

SWATI RAWANI

Professional Summary

Accomplished attorney with over 15 years of experience in complex civil litigation, regulatory law, and public health advocacy, spanning federal agencies, private practice, and nonprofit work. Proven track record of leading high-impact litigation and regulatory strategy in areas including antitrust, public health, pharmaceutical regulation, and consumer protection. Former antitrust associate at a major law firm and counsel at FDA and HHS, with deep expertise in statutory interpretation, government investigations, and cross-agency collaboration. Skilled in managing teams, advising senior leadership, and translating complex legal frameworks into actionable policy and litigation outcomes. I'm passionate about using the law as a tool to protect public health, promote accountability, and serve the public good.

Work Experience

Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Regulatory Policy, White Oak, MD **Regulatory Counsel | 01/2024 – 05/2025**

- Led strategic policy development and regulatory analysis for human drug regulation under the Food, Drug, and Cosmetic Act (FDCA), with a focus on drug shortages, compounding, drug exclusivity, and compliance.
- Proactively advised FDA's Drug Shortage Staff on statutory and regulatory interpretation, mitigation strategies, and legislative initiatives, including reviewing legislative proposals and policy reports for Congress.
- Drove cross-functional litigation strategy for high-profile GLP-1 drug shortage and compounding litigation, collaborating with legal, program leadership, and scientific teams.
- Managed and finalized guidance documents crucial to federal drug shortage response, ensuring alignment with business and stakeholder comments.
- Led and drafted responses to citizen petitions. Acted as key liaison with internal stakeholders, translating complex regulatory risks into actionable recommendations for senior leadership.

U.S. Department of Health and Human Services, Office of the General Counsel, Public Health Division, Rockville, MD **Attorney Advisor | 04/2021 – 01/2024**

- Provided strategic counsel on legislative, regulatory, and litigation matters impacting federal public health programs under HRSA and OASH, including health workforce, graduate medical education, vaccines, and telehealth programs.
- Served as lead attorney on review and clearance of 40+ grant programs, advising on statutory authority, compliance, and implementation of federal policies (Public Health Service Act, CARES Act, ARP Act).
- Collaborated with OIG and DOJ to investigate and litigate fraud and abuse in federal grant health programs; supported DOJ in litigation and negotiations.
- Recognized with a Quality Step Increase for exemplary performance.

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Campaign for Tobacco-Free Kids, Washington, D.C.

Staff Attorney | 05/2019 – 04/2021

- Developed and executed advocacy strategies to influence FDA and state agencies on tobacco product regulation, including enforcement of Tobacco Control Act.
- Successfully led legal challenges and authored amicus briefs in federal and state courts, shaping regulatory policy and advancing organizational priorities on federal and state tobacco control laws.
- Successfully challenged FDA's decision to exercise enforcement discretion to allow e-cigarettes to remain on the market for an extended period before requiring FDA approval and allowing the products to remain on the market during FDA review. (American Academy of Pediatrics, et al., v. FDA).
- Engaged with FDA and advocated for FDA to act on illegal advertising by e-cigarette companies advertising tobacco products as drugs. Met with FDA chief counsel and other senior staff to discuss legal concerns.
- Drafted persuasive letters and written comments to FDA regarding enforcement of FDCA, including regulating menthol, setting nicotine limits in tobacco products, and banning flavored tobacco products.
- Built coalitions and consulted with state attorneys in litigation related to emergency response to vaping-related health crises; crafted legislative language and regulatory commentary to advance state public health goals.

TASSC International, Washington, D.C.

Volunteer Attorney and Legal Services Program Manager | 01/2017 – 04/2019

- Managed legal services program, supervised staff attorneys, argued asylum cases in immigration court and represented clients in USCIS credible fear interviews.

Morgan Lewis & Bockius LLP, Washington, D.C.

Antitrust Associate Attorney, 10/2007 – 01/2017

- Represented domestic and international clients in private class actions, and complex civil antitrust litigation and criminal investigations initiated by the Federal Trade Commission (FTC) and DOJ.
- Advised private equity clients on antitrust aspects of mergers and acquisitions, joint ventures and other strategic transactions. Advised clients through global deal clearance strategy, second requests, premerger conduct counseling.
- Lead responses to regulatory inquiries from FTC and DOJ, drafted and negotiated antitrust provisions in merger agreements, joint-defense agreements, and confidentiality agreements, conducted due diligence and contract negotiations related to merger transactions.

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- Managed all phases of complex federal court litigation. Conducted pre-complaint internal investigations, organized complex evidence, prepared responses to complaints, interrogatories, and other legal papers, prepared motions and legal briefs, negotiated discovery, conducted depositions, collaborated with expert witnesses, and participated in settlement negotiations.
- Representative engagements included counseling international clients in various industries in price-fixing class action cases and government investigations, counseling pharmaceutical companies in FTC investigation regarding pay-for-delay arrangements, anticompetitive conduct, mergers, and collaboration agreements
- Served as Vice-Chair of Pro Bono Committee.

**Federal Trade Commission, Bureau of Competition, Washington, D.C.
Health Care Division, Legal Intern, 01/2006 – 07/2006 (part-time)**

- Supported pharmaceutical drug pricing litigation, reviewed merger filings, and investigated anticompetitive concerns in health insurance industry merger.

Education

American University Washington College of Law, J.D., May 2007

Administrative Law Review, Note & Comment Editor; *Human Rights Brief*, Staff Writer and Articles Editor; Student Attorney in International Human Rights Law Clinic; Democracy and Development Summer Program in South Africa.

Laura Reckman Memorial Endowed Scholarship Recipient (commitment to health and law)

Harvard University, T.H. Chan School of Public Health, M.S. (Health and Social Behavior), June 2003

Johns Hopkins University, B.A., Public Health, May 2000

Bar Admission

District of Columbia