

# Andrew N. Goldfarb

Partner

Andrew N. Goldfarb is an experienced litigator who focuses on food and drug law as well as plaintiff- and defense-side complex civil litigation.

In his food and drug practice, Andrew:

- counsels biopharmaceutical companies and medical device start-ups on a wide range of matters, including drug promotional and advertising activities, FDA warning letters, medical device classifications, health-related mobile applications, intellectual property rights, and HIPAA compliance obligations;
- represents a standard-setting organization on a range of regulatory and internal matters;
- drafted a request for an advisory opinion from the HHS Office of the Inspector General for a proposed study utilizing motivational incentives/contingency management;
- successfully litigated the first case involving the generic exclusivity forfeiture provisions of the Food, Drug, and Cosmetic Act; and
- performed regulatory due diligence in connection with the sale of FDA-regulated companies.

In his complex litigation practice, Andrew:

- represents patients and providers in putative class action cases against health insurance companies over coverage for behavioral health treatments and reimbursement policies under ERISA, Mental Health Parity laws, and the Affordable Care Act;
- represents victims of child sex abuse in an action against the Boy Scouts of America;
- represents individuals subpoenaed by the SEC and state Attorneys General for documents and testimony;
- represents an individual seeking an award under the SEC Whistleblower Program;
- litigated multiple trade secret cases after former employees misappropriated confidential information;



## Washington, DC

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## Practice focus

- Commercial Health Insurance Disputes
- Business Litigation
- Food and Drug
- Health Care
- Plaintiffs and Class Actions
- Investigations
- Pro Bono
- False Claims Act

## Education

- Georgetown University Law Center, J.D., 1995
- Harvard University, A.B., *magna cum laude*, 1990

## Languages

- represented creditors' committees and post-confirmation trustees in contract, fraudulent conveyance, and accounting malpractice cases;
- brought legal actions that secured the right to advancement of legal fees and expenses for directors and officers who were indicted or under investigation;
- counseled biopharmaceutical companies in contract disputes; represented pharmaceutical and biologic companies in contract disputes with their product development, licensing, and commercialization partners;
- represented an individual subpoenaed for testimony and documents in a state grand jury investigation; and
- defended an individual in a criminal prosecution relating to the alleged promotion of fraudulent tax shelters by a major accounting firm.

Andrew is co-editor of *InsightZS*, a legal blog dedicated to thoughtful discourse on emerging litigation and investigations issues of the day.

Prior to joining Zuckerman Spaeder, Andrew was a trial attorney for six years in the U.S. Department of Justice, where he prosecuted the United States's civil RICO action against the tobacco industry that resulted in a 1,650-page opinion finding the defendants liable for RICO violations.

### **Government service**

- Trial Attorney
  - U.S. Department of Justice

### **Community involvement**

- Chairman of the Board, Teens Run DC (2015-present)
- Co-Chair of Social Action Committee, Temple Sinai, Washington, DC (2009-2011)

### **Recognitions**

- Benchmark Litigation, Future Star (Washington, DC)
- The National Law Journal, Class Action Litigation Trailblazer, 2023
- The National Law Journal, Plaintiffs' Lawyer Trailblazer, 2022

### **Bar admissions**

- District of Columbia
- New York
- California

### **Court admissions**

- U.S. Supreme Court
- U.S. Court of Appeals, District of Columbia Circuit
- U.S. Court of Appeals, Ninth Circuit
- U.S. District Court, District of Colorado
- U.S. District Court, District of Columbia
- U.S. District Court, Central District of California
- U.S. District Court, Northern District of California

### **Representative matters**

- Represented patients in class action lawsuits against major insurance companies for their failure to cover an FDA-approved mental health treatment. The plaintiffs alleged breaches of fiduciary duties and wrongful denial of benefits under the Employee Retirement Income Security Act (ERISA). Obtained court-approved class settlements of \$6.2 million and \$2.75 million.
- Represents a leading tobacco control organization in regulatory and litigation matters arising under the Tobacco Control Act (TCA), including representing a coalition of health organizations as amici in a challenge to FDA's "deeming rule" concerning electronic cigarettes; and counseling on proposed and final rules on issues arising under the TCA, including tobacco product applications, warning labels, and substantial equivalence.
- Represented health care providers in actions against a major health insurance company alleging ERISA violations for "cross-plan offsetting," whereby the insurer withheld benefit payments owed by a health plan to the provider for covered services and used those benefits to reimburse a different health plan for alleged prior overpayments to the same provider. The cases were resolved on a non-class basis.
- Filed comments to FDA on behalf of a pharmaceutical and medical device company concerning the scope of orphan drug exclusivity. The company responded to an

FDA solicitation in the wake of a district court decision requiring FDA to award orphan drug exclusivity to a designated orphan drug, even though the drug had not shown “clinical superiority” to a prior orphan drug with the same active ingredient for the same use. It argued that orphan exclusivity should apply only to ANDAs referencing the new orphan drug, but should not keep ANDAs referencing the prior orphan drug from receiving marketing approval. FDA appealed the district court decision, and the D.C. Court of Appeals affirmed the decision in March 2020.

