

Massachusetts

GO TO Lawyers

Healthcare/Life Sciences 2022

MASSACHUSETTS
Lawyers Weekly

Letter from the Publisher



Dear readers,

Welcome to Massachusetts Go To Lawyers, a feature we debuted in 2020 to showcase leaders in the Massachusetts legal community by practice area.

For this list, we've chosen to focus on Healthcare and Life Sciences attorneys. The lawyers featured here were all nominated by their colleagues and chosen by a panel from Lawyers Weekly. We expect that some readers will argue that there are some excellent lawyers who should have been included. Let us know! And please nominate them for future lists. Other practice areas, such as tax, cybersecurity and business litigation, will be topics for future editions of Massachusetts Go To Lawyers.

Susan A. Bocamazo, Esq.

Publisher

Massachusetts Lawyers Weekly

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ROBERT K. BLAISDELL

**Partner, Husch Blackwell
Boston**

After having advised healthcare clients for more than a quarter-century, Husch Blackwell partner Robert K. Blaisdell knows the industry inside and out.

Blaisdell's practice focuses on representing hospitals, healthcare systems, physicians, physician groups, nursing homes and assisted living facilities.

His years spent working on-site at a large hospital afforded him an intricate knowledge of the internal dynamics of healthcare providers and medical staff members, as well as the needs of their staff and administrators.

Blaisdell primarily serves clients as an outside general counsel, providing day-to-day advice on a variety of regulatory compliance issues that include vendor contracting, HIPAA, medical staff credentialing and peer review.

Blaisdell also counsels clients on healthcare fraud and abuse issues including Anti-Kickback, Stark Physician self-referral and False Claims Act analysis, employment law and personnel issues, and nursing home and assisted living facility-specific matters, including discharges, evictions and plans of correction.

Some of Blaisdell's representative engagements include representing hospitals and medical staff members in physician disciplinary and peer review proceedings and representing providers in disciplinary matters before various licensing agencies, including the Board of Reg-



istration in Medicine, the Board of Registration in Nursing and the Division of Professional Licensure.

Additionally, Blaisdell has successfully represented providers in various discrimination actions before the Massachusetts Commission Against Discrimination.

Blaisdell is a sought-after speaker on such as issues as informed consent, privacy and security of personal information, disagreements between providers and caretakers, and landlord-tenant issues faced by assisted living facilities.

Blaisdell prides himself on providing his clients with more than just answers to their legal questions. He aims to serve as a true business partner, evaluating clients' business situations from a legal perspective honed by his 25 years in the industry. *MLW*

Achievements and professional activities

Office managing partner, Husch Blackwell, Boston; member, Boston Bar Association; member, Massachusetts Bar Association; member, American Health Lawyers Association

DAVID V. CAPPILLO

**Partner, Goodwin
Boston**

As co-chair of Goodwin's Healthcare and Digital Health practice, Boston attorney David V. Cappillo advises high-growth technology and healthcare companies and serves as a trusted advisor throughout the entire corporate lifecycle.

Cappillo represented Boston-based wearable technology company WHOOP, which he advised in its successful \$100 million Series E round and, more recently, its \$200 million Series F growth round that valued the company at \$3.6 billion.

He also represents clients on a variety of exit transactions, including his representation of pioneering online pharmacy PillPack during its acquisition by Amazon. The deal drew national headlines for its potential to transform the U.S. pharmacy market.

Meanwhile, over just the past year, Cappillo has represented several local companies and organizations on transactions with global implications.

For example, in June 2021, Cappillo represented leading online platform and education marketplace edX in its agreement for 2U, Inc. to acquire substantially all its assets for \$800 million in cash. Together, 2U and edX will reach more than 50 million learners globally in a free-to-degree online education market-



place.

That same month, Cappillo advised Boston-based TrueMotion in its acquisition by Cambridge Mobile Telematics. The transaction deal unites the two leading companies in the rapidly growing mobile telematics industry and has enabled CMT to provide telematics services to 21 out of the 25 largest auto insurers in the United States and more than 20 other countries.

