Cooley

Sonia Nath

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Life Sciences and Healthcare Regulatory
White Collar Defense and Investigations
Medtech
Digital Health
Life Sciences and Healthcare
Commercial Litigation
Food and Beverage
False Claims Act/Qui Tam/FIRREA
Agricultural Sciences and Technology
Product Compliance and Product Litigation
CooleyREG
Wellness

Sonia is chair of Cooley's global life sciences and healthcare regulatory practice group. She has deep experience in matters involving the US Food and Drug Administration (FDA). Sonia has been recognized in Chambers and The Legal 500 and been shortlisted for the LMG Life Sciences Regulatory Attorney of the Year: FDA Medical Device award annually since 2022. Sonia draws on her nearly 12-year career at the FDA's Office of the Chief Counsel, where she served as a litigation and enforcement attorney, to help clients with litigation, investigations, regulatory counseling, and transactional matters involving the laws and regulations enforced by the FDA.

Sonia's litigation practice includes agency-facing litigation under the Administrative Procedure Act (APA). She has served as lead counsel on several FDA APA cases, including one of the first complaints filed against the agency after the US Supreme Court's landmark ruling in *Loper Bright*, challenging the agency's award of market exclusivity. In addition to administrative litigation, Sonia's practice also includes conducting internal investigations and representing clients in criminal matters involving the FDA and FDA-regulated products.

Sonia's counseling practice includes advising clients on FDA regulatory compliance matters across the full product life cycle. She works with early-stage companies to develop go-to-market strategies, working hand-in-hand with business leaders to ensure the chosen regulatory pathways align with overall business strategy, including plans for developing and protecting intellectual property. Sonia helps clinical stage companies navigate marketing exclusivities and routinely represents companies at pre-submission meetings with the FDA.

Sonia helps commercial-stage companies prepare for and respond to FDA inspections, including drafting responses to FDA Forms 483. She also supports clients in responding to Warning Letters and other letters of regulatory significance. In addition, she assists FDA-regulated entities with product launches, including by reviewing third-party agreements, along with labeling, advertising and promotional materials for compliance with the Federal Food, Drug, and Cosmetic Act and FDA regulations. Sonia has experience working across all FDA-regulated product areas, with a particular emphasis on the biotech and medtech industries – though she also works closely with food, dietary supplement and cosmetic companies.

The transactional side to Sonia's practice involves advising investors, underwriters, and public and private businesses in buy-side and sell-side transactions, as well as in financings involving FDA-regulated products.

During her FDA tenure, Sonia gained subject matter experience across the gamut of FDA-regulated products – including prescription and over-the-counter drugs, medical devices, biologics, foods, cosmetics, dietary supplements and animal drugs. She negotiated dozens of civil consent decrees for the government, defended the FDA in lawsuits brought under the APA and the Freedom of Information Act, and handled False Claims Act litigation for the agency. Sonia also handled criminal investigations and prosecutions involving FDA-regulated products in her appointed role as a special assistant United States attorney (SAUSA) with the US Attorney's Office for the Central District of California. She received numerous accolades for her government service – including the FDA's Award of Merit (the agency's highest recognition), the FDA Commissioner's Award and the Department of Justice's John Marshall Award (the DOJ's highest award offered to attorneys).

Sonia began her legal career as a law clerk to Judge Roger W. Titus of the US District Court for the District of Maryland and worked at a large international law firm as a healthcare associate for several years before joining the FDA. Before attending law school, Sonia was a management consultant for PwC and IBM, where she developed and implemented solutions for complex business problems.

Select speaking engagements and publications:

