



Michael H. Cohen

Affiliated Counsel

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For more than four decades, Michael H. Cohen has advised healthcare providers, entrepreneurs, and organizations on navigating complex regulatory frameworks, structuring compliant business models, and managing legal risk in a rapidly evolving healthcare landscape. His practice focuses on helping clients align innovation with regulatory requirements across a wide range of healthcare and life sciences sectors.

Michael works with healthcare professionals, startups, and established companies on transactional, compliance, and strategic matters involving healthcare delivery, technology, and emerging modalities. He brings a practical understanding of how regulatory structures impact business operations, informed by decades of experience counseling clients and resolving high-stakes disputes.

In addition to his legal practice, Michael has served in academic and research roles that shaped national conversations around healthcare law and policy. He held faculty appointments at Harvard Medical School and the Harvard T.H. Chan School of Public Health, where he developed policies and procedures for integrative medicine across multiple affiliated hospitals and led interdisciplinary research initiatives supported by national grant funding. His work has addressed legal and ethical considerations in healthcare innovation, complementary and alternative medicine, and patient care delivery.

Michael has authored multiple books and more than 100 articles published in peer-reviewed medical journals and leading legal publications. He also has delivered lectures at academic institutions and professional conferences throughout the United States and internationally.

Independent of Offit Kurman, Michael also serves as a healthcare arbitrator and mediator through Healthcare ADR Inc., on the panels of the American Arbitration Association (AAA), the World Intellectual Property Organization (WIPO), the American Health Lawyers Association (AHLA) Dispute Resolution Service, and National Arbitration and Mediation (NAM). As an attorney who arbitrates complex, multi-million-dollar healthcare legal disputes, Michael understands firsthand how regulatory and structural vulnerabilities can translate into litigation, giving the transactional and compliance counsel he helps bring to clients a dimension that few regulatory attorneys can offer.

Services

- Healthcare
- Business Law and Transactions

Areas of Focus:

- **Healthcare Corporate and Commercial**

Advises healthcare providers and organizations on healthcare transactions, including mergers and acquisitions, affiliations, and clinical integration arrangements. Counsels clients on healthcare contracts and regulatory compliance involving physician employment agreements, joint ventures, and vendor relationships, with a focus on aligning business objectives with healthcare regulatory requirements.

- **Healthcare Data Privacy and Security**

Counsels healthcare providers, business associates, and health technology companies on HIPAA compliance, HITECH requirements, and healthcare data privacy laws. Advises on data breach response, risk mitigation, and Business Associate Agreements to ensure regulatory compliance and protection of sensitive health information.

- **Anti-Kickback Statute and Stark Law Compliance**

Advises healthcare organizations on fraud and abuse laws, including the Anti-Kickback Statute and Stark Law. Structures physician compensation and referral arrangements to meet regulatory safe harbors and exceptions, while conducting compliance reviews to mitigate enforcement risk.

- **Corporate Practice of Medicine and MSO Structuring**

Guides healthcare providers, investors, and management services organizations (MSOs) on corporate practice of medicine laws and compliant business structuring. Drafts and negotiates MSO agreements and management arrangements across multiple states, supporting regulatory compliance and operational efficiency.

- **Telemedicine and Digital and Mobile Health**

Advises telemedicine companies and digital health platforms on multi-state regulatory compliance, including licensure, prescribing, and reimbursement requirements. Counsels health technology developers on FDA, FTC, and state regulatory frameworks impacting digital health and innovation.

- **Emerging Healthcare Modalities**

Counsels emerging healthcare businesses including integrative medicine, medical spas, and telehealth venture, on regulatory compliance, licensing, and corporate structure. Advises on healthcare innovation in areas such as regenerative medicine, wellness services, and non-traditional care delivery models.

- **FDA and FTC Regulatory Matters**

Advises life sciences and consumer health companies on FDA and FTC regulatory compliance, including labeling, marketing, and claims substantiation. Counsels on advertising standards, product classification, and enforcement risk across pharmaceuticals, medical devices, and dietary supplements.

- **Healthcare Regulatory Compliance**

Provides healthcare regulatory counsel on federal and state laws, including HIPAA, Stark Law, and Anti-Kickback requirements. Conducts compliance assessments and risk analyses to help healthcare organizations identify vulnerabilities and maintain regulatory compliance.

