KING & SPALDING

Mark S. Brown

Partner
FDA and Life Sciences

Washington, D.C.: +1 202 626 5443
mbrown@kslaw.com

Mark Brown is nationally recognized in Food & Drug Administration regulatory matters, civil litigation, criminal investigations and prosecutions, compliance matters and comprehensive risk assessments. Mark advises pharmaceutical, medical device and biotech companies, and pharmacies, on a broad range of FDA requirements and FDA regulatory issues that arise in products liability litigation and other disputes. A former Associate Chief Counsel for FDA, Mark is the Chair of the FDA and Life Sciences practice.

Mark has developed a national reputation for successfully resolving difficult and complex FDA compliance matters and enforcement actions. For pharmaceutical, medical device and food companies, and pharmacies, he has successfully negotiated and managed numerous complex consent decrees of injunction, successfully defended an injunction action brought by FDA, and persuaded the government not to bring enforcement actions in other civil and criminal matters.

Mark regularly counsels clients on drug safety issues, clinical trials, adverse event reporting, quality systems and manufacturing practices for drugs and devices. He also provides guidance concerning product failure investigations, factory inspections, recalls, product labeling, drug compounding, advertising, promotion, sales and marketing practices, and regularly advises clients on strategies for obtaining FDA approval and clearance for medical products.

Mark also handles FDA-related issues in product liability and commercial litigation. He was an architect of the preemption defense for both pharmaceutical and medical device clients, developing supporting evidence, briefing and arguing federal preemption motions in various federal and state courts.

Before joining the FDA, Mark was an attorney in the Bureau of Consumer Protection at the Federal Trade Commission, where he concentrated on consumer fraud, healthcare advertising and promotional activities. He developed FTC enforcement actions against weight-loss centers, in vitro fertilization clinics and Northern Virginia infertility doctor Cecil B. Jacobson, who was later convicted of defrauding patients.

Matters

***Phillip Morris USA** v. FDA*, 202 F.Supp. 3d (D.D.C. 2016). Represented one of the plaintiffs in a successful legal challenge to an FDA guidance governing the Substantial Equivalence Review

process for tobacco products.

United States v. ***Franck's Lab*****,** 2011 WL 4031102 (M.D. Fla., Sept. 12, 2011). Lead counsel in successful defense of FDA enforcement action against pharmacy compounder of veterinary drugs.

During his 30-year career, he has served as lead counsel and negotiator for numerous consent decrees of injunction, both during his tenure with FDA (1990–1994), and since 1994 in private practice. For example, he has negotiated consent decrees some of the world's largest device manufacturers, including **Medtronic** (2008 and 2015), **The General Electric Company** (2007) and **Baxter Healthcare** (2006).

Since 2002, served on the national counsel team for **GlaxoSmithKline** in the Paxil Products Liability Litigation. Represented GSK on all FDA-related issues, including federal preemption. Argued and won a summary judgment motion on federal preemption grounds in *O'Neal v.* ***SmithKline Beecham*** (E.D. Cal 2008). In 2002, represented GSK in successfully defending an injunction seeking to enjoin GSK from making claims in direct-to-consumer television advertising for Paxil.

From 1995 to 2001, served on **3M**'s National Trial Team in the Silicone Gel-Filled Breast Implant Litigation. Responsible for virtually all FDA issues and had primary responsibility for preparation and handling of defense expert witnesses, and cross-examination of adverse witnesses on FDA issues.

Connaught Laboratories v. ***SmithKline Beecham*****,** 7 F.Supp. 2d 477 (D.Del. 1998), appeal dismissed, 165 F.3d 1368 (1999). Represented SmithKline Beecham in winning one of the few successful motions to compel FDA to provide testimony by its research scientists in patent litigation relating to purified form of pertactin, a component of the pertussis vaccine.

Next Nutrition, Inc. *v. SportPharma USA, Inc.*, No. 97-CV-1898J (1997). Served as lead counsel to a dietary supplement company that brought an action under the Lanham Act alleging false and misleading comparative advertising relating to competing products. Successfully negotiated a favorable settlement by obtaining a consent decree of permanent injunction and a damage award.

Represented **pharmaceutical manufacturers** in grand jury investigations regarding data integrity concerns in regulatory submissions to FDA, and alleged cGMP violations. In both cases, the U.S. Department of Justice declined to prosecute the company and individuals under investigation.