- Represented a generic drug manufacturer in a challenge to the FDA’s approval of its drug under the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act (FDCA). The action for a preliminary injunction was brought against the FDA by a competitor who claimed that the client had forfeited its 180-day generic exclusivity under the FDCA, and Zuckerman’s client intervened. In the first case addressing the generic exclusivity forfeiture provisions of the FDCA, the court refused to enjoin FDA from approving the drug, allowing Zuckerman Spaeder’s client to continue marketing its drug.
- Represented a putative class of patients in an ERISA action against a major insurance company for allegedly discriminating against out-of-network psychiatrists and other mental health providers in the reimbursement for mental health services. Obtained a court-approved class settlement providing injunctive and monetary relief.
- Representing putative classes in actions against major insurance companies alleging that the companies violated ERISA by failing to award benefits for covered health services based on usual, customary, and reasonable rates as required by their health plans.
- Defending an electrical switch manufacturer against tort, contract, and fraudulent conveyance claims in parallel state and federal bankruptcy court actions arising out of a purchase of assets from a company found responsible for environmental contamination in Long Island, New York.
- Conducted an independent internal investigation for a major international pharmaceutical company, after the company failed to disclose to the FDA a preliminary report of a drug safety study before an important advisory committee meeting. The drug had been approved by the FDA to reduce bleeding in certain cardiac surgery patients. After conducting dozens of interviews of all of the key participants in the events at issue, in the United States and Germany, and conducting extensive document discovery, Zuckerman Spaeder prepared a

report detailing the critical events and potential causes of the company's failure to disclose.

- Represented the official committee of unsecured creditors of the Tribune Company as special litigation counsel in the investigation of the \$10 billion failed leveraged buyout (LBO) and the commencement and initial prosecution of three lawsuits against major lenders for fraudulent conveyance; directors and officers, former Tribune shareholders, and others for breaches of fiduciary duty and fraudulent conveyance; and financial advisors to Tribune for malpractice.
- Co-authored a U.S. Supreme Court amicus brief on behalf of former federal district court judges in California Public Employees' Retirement System v. ANZ Securities, Inc., concerning the impact of the American Pipe tolling doctrine on securities class action litigation in district courts.
- Represented a post-confirmation committee in a suit against a leading private equity investor to recover funds on behalf of unsecured creditors of a leading toy retailer. The defendants had engineered a leveraged buyout of the company that burdened the retailer with an unsustainable debt load while the private equity firm extracted substantial returns in a very short period. Zuckerman Spaeder obtained a favorable settlement for the creditors.
- Represented a post-confirmation liquidating trustee in a contract dispute against certain former lenders of a bankrupt investment management firm. The trustee sought damages for alleged violations by minority lenders of a collective enforcement/"no-action" provision in the loan documents.
- Served as class counsel for millions of consumers in Maryland and Virginia who sued gas stations and oil companies over alleged deceptive practices in the retail sale of gas and diesel fuel. The class claimed that retailers sold gas to consumers without adjusting the price to take account of lower fuel content of higher temperature gas. The cases were consolidated for pretrial proceeding in a multidistrict litigation proceeding in the U.S. District Court for the District of Kansas. The class settlement provided significant injunctive relief to the class.
- Represented the litigation trustee of a bankrupt retail mail order company in an accounting malpractice action against KPMG. The trustee alleged that KPMG's negligent audit caused the company to continue operations after it would otherwise have filed for bankruptcy, deepening its

insolvency and injuring creditors. After extensive discovery, including the taking of testimony from German directors and officers under the Hague convention, the parties reached a favorable settlement.

- Defended a chain of yoga studios against claims that it was a racketeering enterprise in violation of RICO and Virginia law. The plaintiff alleged that the company engaged in practices that diminished his ability to exercise free will and independent judgment and induced him to dramatically change his lifestyle and pay significant sums of money to the company for services. The U.S. District Court for the Eastern District of Virginia granted the defendants' motion to dismiss on the grounds that the plaintiff had not adequately pleaded a RICO enterprise distinct from the defendants themselves, and declined to exercise supplemental jurisdiction over the plaintiff's state law claims.