



## Daniel G. Jarcho

Partner

+1 202 239 3254 | [daniel.jarcho@alston.com](mailto:daniel.jarcho@alston.com)

Washington, D.C. | The Atlantic Building, 950 F Street, NW | Washington, DC 20004-1404

### Related Services

Litigation ■ Health Care ■ FDA/Food, Drug & Device ■ Appellate ■ Health Care Litigation ■ International Litigation ■ State Attorneys General Practice Team ■ White Collar, Government & Internal Investigations ■ Agricultural Legislative & Public Policy ■ International Trade & Regulatory ■ FDA Enforcement & Litigation ■ Biotechnology, Pharmaceutical & Life Sciences Patent Litigation ■ Food, Beverage & Agribusiness ■ FDA Compliance & Enforcement ■ Administrative Law

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

Dan'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 by *The Best Lawyers in America*<sup>®</sup> in FDA Law and as a leading practitioner for life sciences in *Who's Who Legal*.

Dan worked as a trial attorney in the DOJ Civil Division's Office of Consumer Litigation, representing the FDA in federal 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. The Legal Aid Society of D.C. honored him with the 2022 Servant of Justice Award for his dedication and achievement in ensuring equal access to justice.

### Representative Experience

- Represented a Native American tribe in an Administrative Procedure Act challenge to Treasury Department decisions allocating \$4.8 billion in federal funds for pandemic relief. *Miccosukee Tribe v. Yellen*, No. 22-5090 (D.C. Cir. 2022).
- Represented a compounding pharmacy in negotiating an FDA consent decree (2022).
- Represented a hospital trade association as amicus curiae in an Administrative Procedure Act challenge to an HHS rule governing Medicare payments to low-wage hospitals. *Bridgeport Hospital v. Becerra*, No 1:20-cv-01574 (D.D.C. 2022).
- Represented a hospital trade association as amicus curiae in an Administrative Procedure Act challenge to an HHS rule governing Medicare payments to low-wage hospitals. *Kaweah Delta Health Care District v. Becerra*, No. 2:20-cv-06564 (C.D. Cal. 2022).
- Represented a manufacturer of active pharmaceutical ingredients in complex multidistrict litigation arising from the opioid crisis (2020 – 2021).

- Represented a nonprofit organization in an Administrative Procedure Act challenge to an Agriculture Department regulation restricting food assistance benefits. *Bread for the City v. Department of Agriculture*, 444 F. Supp. 3d 1 (D.D.C. 2020).
- Represented a beverage company in a challenge to a customs tariff classification for imported merchandise. *InZone Inc. v. United States*, 456 F. Supp. 3d 1309 (Ct. Int'l Trade 2020).
- Represented a hospital trade association as amicus curiae in an Administrative Procedure Act challenge to an HHS regulation governing Medicaid payments to disproportionate-share hospitals. *Children's Hospital Association of Texas v. Azar*, 933 F.3d 764 (D.C. Cir. 2019).
- Represented a compounding pharmacy in negotiating an FDA consent decree (2018).
- Represented a medical device manufacturer in negotiating a nonprosecution agreement concerning FDA regulatory issues (2016).
- Represented a long-term care association as amicus curiae in an Administrative Procedure Act challenge to an HHS regulation governing Medicare rates for clinical laboratories. *American Clinical Laboratory Association v. Azar*, 334 F. Supp. 3d 301 (D.D.C. 2018).
- Represented a drug manufacturer in an Administrative Procedure Act challenge to an FDA decision rescinding a drug approval. *Lannett Company Inc. v. FDA*, 300 F. Supp. 3d 34 (D.D.C. 2017).
- Represented a state agency in an Administrative Procedure Act challenge to an FDA restriction on imported drugs. *Texas Department of Criminal Justice v. FDA*, No. 3:17-cv-00001 (S.D. Tex. 2017).
- Represented a drug manufacturer in negotiating an FDA consent decree (2017).
- Represented taxpayers in an Administrative Procedure Act challenge to a Social Security Administration seizure of tax refunds. *Heard v. Social Security Administration*, 170 F. Supp. 3d 124 (D.D.C. 2016).
- Represented a drug manufacturer in an Administrative Procedure Act challenge to an FDA therapeutic equivalence classification. *Mallinckrodt Inc. v. FDA*, No. 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 wind energy company in defense of an Administrative Procedure Act challenge to Interior Department decisions regarding an offshore wind energy project. *Public Employees for Environmental Responsibility v. Beaudreu*, 25 F. Supp. 3d 67 (D.D.C. 2014).
- 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*, No. 2:12-cv-02264 (D.N.J. 2012).
- Represented an importer in an Administrative Procedure Act challenge to FDA import restrictions.
- Represented an exporter in an Administrative Procedure Act challenge to a Department of the Treasury delay in issuing an export license.
- 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*, No. 1:09-cv-01807 (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 products 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. Or. 1994), *aff'd*, 73 F.3d 852 (9th Cir. 1995).

## **Publications & Presentations**

### **Publications**

- *Topics in Food and Drug Law: How to Comply with Drug CGMPs*, 3rd ed., Food and Drug Law Institute, June 2023.

### **Presentations**

- “Chevron Deference on the Chopping Block,” American Agricultural Law Association (AALA), webinar, April 17, 2024.

## **Professional & Community Engagement**

- Legal Aid Society of the District of Columbia, Trustee and former President
- American Law Institute

## **Education**

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

## **Admitted to Practice**

- District of Columbia