

WILSON SONSINI

Shari Fleishman Esfahani

SENIOR COUNSEL

FDA Regulatory,
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FOCUS AREAS

Advertising, Promotions,
and Marketing

Consumer Litigation

Consumer Products and
Services

Digital Health

FDA Regulatory, Healthcare,
and Consumer Products

Government Investigations

Life Sciences

Patent Litigation

Regulatory

EXPERIENCE

Shari Fleishman Esfahani is senior counsel in the Washington, D.C., office of Wilson Sonsini Goodrich & Rosati, where she is a member of the firm's U.S. Food and Drug Administration (FDA), Regulatory, Healthcare, and Consumer Products practice. Upon graduation from Harvard Law School, Shari clerked for the Honorable Frank A. Kaufman, United States District Court for the District of Maryland, who sat by designation on the U.S. Courts of Appeals for the Federal Circuit, the Fourth Circuit, the Seventh Circuit, and the Eleventh Circuit. Previously a litigation partner at Akin Gump in Washington, D.C., Shari has over 20 years' experience as an extremely seasoned litigator trying high-stakes, complicated cases at the intersection of law, science, and technology. Her practice focuses on regulatory advice, litigation, and dispute resolution in the fields of life sciences, healthcare, consumer products, and intellectual property. She has broad experience litigating matters such as healthcare False Claims Act (*qui tam*) cases, intellectual property disputes (patent and trademark infringement), false advertising, product liability, commercial disputes (breach of contract, business torts), antitrust, including Orange Book delisting challenges, and regulatory enforcement actions.

A substantial part of Shari's practice involves aiding life sciences (pharma, medical device, and biologic) and healthcare companies with internal investigations and working with clients on compliance with government investigations, subpoenas, and investigative demands, as well as the defense of whistleblower *qui tam* suits involving the False Claims Act and the Anti-Kickback Statute. Shari has also managed litigations and helped lead trial teams involving diverse fields of science and technology including pharmaceuticals, various medical fields, and seals used in the semiconductor industry. She specializes in mastering complicated science and technologies and explaining them to judges and juries.

Shari regularly represents companies with FDA-regulated products and healthcare companies on strategic regulatory counseling matters. She also regularly conducts regulatory due diligence for private equity funds, acquirers, sellers, and underwriters in corporate transactions.

Shari also has substantial experience advising clients on complex advertising/promotion issues, including claim substantiation, disputes before the National Advertising Division of the BBB National Programs (NAD), and advertising lawsuits under Section 43(a) of the Lanham Act. She also regularly advises consumer product companies on Consumer Product Safety Commission related compliance.

CREDENTIALS

Education

- J.D., Harvard Law School, 1992
- A.B., Duke University, 1989
Summa Cum Laude, Phi Beta Kappa

Admissions

- Bar of the District of Columbia

- State Bar of Maryland
- U.S. District Court for the District of Maryland
- U.S. District Court for the Western District of Michigan
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Appeals for the Fourth Circuit
- U.S. Court of Federal Claims