POLSINELLI

Claire Davies

SHAREHOLDER

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Claire Davies provides strategic counsel to help clients navigate FDA regulatory and compliance challenges.

Claire has handled a wide range of issues involving medical devices, biological products, drugs and human cells, tissues and cellular and tissue-based products (HCT/Ps). Her experience spans the product lifecycle and includes the following areas:

- Investigational new drug application (IND), investigational device exemption (IDE) and other federal research requirements
- Pathways to market for novel medical devices and digital health products
- Regulatory classification of HCT/Ps and donor eligibility requirements
- Adverse event reporting
- Postmarket manufacturing and product changes
- Responses to FDA Form 483 Observations
- Advertising and promotion

Prior to joining Polsinelli, Claire spent nearly a decade as an attorney in the FDA's Office of the Chief Counsel. Her work at FDA often involved advising agency leadership on high-profile and significant matters, such as responses to emerging public health threats and user fee negotiations with industry. Claire also worked regularly with FDA policy and scientific staff to develop regulations and guidance, resolve disputes with product sponsors, respond to citizen petitions and address compliance concerns through warning letters or other actions.

Education

- University of Minnesota Law School (J.D., *magna cum laude, Order of the Coif*, 2010)
- University of Wisconsin-Madison (B.S., *with distinction*, 2006)

Bar Admissions

- Colorado
- District of Columbia

Capabilities

- Food, Drug & Device
- Medical Devices
- Health Care
- Life Sciences

Memberships

- Food and Drug Law Institute
- Colorado Bar Association
- Denver Bar Association

Recognition

- FDA Outstanding Service Award
- Named one of Washington, D.C.'s *Super Lawyers* "Rising Stars", 2014-2015

Publications

May 5, 2026
Clarity or Corporate Secret? Battle Brews Over FDA Letters
Quoted, Law360

May 1, 2026
FDA Signals it Has No Appetite to Add Popular GLP-1 Drug Substances to the 503B Bulks List

April 23, 2026
Medspas on Alert: The FDA Says You're a Dispenser Too

April 22, 2026
Tiny Chains, Big Changes? What FDA's Latest Actions Mean for Peptide Compounding

March 4, 2026
FDA says it wants individualized medicines. Can we get there?
Quoted, Chemical & Engineering News

February 18, 2026
New FDA Drug Reforms: Congress Extends Voucher Incentive, Clarifies Orphan Exclusivity and Provides Greater Transparency for Q1/Q2 Generic Approvals

February 9, 2026
FDA Tightens the Belt on GLP-1 Compounding, Escalating Threat of Enforcement

February 9, 2026
Opinion: 2025 Reshaped the FDA. What Will 2026 Hold?
Co-Author, BioSpace

January 27, 2026
FDA guidance eases wearables oversight. But experts have questions about what's next.
Quoted, Medtech Dive

January 8, 2026
Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life

Sciences Playbook for 2026

January 8, 2026
Ringing in the New Year with Digital Health: FDA Updates Guidance Documents on Clinical Decision Support Software and General Wellness Products

January 5, 2026
How To Meet FDA Expectations For Hybrid And Decentralized Trial Oversight
Featured, Clinical Leader

December 9, 2025
National Advertising Division Puts Compounded GLP-1 Advertising on a Diet

October 31, 2025
New FDA Guidance Could Speed Biosimilar Approvals and Cut Costs

September 24, 2025
Vanda Ruling Opens Door For Contesting FDA Drug Denials
Co-Author, Law360

September 16, 2025
Stealth, Barth Community Await FDA Verdict With 'Everything at Stake'
Quoted, BioSpace

August 26, 2025
Navigating the FDA: Why Early Strategic Planning is Critical
Author, Life Science Nation Newsletter: Next Phase

May 21, 2025
The Trump Administration Announces Price Targets as It Takes a Second Swing at "Most Favored Nation" Drug Pricing Model