Hogan Lovells

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Biography

As both a physician and a lawyer, John Smith combines clinical and regulatory experience relating to the Food and Drug Administration (FDA) with a practical approach to addressing the FDA regulatory issues facing his clients. He focuses on bringing device-based technologies to market and has worked extensively in the AI-based image analysis space, assisting clients with computer-assisted triage, detection and diagnostic products in radiology, cardiology, gastroenterology, pathology, and ophthalmology, as well as other disciplines. He is familiar with FDA's complex data requirements in the AI-space and well-known to the Agency for his work in the field.

A board-certified diagnostic radiologist and former associate professor of radiology at Harvard Medical School, John joined Hogan Lovells' Medical Device Group in 2005. Since then, he has assisted clients in a range of FDA premarket submissions, including 510(k) notices, de novo requests, humanitarian device exemption applications, and premarket approval applications, including the advisory panel process.

John identifies successful regulatory strategies and presents them to the FDA via the pre-submission process; he assists with problem submissions through submission-issue meetings and administrative appeals. He also navigates the increasingly challenging FDA compliance landscape, addressing 483 and Warning Letter issues.

Having worked in the medical device area in academia,

Languages

English

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advertising and Promotion Compliance

Combination Products

Medical Devices

Premarket Review

industry, and at Hogan Lovells, John understands how to address both pre- and postmarket FDA regulatory issues. His practical approach has guided clients through successful marketing applications, addressed significant differences of opinion with the FDA through submission-issue meetings and regulatory appeals, and provided crucial support through challenging FDA enforcement actions. A *Super Lawyers* designee for multiple years, John is a leader in the medical device bar and well known to the FDA.

Representative experience

Assisting with submissions for diagnostic and therapeutic medical devices, including pre-subs, IDEs, 510(k)s, de novo requests, and PMAs.

Assisting with "first in class" marketing submissions for AI-based devices in radiology, gastroenterology and pathology.

Preparing clients for successful advisory panel meetings for first-in-class medical devices, as well as reclassification petitions.

Assisting clients in successful utilization of the submission-issue meeting request process.

Representing multiple clients in successful supervisory appeals at the Center for Devices and Radiological Health.

Assisting clients in obtaining a direct de novo reclassification for a first-in-class medical device without the need for clinical data.

Assisting a client in the preparation of successful humanitarian use device and humanitarian device exemption applications.

Advising multiple clients regarding advertising and promotional issues related to cleared and approved medical devices.

Awards and rankings

- BTI Client Service All-Stars, *BTI Consulting Group*, 2018

Digital Health

Advisory Panel Preparation

Artificial Intelligence

Medical Device Artificial Intelligence

Education and admissions

Education

J.D., University of Virginia School of Law, Order of the Coif, 1993

M.D., University of Virginia, 1992

B.A., Brown University, magna cum laude, 1986

Memberships

Chair, Committee on Resolutions and Bylaws, Radiological Society of North America

Member, American College of Radiology

Member, Virginia State Bar

Bar admissions and qualifications

District of Columbia

Virginia (inactive)

- FDA: Food and Drugs, *Washington, D.C. Super Lawyers*, 2014-2015
- Editor's Recognition Award for Reviewing with Special Distinction, Radiology, 2002-2004
- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), Rank 3, *Chambers USA*, 2022

Latest thinking and events

- Press releases
  - Hogan Lovells advises Palette Life Sciences on Acquisition by Teleflex
- Hogan Lovells Events
  - AI Health Law & Policy Summit
- News
  - FDA promotes pre-approval for changes to AI devices via Predetermined Change Control Plans
- Press releases
  - Hogan Lovells counsels P-Cure in FDA market authorization of a new proton therapy device for cancer treatment
- News
  - Evolution of FDA regulation of AI-based technology
- Hogan Lovells Events
  - Health Care AI Law and Policy Summit