Conducted internal investigations into the sales and marketing practices of **multiple international pharmaceutical and biotech companies** to develop a risk profile and recommendations for reducing potential liability and risk exposure.

Conducted comprehensive prelaunch risk assessments for **a Top 10 pharmaceutical company's** blockbuster drug to identify potential medical, scientific, regulatory and products liability risk areas.

Conducted a risk assessment for **a top tier biotechnology company's** drug safety system to identify areas for possible improvement in pharmacovigilence planning, postmarket signal detection and investigation, and business decision-making.

Led numerous internal investigations for **biotechnology, pharmaceutical and medical device manufacturers** into allegations made by current and former employees regarding product integrity issues, sales and marketing activities, and manufacturing quality issues.

Represented **several drug and device manufacturers** concerning product approvals, and in

responding to FDA requests for information relating to promotion and advertising, manufacturing practices, field alerts, recalls and numerous post-market issues.

Represented one of the nation's foremost cardiovascular institutes and some of the leading interventional cardiologists in responding to deficiencies identified during FDA inspections and developing appropriate corrective action to avoid further FDA regulatory enforcement.

Represented a device manufacturer in obtaining expedited PMA review and approval in 90 days for a first-of-a-kind device to treat aneurysms in the renal vascular arteries. Successfully obtained approval for a major PMA supplement for the same product.

Represented a device manufacturer and coordinated an extensive product investigation into reported failures of an implantable device featuring sophisticated failure analyses and clinical assessments.

Conducted extensive training on FDA regulatory, IRB and protocol requirements for clinical investigators participating in the study of implantable devices.

Assisted numerous companies in preparing for FDA inspections, developing responses to FDA observations (FDA-483 forms) and warning letters related to manufacturing practices, quality systems, adverse event reporting, deviations from approved drug master files and manufacturing processes, and a variety of other regulatory matters. Assisted these companies in preparing for meetings with FDA compliance officials in District Offices, centers for drugs and devices, and the Office of Chief Counsel.

Credentials

EDUCATION

J.D., St. Louis University
A.B. Political Science, University of Michigan

ADMISSIONS

U.S. Court of Appeals for the Federal Circuit
U.S. Court of Appeals for the Second Circuit
U.S. Court of Appeals for the Seventh Circuit
U.S. Court of Appeals for the Ninth Circuit
U.S. Court of Appeals for the Tenth Circuit
U.S. District Court for the District of Maryland
U.S. District Court for the Eastern District of Wisconsin
District of Columbia
Maryland
Pennsylvania

ASSOCIATIONS

District of Columbia Bar
Maryland State Bar

LANGUAGES

German

Recognition

Recognized by Super Lawyers as Top Rated FDA Attorney
LAW & POLITICS, 2007, 2010–2011, 2013–2017

Ranked Among the Best Life Sciences Lawyers in the U.S.
LEGAL 500, 2016

Named Life Sciences Star
LMG LIFE SCIENCES, 2012–2016

Recognized as one of Washington's Best Lawyers
WASHINGTONIAN MAGAZINE, 2004–2016

Superior Achievement Award
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, 1992

Commendable Service Award
FDA, 1992–1994

Insights

CLIENT ALERT
December 11, 2020
Department of Justice Vows Vigorous Enforcement of Clinical Trial Fraud

FEATURE
January 15, 2021
General Counsel Internal Investigations Decision Tree for the Life Sciences Industry

January 15, 2021
General Counsel Internal Investigations Decision Tree for the Food and Beverage Industry

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Events

CONFERENCE
November 12, 2019
12th Annual King & Spalding Pharmaceutical University

September 5, 2019
12th Annual Medical Device Summit

WEBINAR
March 16, 2021
The New Intensified Scrutiny and Enforcement of FDA-Regulated Clinical Trials

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News

IN THE NEWS
March 6, 2020 • Source: Law360
FDA practice profiled as head of the practice Mark Brown highlights policy issues to watch

RECOGNITION

August 21, 2020

The Best Lawyers in America Recognizes 128 King & Spalding Lawyers in its 2021 Guide

June 15, 2020

King & Spalding Earns Top-Tier Rankings in Legal 500 United States 2020 Guide

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