Rachel Turow

Skadden

Of Counsel, Washington, D.C.

FDA Regulatory



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Education

J.D., University of Michigan Law School, 2006 (with honors)

M.P.H., University of Michigan School of Public Health, 2006

B.A., Stanford University, 2001 (with honors)

Bar Admissions

District of Columbia

Rachel Turow helps clients align their strategic business objectives with the current FDA regulatory landscape, drawing on more than two decades of experience in food and drug law. Her practice spans product development, regulatory strategy and policy advocacy, as well as FDA regulatory issues arising in corporate transactions and litigation.

A former regulatory counsel at FDA and senior in-house counsel, Ms. Turow provides clients with advice that blends distinct perspectives from her time at the agency and a practical understanding of business operations. She counsels clients on compliance and risk management across the full product life cycle and regularly works with Skadden's transactional and litigation teams to identify regulatory risks, assess their business implications and develop clear, actionable strategies.

Prior to joining Skadden, Ms. Turow held senior in-house counsel roles at major pharmaceutical manufacturers, where she oversaw regulatory strategy, policy and compliance. Her work spanned across the drug development life cycle, from preclinical development through post-market activities, including securing FDA approvals and launching new products. She has extensive experience with the development and FDA approval of generic drugs, 505(b)(2) products and biosimilars, including exclusivity and other complex regulatory issues specific to these products. Her medical device experience includes working on drug-led combination products and digital health products.

Most recently prior to joining Skadden, Ms. Turow led the regulatory legal team at one of the world's largest retailers, where she advised on its consumer products, including over-the-counter drugs, dietary supplements, cosmetics and consumer medical devices. She handled regulatory inquiries, coordinated with litigation and government affairs teams on high-priority FDA matters, and developed policies and processes to safeguard business operations. Her experience building and leading regulatory teams informs her approach to identifying inefficiencies, developing practical solutions and securing stakeholder support.

At FDA, Ms. Turow developed and implemented guidance and regulations, responded to citizen petitions and advised on approval issues for drugs and biologics at the Center for Drug Evaluation and Research (CDER) and for medical devices at the Center for Devices and Radiological Health (CDRH). She draws on this experience in helping clients anticipate how the agency may interpret and apply its regulations, as well as to develop regulatory and policy strategies aligned with strategic business objectives.

Ms. Turow's representations have included:

Transactions

- **Chimerix, Inc.** in its $935 million acquisition by Jazz Pharmaceuticals plc
- **International Flavors & Fragrances Inc.** in the $2.85 billion sale of its pharma solutions business unit to Roquette Frères S.A.
- **Banner Life Sciences, LLC** in its acquisition by Cycle Pharmaceuticals, Inc.
- **Exact Sciences Corporation** in its $23 billion acquisition by Abbott Laboratories

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Litigation

- an international arbitration between **a small biotechnology company** and a large pharmaceutical company
- **a biotechnology company** in a dispute with its contract research organization
- **a biopharmaceutical company** in an SEC investigation involving disclosures related to clinical trial developments ahead of an FDA approval submission

Regulatory Counseling and Compliance

- **a major generics and biosimilar manufacturer** as primary regulatory counsel, advising on all regulatory aspects of the company's generic, biosimilar and branded medicines businesses
- **a major pharmaceutical manufacturer** on the regulatory aspects of life cycle management for its flagship drug-device combination product
- **a startup medical device manufacturer** on obtaining a critical 510(k) clearance ahead of its U.S. launch
- **a skincare and consumer health company** on FDA regulatory issues relating to a product with atypical regulatory status and on state pharmaceutical licensing matters related to a change of control