Hogan Lovells

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Biography

Rob Church brings a wealth of knowledge and experience to his pharmaceutical and biotechnology regulatory law practice, having previously served as an Associate Chief Counsel at the Food and Drug Administration (FDA), and in senior positions at Amgen Inc. He currently serves as the global lead of the clinical trials working group at Hogan Lovells.

At the FDA, Rob focused on the regulation of all aspects of the pharmaceutical industry, with particular emphasis on clinical trials, drug development, and new product approvals. At Amgen, Rob served as associate general counsel and the company's lead FDA lawyer. During his last three years at the company, Rob le Amgen's Global Research and Development Compliance Department where he had oversight responsibility for all quality assurance, audit, and compliance activities within Amgen's R&D operations.

Through these experiences, Rob developed an in-depth understanding of the regulatory requirements and operational details of clinical trials, new drug approvals, and the commercialization of pharmaceutical products. In his practice, Rob also frequently helps clients on pharmaceutical and biotechnology product life cycle management strategies, exclusivity questions, and bioequivalence standards.

Additionally, Rob and his team help clients draft and negotiate a wide range of regulatory agreements, including Safety Data Exchange Agreements, Manufacturing Quality Agreements, and all forms of

Practices

Pharmaceuticals and Biotechnology Regulatory

Complex Contracting

Health

Industries

Life Sciences and Health Care

Areas of focus

Product Development and Approval

Clinical Trials

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Pharmaceuticals and Biotechnology

Cell, Tissue, and Gene Therapies

agreements used in clinical trials. He also assists clients with corporate transactional matters, including the assessment of opportunities in the life sciences markets. His knowledge and understanding of the requirements and standards that impact his clients has helped him earn recognition as a Regulatory Star in *LMG Life Sciences*.

Immediately following law school, Rob clerked in the U.S. District Court for the Eastern District of Virginia. He also served as a Peace Corps volunteer in Honduras following his undergraduate studies.

Representative experience

Conducted an investigation of a drug company's compliance with FDA safety reporting regulations for clinical trials.

Helped a company obtain approval of its first drug by responding to significant data integrity and GCP compliance concerns raised by FDA.

Successfully assisted a biotechnology company appeal FDA's initial decision to deny the company's Fast Track designation request.

Assisted many companies draft and negotiate Safety Data Exchange Agreements, Manufacturing Quality Agreements, and all forms of clinical agreements.

Conducted numerous due diligence reviews of pharmaceutical and biotechnology assets being assessed for potential acquisition.

Awards and rankings

- Healthcare: Life Sciences, *Legal 500 US*, 2020

Latest thinking and events

- News
  - FDA issues ambitious new draft guidance to promote clinical trial diversity
- Hogan Lovells Podcasts
  - Podcast: Talking the cure

Transaction and Securities Disclosure Support and Due Diligence

Education and admissions

Education

J.D., William & Mary Law School, 1993

B.A., University of Virginia, 1987

Memberships

Member, Government Relations Committee, BayBio

Bar admissions and qualifications

California

- News
  - Meta ban on health-targeting ads will soon restrict clinical trial recruiters
- News
  - FDA RWD/RWE regulatory considerations in draft guidance highlight opportunities and challenges
- News
  - In sharp rebuke to Trump Administration, HHS notice ending Unapproved Drugs Initiative is withdrawn
- News
  - FDA offers guidance on clinical trial waivers for investigators at non-U.S. sites