Hogan Lovells

# Randy J. Prebula

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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 systems and procedures.

## Representative experience

## Languages

English
Spanish

## Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

## Industries

Life Sciences and Health Care

## Areas of focus

Postmarket Compliance and Enforcement Actions

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 spells out electromagnetic compatibility info needed in medical device premarket submissions
- Insights
  - Senate proposes greater FDA oversight of Lab Developed Tests
- News
  - FDA updates “cybersecurity in medical devices” guidance, seeks industry input
- Hogan Lovells Podcasts
  - Podcast: Talking the cure
- News

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

- COVID-19 Report for Life Sciences and Health Care Companies

- Insights
  - FDA proposes to conform the Quality System Regulation to the ISO 13485 standard