Greenleaf Health

Maura M. Norden, J.D.

Executive Vice President, Medical Device & Combination Products General Counsel

BACKGROUND	• Nearly 15 years advising FDA-regulated entities, investors, and public health organizations on a broad range of FDA regulatory matters
SPECIALTY	• FDA statutes, regulations, and policy • Development, clearance and approval, and marketing of FDA-related products • FDA regulation of in vitro diagnostics and laboratory-developed tests • FDA regulation of digital health • FDA regulatory due diligence
EXPERIENCE	• Joined Greenleaf after almost a decade of professional experience working in the food, drug, and medical device practice group at a large, multinational law firm

Maura Norden joined Greenleaf from the law firm Sidley Austin LLP in January 2015, following nearly a decade advising leading medical device and drug companies and investors on a broad range of FDA regulatory matters.

Maura uses her comprehensive and in-depth understanding of the FDA's statutory jurisdiction, regulatory requirements, and regulatory processes to provide strategic advice to FDA-regulated companies throughout the product lifecycle, from development to FDA premarket review and postmarket regulation. Maura advises a broad range of clients, including early-stage companies, large, multinational industry leaders, trade associations, and public health organizations.

More specifically, Maura's experience includes advising:

- A range of life sciences companies regarding regulation by and engagement with the FDA during the COVID-19 pandemic;
- In vitro diagnostic (IVD) companies on product development, regulatory pathway questions, and premarket review issues;
- Consumer technology companies with respect to potential FDA regulation under the medical device provisions of the Federal Food, Drug, and Cosmetic Act;
- Clinical laboratory clients regarding the FDA's historical and current policies related to laboratory-developed tests (LDTs);
- Digital health companies on the FDA's evolving approach to digital health products;
- FDA-regulated firms on compliance with FDA promotional requirements, drawing on experience gained during temporary assignments to multinational pharmaceutical companies, where she sat on copy review committees;
- Cosmetics companies with respect to permissible claims for cosmetic products;
- Investors by providing strategic advice and conducting regulatory assessments in connection with due diligence for transactions and working with investors post-acquisition on integration activities; and
- Trade associations and other public-health-focused organizations developing positions on various FDA policies, reports, proposed rules, and guidance documents.

Maura received her J.D., with honors, from the George Washington University Law School where she was an associate of *The George Washington International Law Review*. She received her B.A. from the University of Virginia where she was a Jefferson Scholar.