In October 2021, Cappillo advised EverTrue, a leading advancement software platform, in its merger with ThankView, the largest personalized video platform for nonprofits. The integration of the two companies' products will unlock a new and more effective approach to fundraising. *MLW*

Achievements and professional activities

Co-chair, Healthcare and Digital Health practice, Goodwin; member and vice president, board of trustees, Meadowbrook School of Weston; member, founding advisory board, BUILD Boston; guest lecturer, Harvard Business School; lawyer-in-residence, Rock Center for Entrepreneurship and Harvard iLab; TechStars mentor

HANNAH R. BORNSTEIN

**Partner, Nixon Peabody
Boston**

The deputy practice group leader of Nixon Peabody's Government Investigations & White Collar Defense practice, Boston attorney Hannah R. Bornstein counsels life sciences companies through a wide range of FDA compliance, enforcement, and litigation matters.

Whether assessing a potential product approval pathway, conducting due diligence in a transaction or responding to a government investigation, Bornstein helps clients navigate myriad complex government regulations and oversight.

Bornstein counsels clients in matters involving the False Claims Act; Food, Drug, and Cosmetic Act; and the Anti-Kickback Statute. She also helps them respond to governmental inquiries and investigations conducted by the FDA, the U.S. Attorney's Office and the U.S. Department of Justice, among others.

Representative matters have involved government inquiries relating to possible "off-label" promotion and whether a drug or device was marketed in accordance with its approved intended use; possible false or misleading advertising; and compliance with CGMP standards, including investigations that follow FDA 483 warning letters.

Bornstein has also represented life sciences companies in government investigations and audits, provided compliance advice and



assessments on key issues, and acted as fraud, waste, and abuse counsel during negotiations with the DOJ.

More specifically, Bornstein represents life sciences companies, including diagnostics manufacturers, in government healthcare fraud investigations and related civil litigation under the False Claims Act and state counterparts, FD&C, the Medicare/Medicaid Anti-Kickback Statute, the Medicaid Drug Rebate Statute, and state consumer fraud statutes.

Beyond Bornstein's busy practice, she maintains an active pro bono asylum caseload, representing clients from Cameroon, Rwanda, Uganda, Nepal, Syria, Libya and the Dominican Republic before the Boston Asylum Office and Boston Immigration Court. *MLW*

Achievements and professional activities

Deputy practice leader, Government Investigations & White Collar Defense, Nixon Peabody; co-author, "Negotiating False Claims Act Settlements," Health Law Handbook, Thomson Reuters; member, FDLI Enforcement, Litigation, and Compliance Conference Planning Committee and FDLI Webinar Committee; six-time finisher, Boston Marathon



Congratulations to our partner **Hannah Bornstein**, chosen by *Massachusetts Lawyers Weekly* as a **2022 Go-To Lawyer** for life sciences and healthcare clients.



Hannah Bornstein
Partner



Nixon Peabody LLP
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Boston, MA | nixonpeabody.com

HEMMIE CHANG

**Partner, Foley Hoag
Boston**

As co-chair of Foley Hoag’s 150-attorney Life Sciences Group, Hemmie Chang represents major players in the biopharma and medical device spaces, in which she has handled IP licensing matters, development and marketing deals, and closed more than \$12 billion in transactions over the last two decades.

The group represents more than 2,000 biotech, medical device, diagnostic and pharma clients ranging from large pharma and biotech companies like AbbVie, Biogen and Gilead to emerging public companies like Dicerna, Enanta and Organogenesis, as well as academic institutions such as Dana-Farber Cancer Institute, Harvard, MIT and Tufts.

One of Chang’s signature engagements was her representation of Dicerna Pharmaceuticals, which uses RNA interference techniques to target serious disease, in a major licensing and research collaboration deal with pharmaceutical giant Eli Lilly.

