

Helen R. Trilling

Partner

Washington, D.C.

Biography

Widely recognized as a problem solver, Helen Trilling combines deep industry knowledge with an understanding of government enforcement interests to help healthcare clients design competitive business strategies. Working at the forefront of clinical and healthcare reform developments, Helen helps manufacturers and providers assess market opportunities and structure attractive customer offerings while managing compliance risk.

Long before most healthcare companies had "fraud and abuse" concerns on their radar, Helen was helping clients develop compliance programs, and counseling them on anti-kickback, self-referral and false claims risks. As innovation spurs development of new products and services, whether in personalized medicine, companion diagnostics and lab-developed tests, biologics and specialty pharmacies, shared risk plans, healthcare IT, mobile diagnostic and treatment, or other new technologies, Helen's clients rely on her to help identify and evaluate risk in proposed offerings, design mitigation strategies or alternatives, and advocate for regulatory or legislative change where needed.

Helen's vast client base and depth of experience allow her to help clients benchmark against industry norms and evolving expectations of regulators and



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Practices

Health Law

Pharmaceutical and Biotechnology
Regulatory Law

Medical Device Law

Government Relations and Public
Affairs

Industries

Life Sciences and Health Care

Areas of focus

Health Care Services

Hospitals and Health Care Providers

enforcement officials. Helen also regularly counsels clients on Medicare/Medicaid coverage, reimbursement, and billing, and has experience dealing with a wide variety of other federal and state regulatory issues in healthcare.

Helen's legal career includes stints at the Department of Health and Human Services (DHHS) and in the private sector. Perennially highly ranked by peers and clients, healthcare companies seek Helen out for her broad knowledge of the healthcare industry and regulatory environment, useful insight, and practical advice.

Representative experience

Negotiated and assisted clients in implementing Corporate Integrity Agreements in each decade since the earliest imposed in the 1990s.

Assisted biotech company crafting innovative pricing strategy to meet commercial goals and comply with anti-kickback, false claims and pricing laws.

Obtained OIG Advisory Opinions where useful in support of client programs, and Special Fraud Alerts where needed to create a level playing field.

Assisted healthcare IT companies in design of compliant EHR and e-prescribing systems that may include some manufacturer-sponsored features.

Handled hospital internal investigation and first voluntary anti-kickback law disclosure to the DHHS Office of Inspector General.

Regularly furnishes regulatory insight key to defending healthcare investigations, supporting declinations or mitigating settlement penalties.

Regularly works with clients to close compliance program gaps, update policies, develop employee training, and establish monitoring and audit plans.

Regularly helps structure consultant contracts,

Medical Devices

Pharmaceutical and Biotechnology

False Claims Act and Qui Tam

Education and admissions

Education

J.D., Harvard Law School, 1976

A.B., Harvard-Radcliffe College, magna cum laude, 1973

Memberships

Board Member, Women in Law Empowerment Forum

Member, American Health Lawyers Association

Bar admissions and qualifications

District of Columbia

Massachusetts (inactive)

Court admissions

Supreme Judicial Court of Massachusetts

U.S. Court of Appeals, District of Columbia Circuit

U.S. Court of Appeals, 10th Circuit

U.S. District Court, District of Columbia

education/research grants, charitable contributions, business courtesies, patient assistance programs.

Awards and rankings

- Healthcare (District of Columbia), *Chambers USA*, 2006-2018
- Acritas Star: Compliance, Regulatory, *Acritas Stars Independently Rated Lawyers*, 2017
- Health Care, *Washington, D.C. Super Lawyers*, 2009-2018
- Washington's Top Lawyers: Health Care, *Washingtonian*, 2014
- Outstanding Fraud and Compliance Lawyer, *Nightingale's Health Care News*, 2005
- Most Highly Regarded Firms for Life Sciences, *Who's Who Legal*, 2013

Latest thinking and events

- Hogan Lovells Publications
 - New anti-kickback prohibition in opioid bill creates tangled web of compliance obligations
Pharmaceutical and Biotechnology Alert
- Hogan Lovells Publications
 - OIG gives the green light to another innovative warranty
Health Alert
- Hogan Lovells Publications
 - HHS watchdog eyes anti kickback safe harbors for care coordination beneficiary incentives and cost sharing
Health Alert
- Hogan Lovells Publications
 - Massachusetts anti-opioid law bans manufacturer copay assistance
Health Alert
- Hogan Lovells Publications
 - CMS releases Medicare Advantage/Part D final rule
Health alert
- Hogan Lovells Publications

U.S. District Court, District of Massachusetts

U.S. Supreme Court

Accolades

"Helen Trilling is praised by clients for being outstanding in providing practical guidance on a very timely basis."

Chambers

- CMS finalizes National Coverage Determination for Next Generation Sequencing Tests for advanced cancer *Health Alert*