- **Academic and Research Contributions to Healthcare Law**

Brings a strong foundation in healthcare law and policy through academic research, publications, and teaching. Contributed to national and international discussions on healthcare regulation and innovation through peer-reviewed scholarship, grant-funded research, and presentations at leading academic and professional institutions.

Education

- University of California, Berkeley, School of Law (J.D.)
- University of California, Berkeley, Haas School of Business (M.B.A)
- University of Iowa, Iowa Writers' Workshop (M.F.A.)
- Columbia University, Columbia College (B.A.)

Languages

- French – conversational
- Hebrew – conversational
- Spanish – conversational

Recognitions

- Invited Faculty, Medical Institute for Law Faculty, Cleveland Clinic / Cleveland-Marshall School of Law (1995)
- G. Joseph Tauro Distinguished Scholar, Boston University School of Law (1984)
- CJS Award; Am. Jur. Award, Boston University School of Law (1984)
- Invited to Law Review, Boston University School of Law (1984)
- Invited to Law Review, UC Berkeley School of Law (1984)

Research Grants (Selected)

- M.D. Anderson Cancer Center Integrative Medicine Program / NCI, *Consultant* (2005)
- The Epilepsy Foundation: Asian Herbal Products for Epilepsy, *Co-Investigator* (2004–2005)
- Hospital for Sick Children Foundation (Toronto): Decision-Making About Complementary and Alternative Therapies for Children and Youth, *Research Collaborator* (2004–2005)
- The Greenwall Foundation: Pediatric Use of Complementary Therapies by Parents: Ethical and Policy Choices, *Principal Investigator* (2004–2005)
- NIH/NCCAM: International Center for Research on Complementary and Alternative Medicine, *Co-Investigator* (2003–2005)
- NIH/National Library of Medicine: Legal and Social Barriers to Alternative Therapies, *Principal Investigator* (2002–2005)
- Ministry of Science and Research of North Rhine-Westphalia, Germany: Governmental Regulations for Traditional Chinese Herbal Medicine, *Consultant* (2004)
- American Specialty Health Plan: Credentialing Practices, Malpractice Liability Policies, and Guidelines Governing Recommendations Involving Dietary Supplements, *Principal Investigator* (2000–2002)
- NIH/NCCAM: Models of Integrative Care in an Academic Health Center, *Co-Investigator* (2000–2002)
- Medtronic Foundation: Credentialing, Liability and Dietary Supplements Policies, *Co-Investigator* (2000–2002)

State Bar Admissions

- California
- District of Columbia
- Massachusetts
- Nevada
- New York

Professional Affiliations

- Arbitration Panel Member, American Health Lawyers Association (AHLA) Dispute Resolution Service, (2022–Present)
- Faculty, The Leadership Program in Integrative Healthcare at Duke University (2014)
- Advisory Board Member, Integrative Pediatrics Council (2006)
- External Advisory Committee, University of Texas M.D. Anderson Cancer Center, Integrative Medicine (2005)
- Board Member, Society of Integrative Oncology (2005)
- Core Faculty Member, Asian Medicine and Healing Program, Harvard Medical School Osher Institute (2005)
- External Reviewer: Pediatrics; Journal of Law and Religion; Alternative Therapies in Health and Medicine; Medical Journal of Australia; American Journal of Law, Medicine and Ethics; University of Michigan Press (2000–2005)
- Editorial Board, Integrative Medicine: A Clinician's Journal (2004)
- National Advisory Board, Corporate Health Improvement Program, University of Arizona School of Medicine (2004)
- Consultant, Institute of Medicine, National Academy of Sciences, Committee on Complementary and Alternative Medicine Use by the American Public (2003–2004)
- Advised on the work of the Massachusetts Special Commission on Complementary and Alternative Medical Practitioners (2002–2003)
- Advised on the Federation of State Medical Boards Model Guidelines for Complementary and Alternative Therapies (2000–2002)
- Research Advisory Council, Religion, Health and Healing Initiative, Harvard Divinity School (2001–2002)
- Legal Editor, Alternative Healthcare Management (1998–1999)
- Co-Editor, Legal Matters, Alternative and Complementary Therapies (1995–1996)
- Member, American Health Lawyers Association

Representative Matters

Healthcare Corporate and Commercial

- Advised physicians, dentists, podiatrists, and other licensed healthcare professionals in a wide range of commercial arrangements, including mergers and acquisitions, affiliations, recruitment arrangements, and other types of clinical integration transactions across numerous medical and surgical specialties.

