POLSINELLI. What a law firm should be.™

Polsinelli Strengthens Regulatory Bench with Addition of FDA Veteran Claire Davies

(April 24, 2025) Polsinelli is pleased to announce that Claire B. Davies has joined the firm's **Food & Drug Practice** as a shareholder in the Denver office. Davies brings nearly a decade of experience from the U.S. Food and Drug Administration (FDA), where she played a pivotal role in high-profile legal and policy matters, including the FDA's initiatives related to COVID-19.

"With unprecedented change happening at the FDA and other federal health agencies and drastic personnel reductions, companies developing cutting-edge medical and biotech products more than ever need insightful advice on how to keep product development on track," said Stuart Pape, Chair of Polsinelli's Food & Drug Practice. "Claire's experience and knowledge will be invaluable to those companies. We could not be more delighted that she joined our practice."

Davies's arrival marks a significant expansion of the firm's capabilities in the increasingly complex regulatory environment governing FDA-regulated products. Her deep regulatory insight and practical experience includes advising on regulatory and compliance issues affecting biological products, drugs, medical devices and human cells, tissues and cellular and tissue-based products (HCT/Ps). During her time at the FDA, Davies was involved in high-profile and significant matters, including COVID-19 emergency use authorizations and the response to highly pathogenic avian influenza. She played a critical role in negotiations over the reauthorization of the Medical Device User Fee Amendments (MDUFA) and helped develop key clinical research policies, including guidance on digital health technologies in clinical trials.

"Claire's arrival couldn't come at a more critical moment," said Michael M. Gaba, Vice Chair of Polsinelli's Food and Drug Practice. "Clients will greatly benefit from someone who has a practical understanding of the agency's inner workings. Claire brings that rare insight, and her arrival at Polsinelli further strengthens our ability to guide clients with confidence and clarity."

In her previous role, Davies advised FDA leadership on the approval of novel products, including cell therapies, and programs to expedite access to innovative medical devices. Her experience spans the product life cycle and extends to matters involving recalls, inspections, product labeling and promotion, adverse event reporting and post-market product changes, among other areas.

Additionally, Davies has substantial experience in requirements for federally regulated clinical research. She was the principal legal advisor on multiple rulemakings to revise FDA regulations governing informed consent and institutional review boards.

"I am thrilled to be joining the talented group of attorneys at Polsinelli," said Davies. "The firm's multidisciplinary capabilities in health care and life sciences are incredibly impressive. I look forward to working as part of this team to help clients in those sectors develop sound strategies in a shifting FDA regulatory landscape."

“Claire’s arrival demonstrates our ongoing commitment to maintaining the strongest Health Care Practice across the country to respond to the elevated demand from clients amid regulatory and market uncertainty,” said Matthew J. Murer, Chair of Polsinelli’s Health Care, Public Policy, and Government Investigations Department. “Claire joins several former FDA attorneys here at Polsinelli, solidifying our position as a regulatory powerhouse for companies in the health care and biotech space.”

Davies is the ninth shareholder Polsinelli has added to its Health Care Practice over the past 12 months, most recently, Erin Burns in Denver.

Davies earned her J.D., *magna cum laude*, from the University of Minnesota Law School, and her B.S. from the University of Wisconsin-Madison.

As one of the largest health care practices in the country, Polsinelli attorneys work as a fully integrated practice to seamlessly partner with clients on the whole gamut of issues. The group understands the opportunities and challenges that our clients and the broader health care industry face. The firm has built a team that is made up of health care industry experts, including a mix of former in-house counsel at national health care institutions, the FDA, CMS and the Department of Justice.

About Polsinelli

Polsinelli is an Am Law 100 firm with more than 1,000 attorneys in over 20 offices nationwide. Recognized as one of the top firms for excellent client service and client relationships, Polsinelli is committed to meeting our clients’ expectations of what a law firm should be. Our attorneys provide value through practical legal counsel infused with business insight, offering comprehensive corporate, transactional, litigation and regulatory services with a focus on health care, real estate, finance, technology, private equity and life sciences. Polsinelli PC, Polsinelli LLP in California, Polsinelli PC (Inc) in Florida.