

Stuart M. Pape

FOOD & DRUG CHAIR

he / him / his

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Stuart Pape helps clients understand and face challenges presented by regulations imposed by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and similar health and safety regulatory bodies worldwide. He currently serves as chair of the firm's FDA practice and focuses on:

- Assisting clients on the regulation of food ingredients and novel foods
- Advising clients whether food ingredients are generally recognized as safe (GRAS) or whether dietary ingredients require a new dietary ingredient notification (NDI)
- Advising on labeling and promotion of regulated products and claims substantiation and helping clients address challenges to their labeling and promotion
- Assisting clients in obtaining approval of pharmaceuticals and medical devices and complying with post approval requirements
- Assisting in enforcement proceedings initiated by regulatory bodies
- Helping clients develop sound strategies in the face of challenges from NGOs.
- Lobbying in connection with legislative consideration of statutory changes to the laws governing FDA regulated products

Stuart regularly appears before the FDA, USDA, Consumer Product Safety Commission, U.S. Customs and Border Protection, Federal Trade Commission, numerous other federal and state regulatory bodies, and the Congress of the United States, Stuart serves clients across the U.S. and around the world in many capacities. Previously, he served in various positions in the Office of the Chief of Counsel at the FDA, including as associate chief counsel for food. He also served as executive assistant to FDA Commissioner Donald Kennedy.

Education

- University of Virginia School of Law (J.D., 1973)
- University of Virginia (B.A., 1970)

Bar Admissions

- District of Columbia, 1980

Capabilities

- Food, Drug & Device
- Consumer Products & Luxury Goods
- Life Sciences
- Medical Devices
- Advertising & Digital Media
- Agribusiness
- Post Chevron Educational Resources & Updates

Court Admissions

- United States Supreme Court

Memberships

- District of Columbia Bar
- Elizabeth Glaser Pediatric AIDS Foundation
 - Vice Chair, Board of Directors, 2004-2020
- World Food Regulation Review, Advisory Board
- Guide to U.S. Food Labeling Law
 - Editorial Advisory Board

Recognition

- Selected for inclusion in *Best Lawyers in America*® for:
 - FDA Law, 2016-2026
 - Health Care Law, 2023-2024
- Ranked in *Chambers USA: America's Leading Lawyers for Business*, Food & Beverages: Regulatory & Litigation, Band 1, Nationwide, 2014-2025
- Service to FDLI Award, *The Food and Drug Law Institute (FDLI)*, 2022
- Selected for inclusion in *Super Lawyers*
 - *Who's Who in America*
 - *Who's Who in the World*
- FDA Commendable Service Award, 1978
- Judge Learned Hand Award, American Jewish Committee, 2012
- *Natural Products Association*, President's Award, 2015

Publications

May 1, 2026

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

April 22, 2026

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

April 7, 2026

Not Joking Around: FDA Offers Additional Clarification on Compounded GLP-1 Policy in April Fool's Day Announcement

February 9, 2026

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

February 9, 2026

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

January 8, 2026

Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life

Sciences Playbook for 2026

January 2026

FDA Takes Aim at Drug Ads: What It Means for Compounding Pharmacies, Medspas and Telehealth Companies

Co-Author, Employee Benefit Plan Review, Vol 80 No 1

December 9, 2025

National Advertising Division Puts Compounded GLP-1 Advertising on a Diet

September 29, 2025

FDA Takes Aim at Drug Ads: What It Means for Compounding Pharmacies, Medspas and Telehealth Companies

August 7, 2025

Former F.D.A. Chief Backs Kennedy's War on Processed Food

Quoted, The New York Times

April 14, 2025

FDA After the Storm: Drug Review Delays and Increased Executive Oversight Expected

Quoted, BioSpace

March 28, 2025

HHS Job Cuts: FDA, CDC, NIH and CMS Impacted Amidst Significant Restructurings

March 5, 2025

Trump's FDA Staff Cuts Weigh on Agency's Drug Oversight Work

Quoted, Bloomberg Law

February 20, 2025

FDA Reels From 'Indiscriminate' Job Cuts Under Trump as Biopharma Appeals for Clarity

Quoted, BioSpace

February 19, 2025

Thousands of federal employees fired from US regulatory and science funding agencies

Quoted, Chemical & Engineering News

February 19, 2025

MAHA Commission expected to impact approach to medications, vaccines, research

Quoted, McKnights Senior Living

February 19, 2025

The 'GRAS' loophole lets untested additives into Americans' food. Can RFK Jr. close it?

Quoted, Stat News

February 13, 2025

Scientists, drugmakers brace for a Kennedy HHS after confirmation

Quoted, Chemical & Engineering News

February 13, 2025

'No Job Security' at FDA as Trump Team Seeks to Dismantle Workforce

Quoted, BioSpace

February 10, 2025

Monday Morning (Advertising) Quarterback – Unprecedented Hims & Hers Super Bowl Ad Has Legislators Concerned

May 14, 2024

USDA, FDA turf battles hamper responses to outbreaks like H5N1 bird flu

Quoted, STAT

April 16, 2024

What to Know About New York's New Supplement Law Going into Effect this Month

February 27, 2024

FDA 2023-24: A Look Back & A Peek Forward

A Curated FDA Review