

John D. Shakow

Partner
FDA and Life Sciences

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John Shakow's practice focuses on complex regulatory, commercial, investigation and litigation issues related to pharmaceutical government pricing and price reporting. A partner in our FDA and Life Sciences practice, John represents pharmaceutical and biotechnology manufacturers in every facet of government drug payor program compliance.

John has 20 years of experience in helping pharmaceutical and biotechnology clients resolve commercial and organizational challenges while maintaining the integrity of their price-reporting compliance efforts.

He counsels clients on their rights and obligations under Medicaid, Medicare, the Federal Supply Schedule, 340B and related programs, and regularly assists them in interactions with the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, the Department of Health and Human Services Office of Inspector General, and the Veterans Administration.

John often conducts in-depth pricing assessments to develop and implement government price calculation and reporting policies, procedures, systems and methodologies. John has overseen over a dozen substantial *bona fide* service fee analysis projects for large and small drug manufacturers. He is experienced in managing the coordination and integration of pricing methodologies in major pharmaceutical mergers.

John has significant pharmaceutical litigation and investigation experience. He regularly challenges government agencies' positions on drug pricing and reimbursement matters, and defends clients in federal and state investigations related to price reporting. John has counseled drug manufacturers before the House Energy & Commerce and Senate Finance committees in drug-pricing investigations and inquiries; drafted briefs in the only U.S. Supreme Court case to address drug pricing (*Santa Clara County v. Astra*); and represented a major pharmaceutical manufacturer in the nationwide Average Wholesale Price litigation. His pharmaceutical litigation experience also includes best-efforts marketing arbitration between manufacturers and litigation before the Drug Enforcement Administration over licensing to import controlled substances.

Credentials

EDUCATION

J.D., University of Virginia

B.A., Swarthmore College

ADMISSIONS

U.S. Court of Appeals for the D.C. Circuit
U.S. District Court for the Eastern District of Virginia
U.S. District Court for the Central District of Illinois
U.S. District Court for the District of Columbia
District of Columbia
Virginia

ASSOCIATIONS

District of Columbia Bar
State Bar of Virginia

Recognition

Healthcare: Pharmaceutical/Medical Products Regulatory in Band 3, 2021

CHAMBERS

2021 Recommended Key Lawyer

LEGAL 500

Shortlist for Regulatory Attorney of the Year: Pricing & Reimbursement, 2017 and 2018

LMG LIFE SCIENCES

2016 Lifetime Achievement Award

INSTITUTE FOR INTERNATIONAL RESEARCH'S MEDICAID DRUG REBATE PROGRAM

Life Sciences Star: Pricing and Reimbursement, 2012 to 2018

GUIDE TO LEADING LIFE SCIENCES FIRMS AND ATTORNEYS IN NORTH AMERICA

Insights

ARTICLE

March 11, 2021

Biden Administration - What's Ahead for the Life Sciences Industry?

CLIENT ALERT

February 3, 2021

Implementation of Final Rule Excluding PBM Rebates from Discount Safe Harbor Delayed Until 2023

Final Rule on VBP, Patient Assistance and Line Extensions Presents Opportunity and Risk for Drug Manufacturers

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Events

CONFERENCE

November 12, 2019

12th Annual King & Spalding Pharmaceutical University

SPEAKING ENGAGEMENT

October 12, 2021

John Shakow to Speak at Informa Medicaid Drug Rebate Program About 340B

WEBINAR

November 10, 2020

13th Annual King & Spalding Medical Device Summit

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News

IN THE NEWS

November 1, 2021 • Source: Informa Connect

John Shakow explains why there needs to be a major overhaul to the 340B program

June 24, 2021 • Source: Bloomberg Law

John Shakow discusses the impact of the Health and Human Services Department standing its ground in pushing drugmakers to pass along federal discounts to contract pharmacies

RECOGNITION

October 5, 2021

LMG Life Sciences Recognizes King & Spalding With Multiple Rankings in its 2021 Guide

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