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Son is an experienced US Food and Drug Administration (FDA) lawyer, having spent almost 14 years at the agency as associate chief counsel for enforcement, associate chief counsel for devices and combination products, and senior counsel.

During his tenure at the FDA, Son advised the Office of the Commissioner, the Office of Combination Products (OCP), 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 concerning medical devices and combination products. He counseled FDA clients on issues covering the life cycle of medical devices, including jurisdictional determinations, clinical trials, registration and listing, premarket review, labeling and promotion, current good manufacturing practice, adverse event reporting, recalls, banning, and postmarket surveillance and studies. Son also advised on various aspects of the regulation of digital health products, electronic products, in vitro diagnostics (IVDs), laboratory developed tests (LDTs), companion diagnostics (CDx), and pharmacogenetic tests (PGx). 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 Office of Chief Counsel (OCC) device team (most recently as co-team leader) and combination products team (most recently as team leader), where he advised on jurisdictional determinations and center assignments, as well as premarket and postmarket regulation of combination products. He also provided guidance on issues concerning the use of digital health products with drugs, and he 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 significant, 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, and he worked at a multinational law firm as a litigation and regulatory lawyer for several years before joining the FDA. Prior to launching his law career, Son was a management analyst at the National Oceanic and Atmospheric Administration's Office of Atmospheric Research, where he was in

charge of the management control review program.

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