KING & SPALDING

# D. Kyle Sampson

Partner
*FDA and Life Sciences*

Washington, D.C.: +1 202 626 9226
Mobile: +1 202 340 8202
ksampson@kslaw.com

Kyle Sampson focuses on Food and Drug Administration regulatory, compliance and enforcement issues. As a partner in our FDA and Life Sciences practice, Kyle represents companies in the full range of regulatory and enforcement issues.

Kyle advises food, drug, biologics, medical device, cosmetics and dietary supplement companies on FDA compliance, regulatory and enforcement matters. His practice also includes strategic advice and compliance counseling, enforcement, litigation and transactional matters.

Kyle has engaged in extensive public service in every branch of the federal government. He served in the White House as Associate Counsel to the President; at the Department of Justice as a Special Assistant U.S. Attorney and as Counselor and Chief of Staff to two attorneys general; and in the U.S. Senate as Counsel to the Senate Judiciary Committee.

## Matters

Assist **pharmaceutical and medical device companies** in developing and implementing comprehensive regulatory and healthcare fraud and abuse compliance programs involving off-label promotion, anti-kickback violations, federal healthcare program reimbursement, and pricing and false claims actions.

Serve as counsel to **pharmaceutical, biotechnology and medical device companies** in regulatory matters involving product development and commercialization.

Represent **pharmaceutical and medical device manufacturers** in responding to FDA enforcement actions, including Form FDA-483 observations and Warning Letters.

Serve as compliance counsel for **a pharmaceutical company** subject to consent decree resulting from allegation that company provided false scientific data to FDA in regulatory submissions.

Represent **a medical device manufacturer** in consent decree negotiations with FDA and Department of Justice.

With Monitor appointed by U.S. Attorney's Office for the District of New Jersey under Deferred Prosecution Agreement (DPA), oversaw **orthopedic device manufacturer**'s compliance with federal Anti-Kickback Statute and other federal healthcare laws and its implementation of comprehensive compliance program.

Review advertising and promotional materials and activities for prescription drugs, biologics and devices for **various clients.**

Provide advice to **manufacturers of controlled substances and listed chemicals** regarding compliance with the Controlled Substances Act and Drug Enforcement Administration regulations.

Represent **manufacturers of drug, medical device, human food, animal feed and consumer products** in negotiations with the FDA over recalls of manufacturers' products, including proper classification of recall, assessment of health hazard, and development and implementation of recall strategy.

Represent **foreign manufacturers and domestic importers** in responding to the FDA's detention of imports and placement of firms on Import Alert, including negotiating firms' removal from Detention Without Physical Examination (DWPE).

Help **pharmaceutical and medical device companies** respond to widespread counterfeiting of products and unlawful importation by Internet pharmacies and others in violation of the Federal Food, Drug, and Cosmetic Act and the Lanham Act.

Provided advice to two **attorneys general** on legal and policy issues, coordinated Justice Department positions in criminal prosecutions and civil litigation, and formulated and implemented policy initiatives and legislative proposals.

As Special Assistant U.S. Attorney, conducted **trial and appellate litigation,** including arguing three cases in the U.S. Courts of Appeals for the Fourth and Ninth Circuits.

## Credentials

### EDUCATION

J.D., University of Chicago, with honors
B.A., Brigham Young University

### ADMISSIONS

U.S. Court of Appeals for the Fourth Circuit
U.S. Court of Appeals for the Eleventh Circuit
U.S. Court of Appeals for the D.C. Circuit
U.S. District Court for the District of Utah
District of Columbia
Utah

### CLERKSHIPS

Law Clerk, Hon. Karen J. Williams, U.S. Court of Appeals for the Fourth Circuit

## Recognition

Attorney General's Award for Outstanding Service to the Attorney General, the Department of Justice, and to America

U.S. DEPARTMENT OF JUSTICE, 2005

## Insights

CLIENT ALERT

*August 27, 2021*

FDA Rejects Bids To Market CBD-Based Dietary Supplements

*August 6, 2021*

FDA Finalizes “Intended Use” Regulations

*May 5, 2021*

Genus Medical Technologies LLC v. FDA: D.C. Circuit Holds FDA Cannot Regulate Devices as Drugs

VIEW ALL ON KSLAW.COM

## Events

SPEAKING ENGAGEMENT

*March 23, 2021*

Kyle Sampson to Speak on 8th Annual Legal, Regulatory, and Compliance Forum on Cosmetics & Personal Care Products Virtual Conference

WEBINAR

*September 9, 2021*

14th Annual King & Spalding Medical Device Summit

*February 23, 2021*

FDA Inspections in 2021 for Drug and Device Manufacturers

VIEW ALL ON KSLAW.COM

## News

IN THE NEWS

*January 22, 2021 • Source: Medtech Insight*

Kyle Sampson explains why a joint U.S. Department of Health and Human Services and FDA notice that could exempt a plethora of medical devices from premarket review falls under a recent regulatory freeze from the Biden administration

*January 21, 2021 • Source: Bloomberg Law*

Kyle Sampson and John Shakow comment on the Department of Health and Human Services under President Biden inheriting challenges to Trump-era moves to lower drug prices

*November 16, 2020 • Source: MedTech Insight*

Kyle Sampson explains why the new U.S. Congress will work quickly to reestablish key provisions of the Affordable Care Act

VIEW ALL ON KSLAW.COM