Cooley

Sonia Nath

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

Sonia is chair of Cooley's global life sciences and healthcare regulatory practice group. She has deep experience in matters involving the Food and Drug Administration (FDA). Her practice encompasses investigations, litigation and regulatory counseling, as well as advising on transactional matters. Having served for almost 12 years at the FDA's Office of the Chief Counsel as a litigation and enforcement attorney, Sonia represents clients before the FDA, including in FDA enforcement actions and regulatory meetings. She helps clients respond to Warning Letters and FDA inspections, i.e., drafting responses to FDA Forms 483. Sonia's practice also focuses on conducting internal investigations and representing clients in criminal matters involving the FDA and FDA-regulated products. She also advises and represents clients in civil litigation involving FDA regulatory issues.

Sonia routinely counsels clients on FDA regulatory compliance matters, including developing go-to-market strategies for companies – particularly in the medical device space – and representing companies at pre-submission meetings; reviewing labeling, advertising and promotional materials for drugs, devices, biological products, food and dietary supplements; and 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 has experience working across all FDA-regulated product areas, with a particular emphasis on the biotech and medtech industries.

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. Sonia negotiated dozens of civil consent decrees for the government, defended the FDA in lawsuits brought under the Administrative Procedure Act 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. Sonia 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, “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," Food and Drug Law Institute (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 2022 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,

George Washington University Milken Institute School of Public Health
MPH,

Princeton University
AB,

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 – 2024)

LMG Life Sciences Awards: Regulatory Attorney of the Year: FDA Medical Device (shortlist) (2022 – 2023)

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

Legal 500: Product Liability, Mass Tort and Class Action-Defense: Consumer Products (2022)

Memberships & Affiliations

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