

Helen R. Trilling

Senior Counsel

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 health care clients design competitive business strategies. Working at the forefront of clinical and health care reform developments, Helen helps manufacturers and providers assess market opportunities and structure attractive customer offerings while managing compliance risk.

Long before most health care 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, health care 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 enforcement officials. Helen also regularly counsels clients on Medicare/Medicaid coverage,



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Practices

Health

Pharmaceuticals and Biotechnology
Regulatory

Medical Device and Technology
Regulatory

Government Relations and Public
Affairs

Industries

Life Sciences and Health Care

Areas of focus

Hospitals and Health Care Providers

Medical Devices

Pharmaceuticals and Biotechnology

reimbursement, and billing, and has experience dealing with a wide variety of other federal and state regulatory issues in health care.

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, health care companies seek Helen out for her broad knowledge of the health care 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, education/research grants, charitable contributions, business courtesies, patient assistance programs.

Awards and rankings

- Healthcare (District of Columbia), Senior

False Claims Act and Qui Tam
Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., Harvard Law School, 1976

A.B., 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, Tenth Circuit

U.S. District Court, District of
Columbia

U.S. District Court, District of
Massachusetts

U.S. Supreme Court

Accolades

Statespeople, *Chambers USA*, 2006-2022

- Acritas Star, *Acritas Stars Independently Rated Lawyers*, 2017-2020
- 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

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

Chambers

Latest thinking and events

- News
 - New Connecticut rules for drug makers employing sales reps take effect Oct. 1
- Press releases
 - Hogan Lovells advises Labcorp in strategic laboratory agreement with Ascension
- Press releases
 - Hogan Lovells advises Labcorp on US\$575 million acquisition of Personal Genome Diagnostics
- News
 - PhRMA responds: Code on Interactions with HCPs updated following fraud alert on speaker programs
- News
 - HHS Regulatory Sprint takes final shape, Part 2: AKS, Stark regulatory revisions for value-based care
- News
 - HHS Regulatory Sprint takes final shape, Part 1: Substantial Stark Law regulatory revisions adopted