

# Nikki Reeves

Partner  
*FDA and Life Sciences*

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Nikki Reeves is an FDA and healthcare regulatory compliance lawyer with more than 20 years of experience. Nikki co-chairs the firm’s Life Sciences and Healthcare Industry Group, which is comprised of more than 350 lawyers across fifteen practice areas in the firm. Nikki was named a *2020 Law360 Compliance MVP* and 2019 and 2020 *LMG Life Sciences Star* in FDA Pharmaceutical and in FDA Medical Device. A partner in our FDA & Life Sciences practice, Nikki advises pharmaceutical and medical device companies on pre- and post-market FDA regulatory compliance and enforcement matters ranging from clinical trials to good manufacturing practices to labeling, advertising, and promotion of FDA-regulated products. Nikki has been the lead FDA regulatory advisor to her clients on 150+ transactional matters. She is an expert on federal Sunshine, state, and international transparency/disclosure laws and leads two industry compliance coalitions.

Nikki counsels pharma and device companies on FDA inspections, Form 483s, Warning Letters, product recalls, import detentions, clinical holds, and other FDA compliance and enforcement matters. She conducts risk assessments and internal investigations into allegations of FDA and healthcare program noncompliance. She routinely advises company executives and board members and represents her clients before federal agencies. She has established robust compliance programs and policies for numerous life sciences companies. Nikki has also served as an interim General Counsel and as a Chief Compliance Officer for her life sciences clients.

Nikki leads two pharma and device industry coalitions on transparency and disclosure laws. The *Ad Hoc Sunshine and State Law Compliance Group* is a coalition she advises on federal Sunshine Act and state transparency/disclosure and gift ban laws. The *International Marketing and Disclosure Compliance Group* is a separate coalition of companies she advises on the growing area of transparency and disclosure laws and industry codes of conduct in the EU, Australia, Japan, and numerous other countries and regions.

King & Spalding’s FDA & Life Sciences Practice has been named *Law360 Practice Group of the Year* from 2017-2020. King & Spalding’s FDA & Life Sciences Practice is ranked by Chambers Legal, LMG Life Sciences, U.S. News, and Best Lawyers.

Nikki is a frequent speaker and author on FDA advertising/promotion, clinical trials, compliance, and transparency law matters. She currently serves on the Advisory Board for FDAnews. She was formerly on the Food and Drug Law Institute (FDLI) Editorial Advisory Board for the *FDLI Food &*

*Drug Law Journal* and a member of the FDLI Medical Device Committee. Nikki has also served on the Leadership Advisory Board for the National Women’s Law Center and on the Special Gifts Committee for the Arlington Free Clinic.

Nikki was elected by her partners to serve a three-year term on the firm’s Management Committee in 2017. In addition to chairing the firm’s Life Sciences and Healthcare Industry Group, Nikki served for three years on the firm’s Lateral Partner Committee and for three years on the firm's Partners Committee. She was the Hiring Partner for the Washington, D.C. office for two years.

## Matters

Advised companies on FDA advertising and promotion rules for drugs, devices, and cosmetics, including social media, new product launches, DTC, physician and payor communications, broadcast ads, reprints, and investor communications.

Advised on compliance with the federal Physician Payment Sunshine law, state laws targeting industry marketing practices, sales representation licensing, drug price transparency, and disclosure of clinical trial data. Advised on compliance with global transparency laws and industry codes of conduct.

Advised life sciences clients on preparing for FDA inspections of clinical trials sites and manufacturing facilities, and responding to FDA Form 483s, FDA Warning Letters, product recalls, import detentions, and government investigations involving alleged advertising/promotion violations.

Conducted FDA regulatory due diligence and related counseling in connection with more than 100+ transactions involving pharmaceutical, medical device, biotechnology, and cosmetic companies.

Set up healthcare compliance programs for pharmaceutical and medical device manufacturers and related healthcare compliance policies and codes of conduct. Served as interim Chief Compliance Officer for a pharmaceutical manufacturer for a two year period and managed all aspects of the company healthcare compliance program.

Conducted internal investigations into potential FDA GCP, GMP, and healthcare compliance policy violations.

Led risk assessments of healthcare regulatory compliance programs and policies and advised on compliance with FDA regulations, HHS OIG Compliance Program Guidance, and the PhRMA and AdvaMed Codes on Interactions with Healthcare Professionals.

## Credentials

### EDUCATION

J.D., University of Maryland, high honors, Order of the Coif

M.P.A., North Carolina State University, cum laude

B.A., North Carolina State University

### ADMISSIONS

District of Columbia

Maryland

## Insights

## CLIENT ALERT

*September 24, 2020*

FDA Proposes New Rule Modifying its “Intended Use” Regulations

*April 17, 2020*

Europe Update – Life Sciences Products and COVID-19: From Clinical Trials to Regulatory Flexibility

U.S. and EU Regulators and Institutions Issue Guidance on Clinical Trial Conduct during COVID-19 Pandemic

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## Events

### SPEAKING ENGAGEMENT

*April 30, 2020*

Nikki Reeves to Speak on Pharma and Medical Device Ethics and Compliance Webinar

### WEBINAR

*November 10, 2020*

13th Annual King & Spalding Medical Device Summit

*January 29, 2020*

2019 Year in Review for Drug and Device Advertising and Promotion – Lessons Learned from 2019 FDA Enforcement Letters and Other Key Developments

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## News

### IN THE NEWS

*October 13, 2020 • Source: Law360*

Law360 profiles 2020 Compliance MVP Nikki Reeves

### RECOGNITION

Law360 Recognizes Jim Boswell and Nikki Reeves as 2020 MVPs

*June 15, 2020*

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

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