ArentFox Schiff LLP
Attorneys

Abha Kundi*

COUNSEL AND LONGEVITY & HEALTHSPAN INDUSTRY GROUP CO-LEADER

Previously responsible for guiding implementation of the Drug Supply Chain Security Act (DSCSA) at FDA, Abha advises pharmaceutical clients on supply chain regulatory law and policy and other FDA regulatory issues.

Industries

Life Sciences
Longevity & Healthspan

Practices

Food, Drug, Medical Device & Cosmetic
— Drugs & Biologics

Education

Boston University School of Public Health, MPH, 2009

Boston University School of Law, JD, 2008

Kalamazoo College, BA, magna cum laude, 2004

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Abha draws on nearly 15 years of experience handling key leadership responsibilities at FDA to counsel pharmaceutical industry clients on FDA compliance and enforcement matters spanning drug product quality, incident, recall, and shortage strategy, import and export compliance, supply chain security, distribution practices, and manufacturing oversight. Her firsthand perspective into federal regulation of pharmaceutical distribution and serialization-related mandates uniquely positions her to help clients navigate and develop strategies for FDA compliance, particularly related to DSCSA conformance and enforcement.

For over a decade, Abha developed and directed FDA's DSCSA program. She was instrumental in promulgating the regulations of the DSCSA and developing accompanying guidance on compliance for pharmaceutical manufacturers, repackagers, wholesale distributors, third-party logistics providers, dispensers, and other industry stakeholders.

Abha most recently served as Team Lead of the Office of Drug Security, Integrity & Response within the Office of Compliance, Division of Supply Chain Integrity and Supply Chain Security Branch at FDA's Center for Drug Evaluation and Research. She led a critical compliance program and multidisciplinary team of lawyers, regulatory affairs specialists, and medical experts responsible for regulatory oversight of the pharmaceutical commerce landscape, including legal analysis, policy development, compliance actions, incident response, and strategic engagement with industry stakeholders and federal and state regulators.

In addition to and in conjunction with her role in the development of the Office of Compliance's DSCSA program, Abha guided case development, regulatory steps such as warning letters, and enforcement actions; managed responses related to drug supply chain incidents, recalls, and shortages, including evaluating situations to contain public health exposure to potentially harmful drugs; and received Agency-, Center-, and Office of Compliance-level awards for achievements including public health emergency response coordination efforts and critical drug approvals. She maintains strong relationships with FDA experts and leaders, outside regulators, and organizations across the pharmaceutical industry.

**Not admitted in the District of Columbia. Admitted in New York only. Practicing under the supervision of District of Columbia Bar members.*

Bar Admissions

New York