Hogan Lovells

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Biography

Whether describing complex science in straightforward terms to lawyers or translating premarket and compliance regulatory requirements to scientists, Randy Prebula focuses on practical industry experience and a deep understanding of Food and Drug Administration (FDA) regulations to help clients navigate the intersections of science, policy, and law.

As a key resource for medical device, drug, human tissue, and combination product manufacturers, Randy works seamlessly across borders with clients and internal teams to help bring innovative medical products to market and meet patient needs throughout each product's unique life cycle.

As director of the firm's FDA Medical Devices and Technology practice area, Randy helps develop and integrate legal and non-legal professionals into our practice to leverage technical and legal knowledge that provides clients with practical, implementable solutions to meet their regulatory needs. He also helps companies with cutting-edge technologies navigate and optimize the FDA approval process.

He brings a wealth of experience in immunology, biochemistry, and new product development and provides real-world experience in developing, implementing, and maintaining compliant regulatory

Languages

English
Spanish

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

systems and procedures.

Representative experience

Assisted Cohera Inc. with premarket approval (PMA) of novel tissue adhesive, TissuGlu.

Successfully advocated the FDA's downclassification of an imaging device, tissue culture media products, and in vitro diagnostic systems, avoiding the need for a PMA.

Assisted a company with FDA regulation and U.S. marketing authorization for veterinary wound care products.

Assisted a biotechnology company with evaluating FDA regulatory requirements for stem cell and regenerative medicine products and medical device sales and distribution projects.

Assisted clients with Tissue Reference Group advisory opinion requests and Office of Combination Product Requests for Designation (RFD).

Assisted clients with cell sorter and isolation systems, mesenchymal cells of multiple tissue origins for use, and products intended for reproductive technology applications.

Awards and rankings

- Rising Stars, Food & Drugs, *Washington, D.C. Super Lawyers*, 2018

Latest thinking and events

- News
  - FDA warns over use of robotically-assisted surgical devices
- News
  - FDA seeks comments on how to transition approved drug products to device status under Genus

Postmarket Compliance and Enforcement Actions

Advisory Panel Preparation

Cell, Tissue, and Gene Therapies

Combination Products

In Vitro Diagnostics

Premarket Review

Product Development and Approval

Education and admissions

Education

J.D., The Catholic University of America, cum laude, 2010

B.S., University of South Carolina, 1984

Memberships

Member, Regulatory Affairs Professionals Society

Bar admissions and qualifications

District of Columbia

Maryland

- News
  - After a long and winding road, FDA finalizes much-debated “intended use” rule
- News
  - COVID-19 Report for Life Sciences and Health Care Companies
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (July 2021)
- Hogan Lovells Publications
  - Podcast: Talking the cure