Chang also shepherded Dicerna through a global collaboration agreement with Novo Nordisk A/S to discover and develop novel therapies for treating liver-related cardiometabolic diseases. As part of the agreement, Dicerna received an upfront payment of \$175 million, a \$50 equity investment and the potential for up to \$357 million per target in development, regulatory and commercializa-



tion milestone payments.

As chair of Foley Hoag’s Licensing & Strategic Alliances Practice, which she built from a smaller technology transactions practice upon joining the firm, Chang handles an array of high-profile intellectual property matters and has advised on more than \$13 billion in deals over the past several years alone, drawing from her more than two decades in the biopharma, medical device, gene and cell therapy and genomic sectors.

Outside the office, Chang is a co-founder of the Asian American Lawyers Association of Massachusetts, for which she served as its first secretary and as an initial director, and continues to be active in both AALAM and the National Asian-Pacific American Bar Association. **MLW**

ANTHONY J. CICHELLO

**Partner, Krokidas & Bluestein
Boston**

Krokidas & Bluestein partner Anthony J. Cichello brings his healthcare and litigation clients 30 years’ experience providing regulatory and general counseling to nonprofit and for-profit healthcare institutions, human service providers, and individual licensed practitioners.

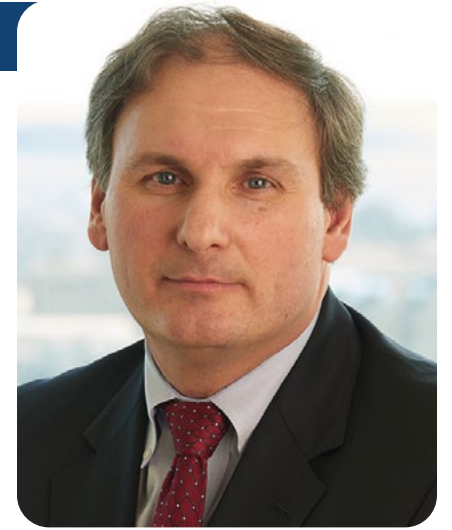
Cichello’s clients span the healthcare continuum, from hospitals, community health centers, nursing homes and assisted living facilities to supportive housing and human service providers and individual providers.

Working collaboratively with organizational leadership, Cichello counsels on governance, employment and compliance issues, survey and certification matters, licensing, credentialing and privileging disputes, peer review, HIPAA and privacy concern, and labor and employment issues.

Cichello also represents providers in licensing and disciplinary matters before boards of registration and both government and private insurers.

Leveraging his regular interaction with regulatory agencies, Cichello helps clients identify and address trends in regulatory oversight. Additionally, he conducts internal investigations into employment, billing, potential false claims, compliance and ethics issues.

Cichello also handles litigation in state and federal courts and before administrative tribu-



nals and private arbitration panels.

More recently, when a nursing home client risked losing its right to participate in Medicaid, Cichello was able to negotiate a successful resolution that allowed the program to continue.

Cichello also helped a behavioral health center navigate practical issues of safety when dealing with potentially violent patients. And during the height of the COVID pandemic, Cichello took calls day and night from clients with questions around mask and vaccine mandates, testing requirements, visitor policies and restrictions, telehealth policies, PPE policies, staffing mandates, and waivers for providers. Such guidance proved critical for CEOs and administrators seeking to keep their clinicians, providers and residents safe and healthy. **MLW**

Achievements and professional activities

Co-Chair, Life Sciences Industry Group, Foley Hoag; chair, Licensing & Strategic Alliances Group, Foley Hoag; member, LMG Life Sciences Hall of Fame; honoree, “Top Women of Law,” Massachusetts Lawyers Weekly; co-founder, Asian American Lawyers Association of Massachusetts

Achievements and professional activities

Chair, board of directors, Beth Israel Deaconess Hospital – Milton; former chair and vice chair, Town of Milton School Building Committee; former co-chair, ADR Committee, Labor and Employment Law Section, Boston Bar Association



