About the Authors

Abraham Gitterman: Abraham Gitterman is an associate in Arnold & Porter LLP’s FDA and Healthcare practice group, where he focuses on FDA and healthcare regulatory matters involving pharmaceuticals and medical devices. He has worked on issues relating to compliant industry promotional and medical activities, including use of social media, mobile health applications, industry/healthcare professional relationships, supply chain and track and trace matters, drug compounding, the Physician Payments Sunshine Act, and continuing medical education (CME). Mr. Gitterman has assisted in extensive reviews of corporate compliance programs for various life science companies and healthcare entities to ensure compliance with the Anti-Kickback Statute and the Federal Food, Drug, and Cosmetic Act. Mr. Gitterman frequently speaks and writes about the Sunshine Act and has authored a number of papers and articles regarding its implications on industry and related stakeholders.

Dan Kracov: Dan Kracov is co-chair of Arnold & Porter, LLP’s FDA and Healthcare practice. He assists clients, including start-up companies, trade associations, and large manufacturing companies, in negotiating the challenges relating to the development, approval and marketing of drugs, biologics, and medical devices. Mr. Kracov regularly handles product and compliance-related investigations, the development of regulatory corporate compliance programs,
and due diligence in financings, mergers and acquisitions. He has a widely-recognized experience in biomedical product-related public policy matters, including Congressional investigations and FDA-related legislative strategies.

**Lauren Miller:** Lauren Miller is an associate in Arnold & Porter LLP’s FDA and Healthcare practice group, where she provides counseling on regulatory and public policy issues for clients in the drug, food, medical device, and healthcare sectors. Her work includes advising clients on food and drug advertising requirements, medical device premarket classification issues, healthcare fraud and abuse, legislative matters and analyzing compliance risks related to mergers and acquisitions of FDA regulated companies. Ms. Miller graduated *cum laude* from Howard University School of Law where she was a Senior Staff Editor on the *Howard Law Journal*, and a legal writing Dean’s Fellow. While in law school, Ms. Miller also served as a judicial intern to Judge Stephen Murphy with the United States District Court for the Eastern District of Michigan. Prior to law school, Ms. Miller received her BA in Psychology from the University of Michigan.

**Alan Reider:** Alan Reider is a Partner in the FDA and Healthcare practice group in Arnold & Porter, LLP’s Washington, DC office, with more than 30 years of experience representing national healthcare corporations, pharmaceutical and medical device companies, as well as institutional providers and individual practitioners and suppliers. His practice focuses on compliance and fraud and abuse counseling, as well as on reimbursement and coverage and certification issues and on relationships with third party payors. He has defended providers and practitioners in Anti-Kickback, Stark law, False Claims Act, Civil Money Penalty, and suspension and exclusion actions. Mr. Reider has extensive experience performing regulatory due diligence in connection with potential acquisition targets, developing compliance programs, and negotiating Corporate Integrity Agreements. He frequently appears before federal agencies, including Centers for Medicare and Medicaid Services, Office of Inspector General,
United States Department of Justice, and state attorneys general offices throughout the country.

Dr. Paul Rudolf: Dr. Paul Rudolf is a partner in Arnold & Porter, LLP's Washington, DC office. Dr. Rudolf has significant experience in both Medicare and FDA legal, regulatory and policy issues, particularly those relating to counterfeit drugs and radiofrequency identification technology as applied to pharmaceuticals and medical devices. He also is widely recognized for his experience with coverage, coding, and reimbursement issues for hospital and physician payment systems under the Medicare payment systems. Dr. Rudolf practiced medicine for more than 15 years and taught at George Washington University before becoming a Medicare Carrier Medical director. He subsequently joined the Centers for Medicare and Medicaid Services where he led policy development for the physician fee schedule and the hospital outpatient prospective payment system, and became recognized for his in-depth experience with coding and reimbursement for Medicare. Dr. Rudolf left the Centers for Medicare and Medicaid Services to join the FDA where he was a senior advisor for medical and health policy in the Office of the Commissioner.

Allison Weber Shuren: Allison Weber Shuren is co-chair of Arnold & Porter, LLP's FDA/Healthcare practice group, where she focuses her practice on a variety of regulatory and legislative healthcare issues involving Medicare coverage, reimbursement and coding issues; fraud and abuse counseling and investigations including defense of allegations of False Claims Act, Anti-Kickback, and Stark Law violations; and implementation and audit of corporate compliance programs and government imposed corporate integrity agreements. Ms. Shuren advises a broad group of clients, including pharmaceutical, medical device, and biotechnology companies, physician practice management companies and physician practices, hospital and academic medical centers, ambulatory surgery centers, healthcare professional societies, diagnostic imaging centers, and Internet-based healthcare companies. Before she began her legal
career, Ms. Shuren was a practicing critical care pediatric nurse practitioner concentrating in pediatric cardiovascular disease and neonatal pediatric surgery.