- Speaker, "When FDA Lets You Off the Hook: The Use, Implications, and Limitations of Enforcement Discretion," Food and Drug Law Institute (FDLI) Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries, December 2024
- Speaker, "Fireside Chat: Regulatory Insider Perspective," 14th Annual Cooley Healthtech Conference, April 2024
- Speaker, "Tackling Regulation & Legislation to Shape Consumer Perception," Future Food-Tech Summit, March 2024
- Speaker, "FDA 101: A Guide to Agency Structure, Jurisdiction, Regulation, and Applicable Laws," American Conference Institute's 42nd FDA Boot Camp, March 2024
- Speaker, "Digital Health Regulatory Roundup: What is Coming in 2024," Cooley Capital Call at Digital Healthcare Innovation Summit West, February 2024
- Speaker, "The New Era of Clinical Decision Support Software: Risks and Unknowns," FDLI Current Developments in Digital Health Technology and Regulation Conference, February 2024
- Speaker, "Navigating Emerging Enforcement Trends in Digital Health," FDLI Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries, December 2023
- Speaker, "Orphan Drug Exclusivity: A Review of Key Case Law and Themes in FDA's Interpretation of ODD and ODE," 2023 Food and Drug Law Journal Symposium – Regulating on Shifting Sands: Analyzing the Impact of Recent and Upcoming Federal Court Decisions on FDA's Authority, November 2023
- Speaker, "AI and Medical Devices: Liability and Opportunity," International Bar Association Annual Conference, November 2023
- Speaker, "FDA Regulation for Early-Stage Biotech Companies," Harvard Life Lab, May 2023
- Speaker, "FDA Regulatory Update: Key Changes in 2023," 13th Annual Cooley Healthtech Conference, May 2023
- Speaker, "The Evolution of Novel Foods: Redefining Your Space for Regulatory Success," Future Food-Tech Summit, March 2023
- Contributor, "Overview of FDA Food Recalls" and "FDA's Approach to Medical Device Recalls in the US," Sedgwick, March 2023
- Moderator, "DOJ, FDA, and Compliance in Criminal Violations of the FDCA," FDLI Enforcement, Litigation, and Compliance Conference, December 2022
- Speaker, "Parallel Enforcement: SEC Authorities and How They Can Impact FDA's Civil and Criminal Enforcement," FDLI Symposium on the Interconnected Regulatory Landscape: Exploring FDA's Relationship With Other Domestic Regulators, November 2022
- Panelist, "Regulatory Compliance in Advertising Digital Health Software," FDLI Advertising & Promotion for Medical Products Conference, October 2022

- Speaker, “FDA and Fraud and Abuse: Navigating Key Regulatory & Compliance Issues for IIS,” 2022 USA Medical Device IIS Conference, July 2022
- Panelist, “Software as a Medical Device (SaMD): FDA’s Recent Guidance Document and Other Developments,” FDLI Annual Conference, June 2022
- Panelist, “Legislative Update for Life Sciences Companies,” 2022 National Association of Bioscience Financial Officers Conference, June 2022
- Panelist, “Delivering Guilt-Free, Indulgent Comfort Foods and Snacks,” Future Food-Tech Summit, March 2022
- Speaker, “What’s Going On in Washington? Legislative and Enforcement Updates in the Healthcare and Life Sciences Industry,” Cooley Life Sciences and Healthcare Innovation Program webinar series, January 2022
- Contributor, “3 things you need to know about the FDA’s new software as a medical device (SaMD) guidance,” BrightInsight Digital Health Blog, January 2022
- Speaker, “The Aftermath of AMG: The Future of FTC Actions and Impact on FDA Enforcement,” FDLI Enforcement Conference, December 2021

Education

The George Washington University Law School JD, with High Honors, Order of the Coif

George Washington University Milken Institute School of Public Health MPH, Health Policy, dean’s list

Princeton University AB, English

Admissions & Credentials

District of Columbia

Maryland

Court Admissions

US Supreme Court

US Court of Appeals for the Second Circuit

US Court of Appeals for the Fourth Circuit

US District Court for the District of Columbia

US District Court for the District of Maryland

Rankings & Accolades

Chambers USA: Healthcare: Pharmaceutical/Medical Products Regulatory – District of Columbia (2023 – 2026)

LMG Life Sciences Americas Awards: Regulatory Attorney of the Year: FDA Medical Device (shortlist) (2022 – 2024)

The Legal 500: Dispute Resolution: Corporate Investigations and White-Collar Criminal Defense: Advice to Corporates (2022)

The Legal 500: Dispute Resolution: Product Liability, Mass Tort and Class Action – Defense: Consumer Products (2022 – 2024)

Memberships & Affiliations

BIO's Emerging Companies Section, governing board member

Food and Drug Law Institute, Enforcement, Litigation, and Compliance Conference Committee