatory due diligence reviews of drug, medical device, and biologics companies, hospitals, and pharmaceutical reverse distributors and advising clients on the regulatory risk profiles of companies subject to pending acquisitions and mergers.
- Reviewing environmental-related statements in securities filings and investor materials for FDA-regulated companies and advising on environmental, social & governance (ESG) issues.
- Advised energy company on ESG and climate-related risks.
- Counseling an international logistics company on environmental matters arising throughout the country.
- Advising engine, vehicle, and equipment manufacturers in the U.S., Europe, and Asia on compliance with Clean Air Act (CAA) emission standards and import and export issues.
- Advised the world's largest vehicle remarketing company on engine emission controls, retrofits, and repairs.
- Counseling on environmental-related requirements for 45Q carbon sequestration tax credits and leakage risks in existing and developing carbon capture projects.
- Advising renewable fuel manufacturers and blenders on EPA's Renewable Fuel Standard, RIN credit generation, and biodiesel tax credits.
- Developed and implemented efficient and effective environmental management systems and compliance programs for equipment manufacturing and oil and gas service companies.
- Serving as national environmental financial assurance counsel to a major oil and gas company. Regularly advises on Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and Safe Drinking Water Act (SDWA) financial assurance matters.
- Providing strategic advice on the use of captive insurance as an environmental financial assurance mechanism.
- Advised oil and gas services companies and an industry trade association on developments in federal, state, and local regulation of hydraulic fracturing and related waste management.
- Counseling national and international chemical companies on Toxic Substance Control Act (TSCA) compliance.

## ***Environmental Enforcement Defense***

- Representing the head of regulatory compliance of a U.S. automobile manufacturer in civil and criminal investigations into auxiliary emission control and defeat device allegations.
- Represented an international construction equipment company and its domestic subsidiary in CAA mobile source civil and criminal enforcement matters.
- Represented renewable fuel producers and executives in response to EPA information requests and criminal fraud investigations related to the EPA's Renewable Fuel Standard (RFS) program.

- Negotiated a RCRA Consent Agreement and Final Order (CAFO) with EPA for alleged financial responsibility and other RCRA violations on behalf of a major energy company.
- Represented an oil and gas services company in negotiating a 92 percent reduction of an environmental civil penalty for alleged violations of the CAA, RCRA, and Clean Water Act (CWA).

## **Publications & Presentations**

### **Publications**

- “INSIGHT: What Do We Do With Covid-19 Waste?” *Bloomberg Law*, May 20, 2020.
- “Food Packaging Chemicals Face Increasing Scrutiny,” *Food Processing*, June 26, 2018.
- “EPA’s Latest Truck Rule Has Broader Effect on Mobile Source Compliance and Enforcement,” *Bloomberg BNA Daily Environment Report*, October 28, 2016.
- “Proposed Hazardous Waste Pharmaceuticals Rule Provides Sector-Specific Regulatory Flexibility for Most Health Care Facilities,” *Bloomberg BNA Health Law Reporter*, October 1, 2015.
- “Managing a Company’s Internal Environmental Investigation,” *Law360*, July 29, 2015.
- “Managing a Company’s Environmental Self-Disclosure,” *Law360*, June 12, 2015.
- “Alameda County’s Drug Take-Back Ordinance,” *Industry Today*, October 22, 2014.
- “EPA May Threaten Reverse Distribution of Pharmaceuticals,” *Law360*, July 21, 2014.
- “How to Enforce a Carbon Tax: Lessons from the Montreal Protocol and the U.S. Experience with the Ozone Depleting Chemicals Tax,” *Vermont Journal of Environmental Law*, Vol. 14, No. 3, Spring 2013.
- “EPA’s Enforcement of RIN Fraud Violations Starts to Bring Stability Back to the Market,” *Environment Reporter*, April 30, 2013.
- “PRIA 3 May Have Hidden Disadvantages for Industry,” *Law360*, November 8, 2012.
- “OTC Crunch Time in California,” *Pharmaceutical Executive*, November 1, 2012.
- “Risky Business: 3 Circuits Affirm CWA Simple Negligence,” *Law360*, June 15, 2012.
- “Linking International Carbon Markets?” *Journal of International Banking and Financial Law*, January 2012.

### **Presentations**

- “FIFRA Section 18 – An Industry Perspective,” HCPA Virtual Mid-Year Meeting, webinar, May 24, 2021.
- “COVID & Beyond: The Legal Nuances of Disinfectants and Sanitizers in 2020,” Environmental Law Institute, webinar, November 18, 2020.
- “Clean Air Act and Regulatory Challenges,” 29th Annual Eastern Boot Camp on Environmental Law, Environmental Law Institute, webinar, November 5, 12, 19, 2020.
- “Emerging Leaders Initiative (ELI),” 28th Annual Eastern Boot Camp on Environmental Law, Environmental Law Institute, District of Columbia, November 18-20, 2019.
- “Hazardous Waste Pharmaceuticals Rule,” 14th Annual Georgia Environmental Conference, Jekyll Island, GA, August 21-23, 2019.
- “Hazardous Waste Pharmaceuticals, Control Substances, and Medical Waste: Enforcement Trends and Takeaways,” Waste 360 Healthcare Waste Conference, Las Vegas, NV, May 8-9, 2019.

- “New Management Standards for Hazardous Waste Pharmaceuticals and Nicotine,” Food and Drug Law Institute (FDLI) and Environmental Law Institute (ELI), webinar, March 6, 2019.
- “2018 FIFRA Case Law & Enforcement Update,” XPAND 2018, the Household & Commercial Products Association Annual Meeting, December 3-5, 2018., Fort Lauderdale, FL, December 3-5, 2018.
- “EPA/FDA Dual Jurisdiction: Food Use & Medical Devices,” American Chemistry Council’s 12th Annual Antimicrobial Workshop, Arlington, VA, June 7-8, 2018.

### ***Professional & Community Engagement***

- Environmental Law Institute Emerging Leaders Initiative (ELI-ELI) Steering Committee, founding member
- Household & Consumer Products Association, Antimicrobial Division
- Healthcare Waste Institute
- Oberlin College EnviroAlums Steering Committee
- ABA Environmental Enforcement and Crimes Committee, former vice chair and newsletter chair
- District of Columbia Bar, Environment, Energy and Natural Resources Section
- D.C. Bar Pro Bono Center, 2017 Capital Pro Bono Honor Roll

### ***Court Admissions***

- U.S. District Court for the District of Columbia
- U.S. Supreme Court

### ***Education***

- Vermont Law School (J.D., 2009)
- Yale University (M.E.M., 2009)
- Oberlin College (B.A., 2004)

### ***Admitted to Practice***

- District of Columbia
- Ohio

### ***Related Services***

Environment, Land Use & Natural Resources | Environmental Enforcement Defense | Internal Investigations & Environmental Audits | Chemical & Product Regulation | Hazardous Materials & Hazardous Waste Compliance | Air Quality | Environmental Compliance, Permitting & Transactions | Climate Change / Carbon Management | Corporate Social Responsibility & Sustainability | Pesticide Law and Regulation, Enforcement and Registration | FDA/Food, Drug & Device | FDA Enforcement & Litigation | FDA Compliance & Enforcement | Consumer Product Safety & Regulatory Compliance