

## Elise N. Paeffgen

Partner

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*Clients depend on Elise to navigate EPA, FDA, and DEA regulations and to guide them through environmental enforcement actions. Elise has significant experience in cross-cutting issues in health care, such as antimicrobials, distribution, and waste, and frequently counsels clients on product development and marketing, including environmental attributes and claims, and ESG and climate strategies.*

Elise Paeffgen’s environmental practice centers on health care and FDA-regulated industries. Elise works with manufacturers, importers, and forward and reverse distributors to effectively navigate EPA, FDA, and DEA regulations and minimize enforcement risks. She provides hazardous, medical, pharmaceutical, and controlled substance waste compliance counsel to companies in every facet of the supply chain. She works closely with manufacturers developing and marketing antimicrobials and products with environmental claims.

On ESG, climate, and environmental compliance and enforcement matters, Elise represents domestic and international companies in the health care, pharmaceutical, medical device, cosmetic, food and beverage, consumer product, pesticide, 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, Pesticide/Antimicrobial, and Consumer Product Manufacturing, Labeling, Distribution, and Disposal***

- Advising health care facilities and medical waste service providers on medical/infectious waste and hazardous waste pharmaceutical management.
- 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 a manufacturer on environmental compliance and enforcement matters pertaining to water and waste from its pharmaceutical manufacturing operations.
- Providing EPA and FDA strategic counsel as companies develop and market antimicrobial consumer products, coatings, treated textiles, medical devices, pesticide devices, air filters and purifiers, disinfectants, and sanitizers.

- Counseling consumer products companies on the development of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) exempt treated articles and antimicrobial, biopesticide, conventional, and minimum risk pesticides.
- Providing strategic advice on cosmetic and consumer product development, marketing, and acquisitions, including compliance with the FTC Green Guides, Federal Food, Drug, and Cosmetic Act (FFDCA), Fair Packaging and Labeling Act (FPLA), and Proposition 65.
- 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.

### ***ESG, Climate & Environmental Compliance Counseling***

- Reviewing environmental-related statements and disclosures in securities filings and investor materials and advising on ESG issues.
- Helping an insurance company stand up its ESG program.
- Advised an energy company on ESG and climate-related risks.
- Guided manufacturers through climate and deforestation-related shareholder proposals.
- Advising food and beverage manufacturers and retailers on novel climate strategies, sustainability reporting, and product labelling.
- Advising clients on carbon reduction strategies and related marketing claims and disclosures.
- Counseling clients on voluntary and compliance carbon offset generation and purchasing, carbon sequestration strategies, and cap-and-trade compliance strategies.
- Advising on environmental-related requirements for 45Q carbon sequestration tax credits and leakage risks in existing and developing carbon capture projects.
- Conducting environmental 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.
- Counseling an international logistics company on environmental matters involving state and federal environmental agencies arising throughout the country, including on novel and multi-agency (EPA/DEA/state) waste issues and financial assurance.
- 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.
- 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.
- Advising renewable fuel manufacturers and blenders on EPA's Renewable Fuel Standard, RIN credit generation, and biodiesel tax credits.

## ***Environmental Enforcement Defense***

- Representing the head of regulatory compliance of a U.S. automobile manufacturer in litigation relating to 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.

### ***Presentations***

- "EPA Enforcement on Imports and Devices," Household & Consumer Products Association's XPAND 2022 Annual Meeting, Fort Lauderdale, FL, December 4-7, 2022.
- "Clean Air Act," 31st Annual Eastern Boot Camp on Environmental Law, Washington, D.C., November 16-18, 2022.
- "Environmental Justice, Climate Change and Siting Facilities" and "The FEDs.," Waste360 Healthcare Waste Conference, Las Vegas, NV, May 10-11, 2022.

- “Clean Air Act and Regulatory Challenges,” 30th Eastern Boot Camp on Environmental Law®, November 3, 10, 17, 2021.
- “What the “E” in ESG Means for You: Building Your Practical Toolkit for Assessing and Managing Risks,” Society of Corporate Compliance and Ethics Dallas Regional Compliance & Ethics, webinar, October 22, 2021.
- “FIFRA Section 18 – An Industry Perspective,” HCPA Virtual Mid-Year Meeting, webinar
- “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), founding member; Steering Committee (2019-2021)
- Household & Consumer Products Association, antimicrobial division
- Healthcare Waste Institute, vice chair
- Crystal Lake Camps, board of trustees
- Oberlin Environmental Education Alumni Association (EnviroAlums), steering committee
- ABA Environmental Enforcement and Crimes Committee, former vice chair and newsletter chair
- 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 | Perfluoroalkyl & Polyfluoroalkyl Substances (PFAS)