

## 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

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### Industries

Life Sciences and Health Care

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### 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

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## Education and admissions

### Education

J.D., Harvard Law School, 1976

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

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## Memberships

Board Member, Women in Law Empowerment Forum

Member, American Health Lawyers Association

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## Bar admissions and qualifications

District of Columbia

Massachusetts (inactive)

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## 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

U.S. District Court, District of Massachusetts

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

## Awards and rankings

- Acritas Star: Compliance, Regulatory, *Acritas Stars Independently Rated Lawyers*, 2017
- Healthcare (District of Columbia), *Chambers USA*, 2006-2017
- 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
  - CMS releases Medicare Advantage/Part D final rule *Health alert*
- Hogan Lovells Publications
  - CMS finalizes National Coverage Determination for Next Generation Sequencing Tests for advanced cancer *Health Alert*
- Hogan Lovells Publications
  - New Jersey issues rules to chill drug manufacturer payments to prescribers *Health Alert*
- Hogan Lovells Publications
  - CMS proposes key changes to the Medicare Advantage program *Health Alert*
- Hogan Lovells Publications
  - New California law limits drug manufacturer co-pay cards and other discounts in California *Health Alert*
- Hogan Lovells Publications

U.S. Supreme Court

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## Accolades

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

*Chambers*

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- A path forward: Corporate Integrity Agreement sheds light on manufacturer interactions with independent charitable foundations *Health Alert*