KING & SPALDING

Eva A. Temkin

Partner
FDA and Life Sciences

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A partner in our FDA and Life Sciences practice, Eva provides strategic counsel to clients regarding significant and complex issues associated with FDA-regulated biomedical products. Eva draws upon her deep experience with these products at FDA to help clients navigate development, approval, post-market regulation and life-cycle management of drugs and biologics, biosimilars, and combination products.

Most recently, Eva acted as Director for Policy at the FDA's Office of Therapeutic Biologics and Biosimilars. In that position, Eva was the Agency lead for the Biosimilars Action Plan, FDA's roadmap for building a competitive market for innovator biologics and biosimilars, and she oversaw policy development related to biosimilars and other therapeutic biologics, including development of analytical and clinical data, review and approval of biologics license applications, data reliance, novel technologies and device presentations, exclusivity and life-cycle management considerations, and post-market issues. Additionally, as Associate Chief Counsel at the FDA's Office of Chief Counsel, Eva provided strategic counseling to government regulators on a wide range of biomedical-product issues and legislative initiatives, including data development and evidentiary standards, expedited approval pathways, product jurisdiction, patient focused drug development, real world evidence, drug supply chain security, and over-the-counter monograph reform. While at FDA, Eva oversaw the development of numerous guidances and rulemakings.

Eva earned her undergraduate degree from the University of Michigan and her J.D. from New York University School of Law, where she was the Law and Economics Fellow (merit-based full-tuition award) and editor of the *NYU Annual Survey of American Law*. She clerked for Judge John Gleeson on the U.S. District Court for the Eastern District of New York and then worked for several years in private practice, focusing on complex commercial litigation and administrative law matters.

Credentials

EDUCATION

J.D., New York University
B.A. Economics, University of Michigan

ADMISSIONS

District of Columbia
New York

CLERKSHIPS

Law Clerk, Judge John Gleeson, U.S. District Court for the Eastern District of New York

Insights

ARTICLE

September 20, 2021 • Source: Chain Drug Review

Fulfilling interchangeables' promise will take work

CLIENT ALERT

November 9, 2021

A Magic Mixing Cauldron for the 21st Century: FDA's new guidances on using real-world data in regulatory decision-making

October 18, 2021

HHS Continues Focus on Women's Health: AHRQ Calls for Data on Telehealth for Women

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Events

SPEAKING ENGAGEMENT

November 10, 2021

Eva Temkin to Speak at GRx+Biosims Generics + Biosimilars Conference

October 13, 2021

Eva Temkin to Speak at Food and Drug Law Institute's Advertising and Promotion for Medical Products Conference

October 5, 2021

Eva Temkin to Speak at DIA Biosimilars Conference

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News

IN THE NEWS

September 27, 2021 • Source: Pink Sheet

Eva Temkin explains why the planned research and new guidances included in the reauthorization of the US FDA's biosimilar user fee program should help answer several lingering interchangeability and biosimilar development questions

April 26, 2021 • Source: The Pharma Letter

Eva Temkin explains why the U.S. Food and Drug Administration's recent guidance on new drug applications during the pandemic fails to address certain key issues

April 12, 2021 • Source: Pink Sheet

Eva Temkin comments on Patrizia Cavazzoni being named the permanent director of the Center for Drug Evaluation and Research

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