# KENNETH A. WEINSTEIN
## Managing Principal

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Mr. Weinstein specializes in the application of quantitative methods to real-world problems involving decision making, strategy, risk management, and litigation in a variety of sectors. His work in the health care sector includes building algorithms for real-time suspicious order monitoring (SOM) of controlled substance distribution by manufacturers and wholesalers, as well as statistical assessments of controlled substance dispensing issues at the pharmacy and prescriber levels. He has also led the creation of flexible damages models for use in litigation matters involving the False Claims Act, the Anti-Kickback Statute, intellectual property, and controlled substance regulation. He has served as an expert witness, testifying in administrative proceedings before the Drug Enforcement Administration (DEA).

Mr. Weinstein has managed the analysis of large transaction-level and claims databases. He also has broad experience supporting leading academic experts, working with cross-functional client teams, and presenting analytical results to top executives and government officials, including those at the DEA, US Attorneys' Offices, and state attorneys general. In his work at Analysis Group, Mr. Weinstein builds on his prior experience, which includes contributing to economics research on 401(k) savings behavior, forecasting consumer demand at Zipcar, and advising foundations and government agencies on how to track and interpret data.

## EDUCATION

M.B.A.        MIT Sloan School of Management

A.B.          Harvard University, applied mathematics, subfield economics *(cum laude)*

## PROFESSIONAL EXPERIENCE

2010–Present   Analysis Group, Inc.
               *Managing Principal (2021–Present)*
               *Vice President (2017–2021)*
               *Manager (2013–2016)*
               *Associate (2010–2012)*

2008–2010      The Bridgespan Group
               *Consultant*

2007           Zipcar
               *Summer Analytics Consultant*

2003–2006      Analysis Group, Inc.
               *Senior Analyst (2005–2006)*
               *Analyst (2003–2004)*

2001–2002      National Bureau of Economic Research
               *Research Assistant to Professor David Laibson*

## SELECTED LITIGATION CASE EXPERIENCE

- ***Morris & Dickson Co., L.L.C. v. Sessions, et al.***
  *US District Court, Western District of Louisiana*
  Submitted expert declarations regarding DEA analysis of Morris & Dickson controlled substance distribution data.

- ***DEA v. Morris & Dickson Co., L.L.C.***
  *DEA Office of Administrative Law Judges*
  Testified in administrative proceedings on statistical issues related to controlled substance distribution and monitoring.

- **Government investigations concerning manufacturing, distribution, and dispensing of controlled substances**
  Provided statistical expertise to counsel on rebutting the government's proposed causation and damages models. Prepared alternative damages models and presented them to government investigators.

- **Government investigations and litigation concerning billing and utilization of dialysis-related services**
  Provided statistical expertise to counsel to assess relevant trends and identify statistical outliers. Led the analysis of claims data and quality metrics pertaining to Medicare billing. Presented models to government investigators. Supported an academic affiliate in filing rebuttal report.

- ***DEA v. Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #219 and #5195***
  *US District Court, District of Columbia*
  Supported expert declarations on behalf of CVS in administrative proceedings before the DEA. Analysis included attention to the dispensing patterns of certain controlled substances.

- **Government investigations concerning prescription drug and medical device marketing practices, including:**
  - AzaSite/Merck (Southern District of New York)
  - Dermagraft/Shire Regenerative Medicine (Middle District of Florida, District of Columbia)
  - Eye care products/Allergan (Eastern District of Pennsylvania)
  - Lialda, Pentasa/Shire (District of Massachusetts)
  - NovoSeven/Novo Nordisk (District of Maryland)
  - Risperdal/Johnson & Johnson (Eastern District of Pennsylvania)
  - Adderall, Daytrana, Vyvanse/Shire (District of Massachusetts)

Evaluated the alleged conduct; quantified the relevant sales; and assessed the causal connection, if any, between allegations in the case and sales at issue using economic, biostatistical, and epidemiologic approaches.

