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Life Sciences and Healthcare Regulatory
Medtech
Life Sciences
Digital Health
Commercial Litigation
Wellness

Son is an experienced US Food and Drug Administration (FDA) lawyer, having spent almost 14 years in the industry as associate chief counsel for enforcement, associate chief counsel for devices and combination products, and senior counsel. Having worked on some of the most complex regulatory issues while at the FDA and in private practice, Son brings a practical, creative approach to solving problems. He advises a wide range of life sciences clients, with a focus on medical devices, pharmaceuticals, biotechnology, dietary supplements, food, cosmetics and combination-product companies. His practice spans all stages of the product life cycle, including premarket product development and launch strategy, clinical trials and preclinical testing, premarket submissions, product marketing and promotion, current good manufacturing practice, adverse event reporting, FDA inspections, recalls, and imports and exports. Son also advises clients on regulatory matters in connection with capital markets, financing and M&A transactions involving FDA-regulated entities.

In 2024, Son was seconded to a device startup company to serve as director of quality assurance and regulatory affairs, steering the company through the product-development phase while providing overall regulatory advice and strategy.

During his tenure at the FDA, Son advised the Office of the Commissioner, the Office of Combination Products, the medical product centers (the Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and Center for Biologics Evaluation and Research), and agency leaders on statutory and regulatory issues covering the life cycle of medical devices and combination products. He also advised on various aspects of the regulation of digital health products, electronic products, in vitro diagnostics, laboratory developed tests (LDTs), companion diagnostics and pharmacogenetic tests. In addition, he provided input on development of guidance documents, including Federal Register notices, and proposed and final rules and administrative orders.

Son served on the FDA's Office of Chief Counsel device team (most recently as co-team leader) and combination products team (most recently as team leader), where, in addition to advising on jurisdictional determinations, center assignments, and pre- and postmarket regulation of combination products, he provided guidance on issues concerning the use of digital health products with drugs and participated in working groups that formulated policies concerning prescription drug-use-related software (PDURS) and software used with drugs having additional conditions for nonprescription use (ACNU).

As associate chief counsel for enforcement, Son handled major enforcement actions brought by the FDA, including injunction, seizure, civil monetary penalty and contempt actions. He negotiated numerous civil consent decrees for the government. He also defended the FDA and its officials in several high-profile lawsuits brought under the US Constitution, Administrative Procedure Act, Whistleblower Protection Act and Freedom of Information Act. Son advised on enforcement and compliance issues involving FDA-regulated

products such as drugs, devices, food (including dietary supplements), veterinary drugs and biological products. He received numerous awards for his government service, including the Commissioner's Special Recognition Award, FDA Outstanding Service Award, Commissioner's Special Citation and FDA group awards.

Son began his legal career as a law clerk to now-retired Judge Marvin J. Garbis of the US District Court for the District of Maryland. He worked for several years at a multinational law firm as a litigation and regulatory lawyer before joining the FDA.

Select speaking engagements

- Speaker, "US Election Implications, Session 5: Election Implications for the Life Sciences Sector," CooleyREG Talks (January 2025)
- Moderator, "FDA's Regulation of Laboratory Developed Tests (LDTs) and Enforcement: What's Next?," FDLI's Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries (December 2024)
- Moderator, "Diagnostic Company Oversight," FDLI's Advertising & Promotion for Medical Products Conference (October 2024)
- Speaker, "Post-Market Surveillance of Medical Devices in the US: Requirements and Best Practices," TT LifeSciences US Annual Medical Device and Diagnostic Post-Market Surveillance and Vigilance Conference (June 2024)
- Speaker, "Interplay Between IP Protection and FDA Approval," San Francisco Intellectual Property Law Association Annual Seminar (April 2024)

Select publications

- Contributor, "Artificial Intelligence/Machine Learning Medical Device Regulatory Handbook," Cooley Life Sciences and Healthcare Regulatory Practice Group (September 2024)
- Contributor, "Sunsetting Enforcement Discretion for CLIA-Certified High-Complexity Tests – FDA Presses Ahead With LDT Final Rule," Cooley alert (May 6, 2024)
- Contributor, "Playing Nice in the Sandbox: FDA (Finally) Harmonizes Medical Device Manufacturing Requirements with ISO," Cooley alert (March 12, 2024)
- Author, "Companies Beware: More FDA Enforcement Ahead," Sedgwick's State of the Nation 2024 Report (February 2024)
- Contributor, "Proposed Rule on Laboratory-Developed Tests Takes Center Stage," Cooley alert (November 29, 2023)
- Contributor, "Overview of Medical Device Recalls," Sedgwick's 2023 Edition 3 Recall Index (November 2023)

Education

University of Maryland Francis King Carey School of Law
JD, 1999

Carroll College
BA, 1992

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 Court of Appeals for the Sixth Circuit

US District Court for the District of Maryland

US District Court for the District of Illinois

Memberships & Affiliations

Food and Drug Law Institute (FDLI) Digital Health Technology and Regulation Conference Committee, co-chair

FDLI Medical Products Committee

American Bar Association (ABA)