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 leverages nearly two decades of experience in food and drug law to guide clients through a full range of FDA regulatory issues, with a focus on product development and regulatory strategy. A former regulatory counsel at FDA, Ms. Turow also served as in-house counsel at multinational developers and sellers of highly regulated products. She utilizes her extensive experience in advising on corporate transactions and litigation, as well as on developing regulatory risk management strategies and defending against regulatory enforcement actions.

Prior to joining Skadden, Ms. Turow oversaw regulatory strategy and compliance in various in-house counsel roles for major pharmaceutical manufacturers. Her regulatory work spans new drug development, from preclinical through post-market, and she has direct experience gaining FDA approval and launching new products. She has also worked extensively on developing and securing FDA approval of generic drugs, 505(b)(2)s and biosimilars, and has in-depth knowledge of exclusivity and other complex regulatory issues unique to those product categories. Ms. Turow also has medical device regulatory experience, with a particular focus on drug-led combination and digital health products.

Most recently, she led the regulatory legal team at one of the world's largest retailers. During this time, she directed a team of lawyers focused on a variety of regulatory issues related to consumer products, reduced legal risks across diverse product categories, developed policies and processes to safeguard business operations, handled regulatory inquires and enforcement actions and coordinated with the government affairs and litigation teams on high-priority FDA-related issues. In this capacity, Ms. Turow leveraged her knowledge of common regulatory issues that arise regarding over-the-counter drugs, dietary supplements, cosmetics and consumer medical devices.

At FDA, Ms. Turow developed and implemented guidance and regulations, responded to citizen petitions, and advised on issues relating to the approvals of drugs and biological products as part of the Center for Drug Evaluation and Research (CDER) and medical devices at the Center for Devices and Radiological Health (CDRH).

Ms. Turow's representations have included:

- International Flavors & Fragrances Inc. in the $2.85 billion sale of its pharma solutions business unit to Roquette Frères S.A.
- Chimerix, Inc. in its $935 million acquisition by Jazz Pharmaceuticals plc
- Paratek Pharmaceuticals, Inc., a portfolio company of B-FLEXION and Novo Holdings A/S, in its $330 million acquisition of OptiNose, Inc.
- BioCryst Pharmaceuticals, Inc. in the sale of its European ORLADEYO business to Neopharmed Gentili S.p.A. for $250 million upfront and up to $14 million in future milestone payments
- Capitol Hill Group and its related entities, along with Worldwide Golf Shops LLC, in its $112.7 million acquisition of Big 5 Sporting Goods Corporation
- Banner Life Sciences, LLC in its acquisition by Cycle Pharmaceuticals, Inc.
- Sage Therapeutics, Inc. in the board of directors' exploration of strategic alternatives following its rejection of an unsolicited bid by Biogen Inc. to acquire the remaining share in Sage it did not already own