- Advised digital and mobile health entrepreneurs on fundamental regulatory and business structural issues.
- Drafted and negotiated complex commercial contracts among and between healthcare providers and pharmaceutical and medical device manufacturers.
- Drafted and negotiated a wide range of healthcare-related contracts, including physician employment agreements, buy-sell agreements, operating agreements, vendor contracts, and joint venture agreements.
- Negotiated contracts between healthcare providers, insurers, and suppliers, ensuring compliance with regulatory requirements.

Healthcare Data Privacy and Security

- Advised healthcare providers, business associates, and health technology companies on the interpretation of HIPAA and HITECH regulations.
- Coordinated data breach responses involving protected health information subject to HIPAA and personally identifiable information subject to state breach law.
- Drafted and negotiated Business Associate Agreements for healthcare providers, technology companies, and other covered entities and business associates.

Anti-Kickback Statute and Stark Law Compliance

- Advised healthcare providers, facilities, and ventures on Anti-Kickback Statute and Stark Law compliance, including structuring physician compensation arrangements, referral relationships, employment agreements, and ancillary service arrangements to comply with applicable safe harbors and exceptions.
- Counseled healthcare entities on fraud and abuse risk assessment and mitigation, including review of existing business arrangements for compliance with federal and state fraud and abuse laws.

Corporate Practice of Medicine and MSO Structuring

- Counseled healthcare providers, management companies, and investors on corporate practice of medicine laws across multiple states, including designing compliant business structures, drafting MSO agreements, advising on permissible management fee arrangements, and resolving regulatory compliance issues for physician practices, medical spas, telemedicine ventures, and other healthcare businesses.
- Drafted and negotiated management agreements and administrative services agreements for national MSOs and their affiliated healthcare providers.

Telemedicine and Digital and Mobile Health

- Advised telemedicine companies, digital and mobile health startups, and online wellness platforms on regulatory compliance across multiple states, including corporate practice of medicine, medical licensure, prescribing authority, and billing requirements.
- Counseled mobile medical application developers, wearable technology ventures, augmented and virtual reality health companies, and other health technology businesses on FDA, FTC, and state regulatory requirements.

Emerging Healthcare Modalities

- Counseled a broad range of emerging and non-traditional healthcare businesses and practitioners, including integrative and functional medicine centers, anti-aging and

regenerative medicine providers, stem cell therapy practices, IV hydration clinics, medical cannabis providers, addiction and behavioral health treatment facilities, and other technology-enabled and emerging healthcare businesses on regulatory compliance, corporate structure, licensing, and business formation.

- Advised aesthetic medicine providers, medical spas, and related healthcare businesses on corporate practice of medicine compliance, fee-splitting restrictions, licensing requirements, and regulatory matters across multiple states.
- Counseled healthcare practitioners providing complementary, alternative, and integrative therapies — including acupuncture, chiropractic, naturopathic, homeopathic, and other modalities — on regulatory requirements, scope of practice issues, and patient care standards.

FDA and FTC Regulatory Matters

- Advised manufacturers, distributors, and marketers of dietary supplements, nutraceuticals, vitamins, minerals, herbs, and functional foods on FDA and FTC regulatory requirements, including claims substantiation, structure-function claims, labeling compliance, good manufacturing practice requirements, and enforcement risk.
- Counseled manufacturers and marketers of cosmetics, OTC drugs, homeopathic products, and medical devices on FDA classification, labeling, marketing, and regulatory compliance.
- Advised healthcare companies and practitioners on FTC advertising standards and enforcement risks applicable to health product and service marketing claims.
- Counseled on informed consent requirements, off-label use and promotion, and permissible communication of scientific information in connection with medical treatments and therapeutic products.
- Advised companies on contract manufacturing arrangements for dietary supplements, cosmetics, and medical products, including regulatory compliance and quality agreements.

Healthcare Regulatory Compliance

- Advised healthcare organizations on regulatory compliance matters, including fraud and abuse laws, patient privacy regulations, and state and federal healthcare regulatory requirements.
- Conducted compliance reviews and regulatory analysis to identify and mitigate legal risks with respect to core healthcare laws and regulations, including the Anti-Kickback Statute, Stark Law, HIPAA, and the Corporate Practice of Medicine.

