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Services

Litigation
Health Care
Food, Drug & Device / FDA
Appellate
Health Care Litigation
International Litigation

Education

Harvard University
(J.D., 1984)

Harvard College
(B.A., 1981)

Admitted to Practice

District of Columbia

Daniel G. Jarcho

Partner

Dan Jarcho's practice focuses on litigation involving the Food and Drug Administration and the industries that FDA regulates. He also counsels clients about resolving regulatory compliance disputes with FDA that could lead to litigation, including disputes over inspections, Form 483 observations, Warning Letters, recalls, and import alerts.

Mr. Jarcho has represented clients in numerous FDA-related civil actions for seizures, injunctions, and civil penalties and in a wide variety of criminal investigations initiated by FDA. He also has significant experience representing plaintiffs in lawsuits challenging FDA regulatory actions under the Administrative Procedure Act. Mr. Jarcho also has litigated the federal preemption defense in a large number of product liability lawsuits involving products regulated by FDA. He litigates cases in both the federal trial courts and the federal appellate courts.

Before entering private practice, Mr. Jarcho was a Trial Attorney in the U.S. Department of Justice's Office of Consumer Litigation, where he represented FDA in federal court civil and criminal litigation, including enforcement actions for seizure and injunction, Administrative Procedure Act cases, and grand jury investigations.

Representative Experience

- Represented a drug manufacturer in an Administrative Procedure Act challenge to an FDA therapeutic equivalence classification. *Mallinckrodt Inc. v. FDA*, 8:14-cv-03607 (D. Md. 2014).
- Represented a medical device distributor in an Administrative Procedure Act challenge to a device classification. *Plymouth Direct, Inc. v. FDA*, 1:14-cv-01848 (D.D.C. 2014).
- Represented a medical device manufacturer in an FDA civil seizure action. *United States v. Articles of Device*, 2:12-cv-2264 (D.N.J. 2012).
- Represented an importer in an Administrative Procedure Act challenge to FDA import restrictions. *Del Monte Fresh Produce Company v. FDA*, 8:11-cv-02338 (D. Md. 2011).
- Represented a trade association in an Administrative Procedure Act challenge to a Department of Defense rule regarding pharmaceutical procurement. *Coalition For Common Sense In Government Procurement v. United States*, 671 F. Supp. 2d 48 (D.D.C. 2009).

- Represented an importer in an Administrative Procedure Act challenge to FDA import restrictions. *NewStar Fresh Foods, LLC v. United States*, 1:09-cv-1807 (D.D.C. 2009).
- Defended a medical device manufacturer in an FDA enforcement action for permanent injunction. *United States v. Utah Medical Products, Inc.*, 404 F. Supp. 2d 1315 (D. Utah 2005).
- Represented a trade association in a case involving federal preemption defenses to product liability claims. *Horn v. Thoratec Corporation*, 376 F.3d 163 (3d Cir. 2004).
- Represented a medical device manufacturer in a Supreme Court case addressing federal preemption defenses to product liability claims. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).
- Defended a medical device manufacturer in an FDA enforcement action for preliminary and permanent injunction. *United States v. Laerdal Manufacturing Corporation*, 853 F. Supp. 1219 (D. Oregon 1994), *aff'd*, 73 F.3d 852 (9th Cir. 1995).

Membership

- President, Board of Trustees, Legal Aid Society of D.C.
 - American Law Institute
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