EPSTEIN BECKER GREEN

Gail H. Javitt

Member of the Firm

Washington, DC
1227 25th Street, NW
Suite 700
Washington, DC 20037
Tel: 202-861-1881
Fax: 202-861-3507

gjavitt@ebglaw.com

GAIL H. JAVITT is a Member of the Firm in the Health Care and Life Sciences practice, in the Washington, DC, office of Epstein Becker Green. Ms. Javitt provides strategic FDA regulatory advice for leading medical device, diagnostics, pharmaceutical, biological products, human cellular, and tissue-based products (HCT/Ps), and dietary supplement companies throughout the product life cycle and has successfully resolved disputes at both the pre- and post-market stage. She also has significant experience advising clinical laboratories on FDA and CLIA requirements for laboratory developed tests.

Ms. Javitt's services include:

- Providing premarket strategic advice to clients interested in bringing innovative medical technologies to market
- Advising on the NDA, 510(k), and PMA review pathways and the regulatory implications of post-market product modifications
- Counseling clients on clinical trial (GCP) compliance, including the responsibilities of sponsors and investigators, IRB engagement, and the submission of investigational device exemption (IDE) and investigational new drug (IND) submissions
- Preparing client communications to FDA, including requests for designation, Citizen Petitions, and comments to proposed regulations and guidance documents, and representing clients in engagements with the agency
- Providing post-market compliance counseling, including medical device reporting and corrections and removals, and assisting clients in resolving Form 483 inspectional observations and Warning and Untitled Letters

Ms. Javitt's experience prior to joining Epstein Becker Green includes serving as counsel in a major Washington, DC, FDA Regulatory practice and as a law and policy director at the Genetics and Public Policy Center, part of Johns Hopkins University. At the Center, she was responsible for developing policy options to guide the development and use

of reproductive and other genetic technologies. Earlier in her legal career, Ms. Javitt clerked for the Honorable Gary Taylor of the U.S. District Court for the Central District of California.

In addition, Ms. Javitt has published and spoken widely on issues at the intersection of law and science, including FDA regulation of genetic testing, precision medicine, and next-generation sequencing. Her academic experience has included serving as a faculty member at the Berman Institute of Bioethics at Johns Hopkins University and as an adjunct professor at the Georgetown University Law Center, American University's Washington College of Law, and the University of Maryland School of Law. She was previously a Greenwall Fellow in Bioethics and Health Policy, a collaborative effort between Johns Hopkins University and Georgetown University.

Education

- Johns Hopkins Bloomberg School of Public Health (M.P.H., 2000)
- Harvard Law School (J.D., cum laude, 1993)
- Columbia College, Columbia University (B.A., magna cum laude, 1990)
    - Phi Beta Kappa

Bar Admissions

- District of Columbia
- Maryland
- New York

Practice Areas

- Food and Drug Law
- Health Regulatory Due Diligence
- Product Marketing

Industries

- Health Care and Life Sciences Industry
- Academic Medical Centers
- Pharmaceuticals
- Medical Devices and Combination Products

Memberships

- National Advisory Committee Member, Victor Centers for Jewish Genetic Diseases

Languages

- Hebrew