

## Roger D. Klein, MD, JD, FCAP

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### Key Leadership Contributions

- **Healthcare Innovation:** Pioneered advancements in genomic medicine and molecular diagnostics, integrated cutting-edge technologies into clinical practice.
  - **Policy Advocacy:** Influenced national healthcare policies through advisory roles with HHS, FDA, CMS, and CDC and leadership on and participation in major national medical committees such as CAP, AMP, AMA, ASCO, and CLSI.
    - Integral role in the design of the AMA CPT Molecular Pathology code set.
    - Former Co-Chair of the evidence-based Evaluation of Genomic Applications in Practice and Prevention Working Group (EGAPP).
    - Key advisor and expert in Association for Molecular Pathology v. Myriad Genetics (569 U.S. 576), in which Supreme Court unanimously invalidated patents on human genes.
  - **Corporate Strategy:** Leadership roles in exponential laboratory growth, marketing, and sales strategies, and sale of genomics company to large national laboratory.
  - **Data Analysis Expertise:** Oversaw application of informatics and analytics to optimize laboratory operations, test performance, and enhance clinical decision-making.
  - **AI Regulation and Application:** Currently working on proposals for healthcare AI regulation and reimbursement.
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### Professional Experience

#### Strategic Director, Head of Medicine, OmniSeq (subsidiary of LabCorp) | 2021 – 2023

- Key role in OmniSeq's integration into LabCorp, ensuring successful transition.
- Grew business through innovative strategies, client-focused enhancements.
- Oversaw Knowledge Informatics Team (data analysis).
- Laboratory performance monitoring improved test quality and customer satisfaction.
- Subject matter expert for LabCorp Ventures.

#### Chief Medical Officer, OmniSeq | 2020 – 2021

- Led medical-commercial strategy resulting in substantial business growth.
- Directed successful coverage and reimbursement strategy with Medicare contractor.
- Important role in engineering the company's sale to LabCorp.

#### Principal, Roger D. Klein, MD, JD Consulting | 2016 – present

- Provide medical, legal, and business consulting services on commercial strategy, regulation, CPT coding and reimbursement, intellectual property, and compliance for the biotechnology, diagnostics, clinical laboratory, healthcare, artificial intelligence, and investment industries.

- Mentor, Endless Frontier Labs startup incubator, NYU Stern School of Business.
- Faculty Fellow, Center for Law, Science & Innovation, Arizona State Law School.
- Expert, Regulatory Transparency Project, FDA and Health Working Group.
- Representative clients have included a major medical device manufacturer, leading Silicon Valley law firm, major Medicare contractor, and government entities. Have served on several large pharmaceutical company and smaller company advisory boards.

**Medical Director, Molecular Pathology (Oncology and Genetics), Cleveland Clinic Foundation** | 2012 – 2016

- Led molecular pathology reference laboratory at major academic medical center.
- Expert consultant to world-class oncology specialists and subspecialists.
- Enhanced laboratory capabilities to support emerging technologies in precision oncology, including oversight of NGS implementation.

**Medical Director, Molecular Oncology, BloodCenter of Wisconsin** | 2008 – 2012

- Established molecular oncology testing program focusing on hematologic malignancies for commercial reference laboratory, including nationally recognized acute myelogenous leukemia (AML) testing menu.
- Collaborated with oncologists to integrate genomic insights into treatment planning.

**Medical Director, Molecular Diagnostics, H. Lee Moffitt Cancer Center** | 2007 – 2008

- Created molecular pathology laboratory at large cancer center.
- Promoted to Medical Director, Diagnostic Laboratories.

**Attorney, Klein & Klein Co. LPA** | 1998 – 2001

- Appellate litigation, including landmark outcomes in state and federal courts.

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## Education

- **Juris Doctor**  
Yale Law School | 1996
  - Articles Editor, Yale Journal on Regulation.
  - Olin Fellow in Law, Economics, and Public Policy.
  - Honors grades in 9/20 graded courses, including administrative law and health policy and management (Yale School of Management).
  - Summer associate, intellectual property and structured finance, Kaye, Scholer, Fierman, Hays & Handler. Offer of permanent employment received.
- **Molecular Genetic Pathology Fellow**  
Mayo Clinic | 2005 - 2006

- **Postdoctoral Fellow Molecular Genetics**  
Yale University School of Medicine | 2004 - 2005
  - **Winchester Fellow in Medical Microbiology**  
Yale University School of Medicine | 2003 - 2004
  - **Resident, Laboratory Medicine**  
Yale-New Haven Hospital, New Haven, CT (Yale) | 2001 – 2003
  - **Intern, Internal Medicine**  
Mt. Sinai Hospital, Cleveland, OH (CWRU) | 1991 – 1992
  - **Doctor of Medicine**  
Case Western Reserve University | 1990
  - **Bachelor of Arts in Chemistry** (Magna Cum Laude),  
Case Western Reserve University | 1984
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## Certifications & Licenses

- Board-Certified in clinical pathology and molecular genetic pathology.
  - Licensed Attorney (District of Columbia, Ohio. Admitted: U.S. Supreme Court).
  - Licensed Physician in New York, Florida, and Ohio.
  - New York State Clinical Laboratory Director Certificate of Qualification, Molecular and Cellular Tumor Markers (2021 – present).
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## Publications & Media

Authored over 65 peer-reviewed articles and book chapters. Opinion contributor to national media outlets and frequent speaker at professional and industry conferences. Over 350 media appearances, including many national radio and television segments.

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## Editorial Advisory Boards

- Pharmacogenetics (2008 – present).
  - Expert Review of Molecular Diagnostics (2010 – present).
  - Inside Precision Medicine (2016 – present).
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## Community & Advisory Roles

- National Campaign Advisory Council, Israel Bonds (2022 - present).
- Chair, Northeast Ohio Campaign Advisory Council, Israel Bonds (2019 – 2021).

- Board of Advisors, Liberty & Law Center, Antonin Scalia Law School (2018 – present).
  - Member, Yale Law School Association Executive Committee (2014 -2017).
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## **Selected Honors**

- Jeffrey A. Kant Leadership Award, Association for Molecular Pathology (2018).
- Meritorious Service Award, Association for Molecular Pathology (2015).
- Travel Award, XXIV International Association for Comparative Research on Leukemia and Related Diseases Symposium (IACRLRD) 2009.
- Paul E. Strandjord Young Investigator Award, Academy of Clinical Laboratory Physicians and Scientists (2004, 2005, 2006).
- Travel Scholarship Award Institute for Justice (1994).
- Phi Beta Kappa.
- Phi Alpha Theta.