

Daniel G. Jarcho

Partner

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Dan Jarcho represents clients in federal trial court and appellate litigation involving federal regulatory issues. Mr. Jarcho has litigated numerous Administrative Procedure Act challenges to federal agency actions, including cases involving the U.S. Food and Drug Administration, the Defense, Agriculture, Treasury and Interior Departments, and U.S. Customs and Border Protection. He has extensive experience litigating federal preemption defenses to state law claims. He also has defended clients in a wide variety of investigations and enforcement actions initiated by federal agencies and the U.S. Department of Justice.

Mr. Jarcho's enforcement work focuses on representing clients facing FDA civil actions for seizures, injunctions and civil penalties and FDA-related criminal investigations. He also counsels clients on resolving regulatory compliance disputes with FDA that could lead to litigation, including disputes over inspections, Form 483 observations, Warning Letters, recalls and import alerts. He is recognized as a leading practitioner for life sciences in *Who's Who Legal*.

Before entering private practice, Mr. Jarcho worked at the U.S. Department of Justice as a trial attorney in the Civil Division's Office of Consumer Litigation, where he represented FDA in federal court civil and criminal litigation. He also served as a Special Assistant U.S. Attorney in the Criminal Division of the U.S. Attorney's Office for the Eastern District of New York. Following law school, Mr. Jarcho was a law clerk for the chief judge of the U.S. District Court for the District of Utah.

Representative Experience

- Represented a compounding pharmacy in negotiating an FDA consent decree (2018).
- Represented a drug manufacturer in negotiating an FDA consent decree (2017).
- Represented a drug manufacturer in an Administrative Procedure Act challenge to an FDA decision rescinding a drug approval. *Lannett Company, Inc. v. FDA*, 1:16-cv-1350 (D.D.C. 2016).
- Represented a medical device manufacturer in negotiating a non-prosecution agreement concerning FDA regulatory issues (2016).
- Represented a drug manufacturer in an Administrative Procedure Act challenge to an FDA therapeutic equivalence classification. *Mallinckrodt Inc. v. FDA*, 15-1933 (4th Cir. 2015).
- Defended Amtrak against claims by New York City seeking reimbursement for multimillion-dollar infrastructure costs. *City of New York v. Amtrak*, 776 F.3d 11 (D.C. Cir. 2015).
- Represented a trade association in the defense of an Administrative Procedure Act challenge to a Department of Agriculture regulation. *Philip Morris U.S.A. Inc. v. Department of Agriculture*, 736 F.3d 284 (4th Cir. 2013).
- 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 an exporter in an Administrative Procedure Act challenge to a Department of the Treasury delay in issuing an export license. *Del Monte Fresh Produce Company v. United States*, 570 F.3d 316 (D.C. Cir. 2009).
- Represented an importer in a challenge to a Customs tariff classification for imported merchandise. *Faus Group, Inc. v. United States*, 581 F.3d 1369 (Fed. Cir. 2009).
- Represented a trade association in an Administrative Procedure Act challenge to a Department of Defense rule governing 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 the Secretary of the Interior concerning contempt of court charges in an Administrative Procedure Act case. *Cobell v. Norton*, 334 F.3d 1128 (D.C. Cir. 2003).
- Represented an exporter in a jurisdictional dispute governing the scope of a refund of an unconstitutional export tax. *Swisher International, Inc. v. United States*, 205 F.3d 1358 (Fed. Cir. 2000).
- 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).

Professional & Community Engagement

- Board Member and Former President, Legal Aid Society of the District of Columbia
- American Law Institute

Education

- Harvard University (J.D., 1984)
- Harvard College (B.A., 1981)

Admitted to Practice

- District of Columbia

Related Services

Litigation | Health Care | Food, Drug & Device / FDA | Appellate | Health Care Litigation | International Litigation | State Attorneys General Practice Team | White Collar, Government & Internal Investigations | Agribusiness | International Trade & Regulatory | FDA Enforcement & Litigation | Biotechnology, Pharmaceutical & Life Sciences Patent Litigation | Agribusiness, Food, Beverage & Cosmetics