Greenleaf Health

Maura M. Norden, J.D.

Executive Vice President, Medical Devices & Combination Products
General Counsel

BACKGROUND	• More than 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-regulated 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 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 groups.

More specifically, Maura's experience includes advising:

- Digital health companies on the FDA's evolving approach to digital health products;
- 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);
- 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;
- Trade associations and other public-health-focused organizations developing positions on various FDA policies, reports, proposed rules, and guidance documents;
- In vitro diagnostic (IVD) companies on product development, regulatory pathway questions, and premarket review issues; and
- A range of life sciences companies regarding regulation by and engagement with the FDA during the COVID-19 pandemic.

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.