- ***In re: Lamictal Direct Purchaser Antitrust Litigation***
  *US District Court, Eastern District of New Jersey*
  On behalf of GlaxoSmithKline and Teva, supported an academic expert in the assessment of class certification issues related to alleged reverse payments and delay of generic entry in the pharmaceutical industry.

- ***Trana Discovery, Inc. vs. Southern Research Institute (SRI)***
  *US District Court, Eastern District of North Carolina*
  On behalf of SRI, supported a damages expert in case regarding the alleged failure to identify compounds as potential HIV treatments. Case was resolved with summary judgment for SRI.

- ***Louis Vuitton Malletier, S.A. vs. Hyundai Motor America***
  *US District Court, Southern District of New York*
  Supported a damages expert in case regarding the infringement and dilution of Louis Vuitton's trademark. Designed methodology for estimating the impact of the misuse of the trademark in Hyundai's national television advertising.

- **Other litigation assignments**

  - Supported an economic expert in a case regarding alleged monopolistic overpricing for pharmaceutical products in Latin America. Conducted an analysis of price data and led research on historical economic definition of "natural price."

  - Supported a damages expert in an intellectual property case regarding alleged trademark infringement by a mobile home builder. Jury found no infringement.

  - Developed a methodology to estimate damages related to a real estate condemnation dispute, in which the plaintiff alleged that he was prevented from receiving traditional financing due to the misconduct of the condemnor. Supported industry and damages experts.

  - In cases regarding allegedly inappropriate discount programs provided by a pharmacy chain for government-reimbursed prescriptions, led analyses of large dispensing databases to quantify potentially inappropriate transactions.

  - Supported a damages rebuttal expert in case regarding allegedly infringed patent for use of a drug as preventive treatment for specific conditions. Employed IMS data to evaluate prescription trends over time for relevant patient characteristics. Replicated and critiqued the opposing experts' "stock and flow" model of patient adoption rates.

## SELECTED CONSULTING EXPERIENCE

- **Support of pharmaceutical manufacturers, distributors, and pharmacy chains in strategic risk management for controlled substances**

  - *Development and implementation of SOM algorithms to mitigate risk for all levels of the controlled substance supply chain, including manufacturers, distributors, pharmacy chains, and third-party logistics suppliers.* Developed real-time monitoring algorithms for clients to

    fulfill DEA regulations by monitoring the distribution of controlled substances for order of unusual size, frequency, or pattern.

- *Development and implementation of store- and prescriber-level risk algorithms for pharmacy chains to identify potentially inappropriate dispensing of controlled substances.* Assessed risk factors associated with the diversion and abuse of controlled substances, and developed a methodology to identify these factors in large dispensing databases. Developed and implemented quarterly algorithms to identify highest-risk pharmacies and prescribers.

- Led analysis of historical data to determine appropriate statistical approaches, testing of potential methods on actual client data, presentation to and training of client staff in algorithm methods, and eventual handoff to internal technology groups for long-term implementation and maintenance of algorithms. Presented on behalf of clients to officials from the DEA, US Department of Justice, and state attorneys general offices.

## PUBLICATIONS AND PRESENTATIONS

"Assessing CDC's Revised Guideline On Opioid Prescriptions," with Nicholas Van Niel and Kate Uthe, Law360, March 6, 2024

"A New Standard For Suspicious Order Monitoring," with Crystal Pike and Nicholas Van Niel, *Law360*, August 21, 2017

"Tracing The Path To Health Care Investigation Settlements," with Paul Greenberg and Crystal Pike, *Law360*, April 17, 2017

"Viewing Recent Opioid Regulations In Context," with Paul Greenberg, Crystal Pike, and Pavel Darling, *Law360*, April 1, 2016

Presentations on "Legal Perspectives and Analytical Trends on Controlled Substance Act Issues" with John Gilbert at American Conference Institute 3rd and 4th Annual Summits on Controlled Substances Regulation, Litigation, and Enforcement, July 2020 and June 2021

## PROFESSIONAL ASSOCIATIONS

American Society for Pharmacy Law, Member