KING & SPALDING

Sheldon Bradshaw

Partner
FDA and Life Sciences

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Sheldon Bradshaw counsels clients whose products are regulated by the Food and Drug Administration (FDA). A partner in our FDA and Life Sciences practice with a focus on life sciences and healthcare, Sheldon provides legal and regulatory advice to companies ranging from small growth firms to large multinational corporations.

Previously, Sheldon served as Chief Counsel of the FDA from 2005 to 2007. In that role, he provided legal advice to the Secretary and Deputy Secretary of the U.S. Department of Health and Human Services, as well as to FDA's senior leadership, on issues relating to drugs, biologics, medical devices, food, animal feed and drugs, cosmetics, dietary supplements and other regulated products.

As FDA Chief Counsel, Sheldon also supervised all agency litigation, and reviewed and cleared every significant FDA regulation, guidance document and warning letter issued by the Agency.

Before joining the FDA, Sheldon held senior positions at the U.S. Department of Justice (DOJ), where, among other responsibilities, he provided advice to the FDA and testified before Congress on matters under the FDA’s jurisdiction.

Matters

Advised **pharmaceutical companies** on drug approval strategies involving new drug applications, 505(b)(2) applications, suitability petitions, and abbreviated new drug applications (ANDAs); biotech companies on biologics licensing strategies involving biologics licensing applications (BLAs) and biosimilars; and device manufacturers on 510(k) and pre-market approval (PMA) applications and FDA's de novo classification process.

Counseled clients regarding **product life cycle management** (including the development of new products and line extensions), **Hatch-Waxman issues** (including patent and non-patent exclusivities, 30-month stays and FDA's Orange Book), **user fees, and risk evaluation and mitigation strategies (REMS).**

Assisted **pharmaceutical, biotech and device manufacturers** with post-approval issues, including labeling changes, manufacturing changes, adverse event reporting, current good manufacturing

practice requirements (cGMPs) and promotional activities.

Helped clients respond to 483 **inspectional observations** issued by FDA investigators and Warning and Untitled Letters issued by FDA officials.

Assisted clients who have had facilities or products placed on an **import alert** or **the application integrity policy.**

Advised clients on issues related to the practices of **medicine and pharmacy,** including issues related to compounding and the distinction between traditional pharmacy compounding and outsourcing facilities.

Represented companies in **interactions with regulatory officials** from the FDA, HHS and DEA.

Assisted clients with **due diligence** on FDA-regulated entities.

Advised clients on issues related to **drug shortages.**

Assisted companies with FDA's review of **proprietary drug names.**

Assisted companies in **government investigations** involving data integrity, healthcare fraud and abuse, qui tam lawsuits, preemption, off-label promotion, misbranding, adulteration and the Anti-Kickback Statute, along with criminal, civil and administrative enforcement actions and related civil litigation regarding the same.

Helped companies negotiate **consent decrees** with FDA and DOJ and **corporate integrity agreements** with HHS's Office of the Inspector General.

Advised clients regarding **"intended use"** and the types of claims that distinguish drugs and devices from cosmetics, dietary supplements and food.

Reviewed **labeling** of drugs, both Rx and OTC, biologics, devices, dietary supplements, food and cosmetics for compliance with the FD&C Act.

Advised clients on **Rx to OTC switches.**

Counseled clients on legal issues related to the design and implementation of **clinical trials,** including the preparation of investigational new drug (IND) applications and investigational device exemption (IDE) applications and the submission of information to the clinical trial registry and the new clinical trial results database.

Provided clients with **crisis management counseling** on product recalls, government inspections and seizures, adverse events and similar issues.

Served as an expert witness on **FDA regulatory issues** in multiple cases.

Credentials

ADMISSIONS

U.S. Court of Appeals for the Fourth Circuit
U.S. Court of Appeals for the Tenth Circuit
U.S. District Court for the District of Montana
U.S. District Court for the District of Columbia
District of Columbia
Montana

Insights

ARTICLE

April 1, 2018 • Source: The Wall Street Journal

The Twisted Case of the 'Deceptive' Pretzels

CLIENT ALERT

May 14, 2019

CMS Issues Final Rule Requiring the Disclosure of Drug List Prices in Direct-to-Consumer Television Ads

Events

CONFERENCE

September 5, 2019

12th Annual Medical Device Summit

November 13, 2018

11th Annual King & Spalding Pharmaceutical University

WEBINAR

November 10, 2020

13th Annual King & Spalding Medical Device Summit

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News

IN THE NEWS

November 13, 2020 • Source: Law360

Daniel Sale, Jeff Bucholtz, Sheldon Bradshaw and Paul Mezzina represent Genus Lifesciences in a lawsuit against the FDA

November 11, 2020 • Source: Medtech Insight

Sheldon Bradshaw explains why President-elect Joe Biden will rush to get the heads of the HHS and the FDA confirmed by the Senate quickly to deal with the coronavirus pandemic

November 10, 2020 • Source: MedTech Strategist

Sheldon Bradshaw why it will be a challenge to accelerate the release of regulations and guidance documents in the closing months of this year

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