Academic and Research Contributions to Healthcare Law

- Pioneered and taught Complementary and Alternative Medicine: Health Law and Policy at the Harvard T.H. Chan School of Public Health.
- Developed policies and procedures for integrative medicine across 14 Harvard-affiliated hospitals as faculty member at Harvard Medical School and Harvard T.H. Chan School of Public Health.
- Principal Investigator, NIH/National Library of Medicine: Legal and Social Barriers to Alternative Therapies.
- Principal Investigator, The Greenwall Foundation: Pediatric Use of Complementary

Therapies by Parents: Ethical and Policy Choices.

- Principal Investigator, American Specialty Health Plan: Credentialing Practices, Malpractice Liability Policies, and Guidelines Governing Recommendations Involving Dietary Supplements.
- Published six books and more than 100 peer-reviewed articles in medical, legal, and professional journals.
- Delivered more than 100 invited lectures at professional conferences and academic institutions nationally and internationally.
- Consultant, Institute of Medicine, National Academy of Sciences, Committee on Complementary and Alternative Medicine Use by the American Public.
- Consultant, M.D. Anderson Cancer Center Integrative Medicine Program / National Cancer Institute.
- Consultant, Ministry of Science and Research of North Rhine-Westphalia, Germany: Governmental Regulations for Traditional Chinese Herbal Medicine.
- Faculty, The Leadership Program in Integrative Healthcare, Duke University.
- Fortieth Anniversary Senior Fellow, Center for the Study of World Religions, Harvard Divinity School.

Publications

Authored Books

- "Healing at the Borderland of Medicine and Religion," University of North Carolina Press, 2006.
- "Legal Issues in Integrative Medicine," Washington, NAF Press, 2005.
- "Future Medicine: Ethical Dilemmas, Regulatory Challenges, and Therapeutic Pathways to Health and Healing in Human Transformation," University of Michigan Press, 2003.
- "Beyond Complementary Medicine: Legal and Ethical Perspectives on Health Care and Human Evolution," University of Michigan Press, 2000.
- "Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives," Johns Hopkins University Press, 1998.
- "Creative Writing for Lawyers," Citadel Press, 1990.

Selected Peer-Reviewed Articles in Medical Journals

Over 100 articles in publications including Annals of Internal Medicine, Archives of Internal Medicine, Pediatrics, Journal of Medical Ethics, Medical Journal of Australia, Epilepsy and Behavior, and others. Selected:

- Ernst EE, Cohen MH. Informed consent in complementary and alternative medicine. Arch Intern Med 2001;161:2288-2292.
- Cohen MH, Eisenberg DM. Potential physician malpractice liability associated with complementary/integrative medical therapies. Ann Intern Med 2002;136:596-603.
- Eisenberg DM, Cohen MH, et al. Credentialing complementary and alternative medical

providers. *Ann Intern Med* 2002;137:965-973.

- Cohen MH, Kemper KJ. Complementary therapies in pediatrics: A legal perspective. *Pediatrics* 2005;115:774-780.
- Cohen MH, et al. Emerging credentialing practices, malpractice liability policies, and guidelines governing complementary and alternative medical practices: a descriptive study of 19 integrative health care centers. *Arch Int Med* 2005;165:289-295.
- Gilmour J, Harrison C, Asadi L, Cohen MH, Vohra S. Pediatric use of complementary and alternative medicine: legal, ethical, and clinical issues in decision-making. *Pediatrics* 2011;128:S149-154. [and 8 companion articles in same issue]

Selected Articles in Law Reviews and Journals

- Cohen MH. Reconstructing the implied covenant of good faith and fair dealing as a tort. *Calif L Rev* 1985;73:1291-1331.
- Cohen MH. A fixed star in health care reform: the emerging paradigm of holistic healing. *Ariz State L J* 1995;27:79-173.
- Cohen MH. Holistic health care: including complementary and alternative medicine in insurance and regulatory schemes. *Ariz L Rev* 1996;38:83-164.
- Cohen MH. U.S. dietary supplement regulation: belief systems and legal rules. *Hastings W Law J* 2000;11(1):3-21.
- Cohen MH. Negotiating integrative medicine: a framework for provider-patient conversations. *Negotiation J* 2004;30(3):409-433.
- Cohen MH. Healing at the borderland of medicine and religion: regulating potential abuse of authority by spiritual healers. *J Law and Relig* 2004;18(2):373-426.
- Cohen MH, Ruggie M. Integrating complementary and alternative medical therapies in conventional medical settings: legal quandaries and potential policy models. *Cinn L Rev* 2004;72(2):671-729.

News

July 20, 2026

Offit Kurman Strengthens National Healthcare Platform with Addition of Michael H. Cohen