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Krokidas & Bluestein

congratulates our colleague and friend

Anthony Cichello

2022 Go To Health Care Lawyer

and all the 2022

Go To Life Science/Health Care Lawyers



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Massachusetts Legal Profession**



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ATTEND AN EVENT**



**GET ANSWERS
& RESOURCES**



**SIGN UP FOR
OUR EMAILS**

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KRISTIN A. CONNARN**Partner, Hogan Lovells
Boston**

Not many attorneys can claim to have a previous career spent combatting some of the world's most feared diseases. Kristin A. Connarn is not like many other attorneys.

Before becoming a lawyer, Connarn worked as a researcher for the Cancer Bioscience and CNS groups at AstraZeneca R&D Boston, where she applied molecular and cell biology techniques to research cancer and Alzheimer's disease. She also researched gene activation with Transkaryotic Therapies.

Now a partner with Hogan Lovells in Boston, Connarn leverages her background in biotechnology and cancer research as a trusted counselor for clients that range from startups to international pharmaceutical companies and from nonprofits, medical centers, and universities to venture capital and private equity investors.

Specifically, Connarn supports clients in strategic counseling, patent portfolio development and management and patent prosecution while also guiding them through transactions and agreements that involve intellectual property assets, including development agreements, sponsored research agreements, licenses and complex commercial transactions.

Of particular significance is the practice she built working with companies developing novel biologics in the cell and gene therapy spaces, including oncology, autoimmune and inflammatory diseases.

In that capacity, Connarn assists clients in developing and executing IP protection strategies on therapeutic antibodies, recombinant proteins, targeted



delivery of therapeutics including using antibodies and nanoparticles, and therapies including microbiome transplantations, CAR-T, CAR-NK and TCR-T cells.

Additionally, Connarn counsels companies developing biologics to treat and prevent infections, including COVID-19.

Connarn also brings clients a wealth of patent prosecution experience, including methods of treatment and diagnostics, dry powder inhalation therapies, food science, vaccines and medical device while also training in-house legal and scientific teams on such matters as invention disclosures, patentability and inventorship.

Connarn recently represented Pyxis Oncology, managing its global patent portfolio and supporting IP diligence activities for a \$152 million Series B financing, followed shortly thereafter by its upsized \$168 million IPO.

Connarn currently manages the patent portfolio for emerging company Tevogen Bio, and has overseen in the issuance of three U.S. patents towards novel T-cell therapy for treatment of COVID-19. **MLW**

Achievements and professional activities

Panelist, JP Morgan and Biotech Showcase; honoree, IAM Patent 1000 — World's Leading Patent Practitioners

MAYA P. FLORENCE**Partner, Skadden
Boston**

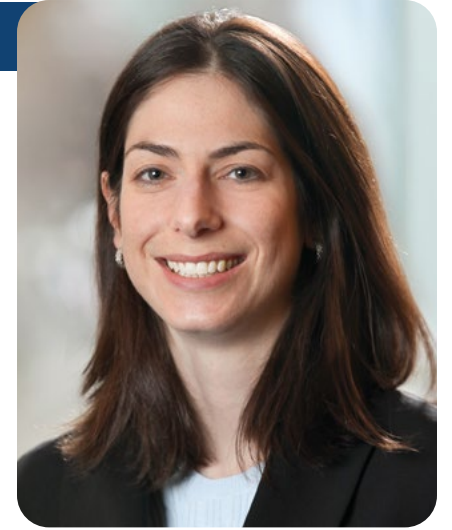
Maya P. Florence takes an approach that's decidedly different from the typical attorney in the life sciences arena.

Rather than concentrating on a single, highly focused area — like a particular stage of the life cycle for FDA-regulated products or the application of specific healthcare fraud-and-abuse-laws to life sciences companies — Florence takes a holistic approach to matters, providing deep experience across all disciplines, from government and internal investigations and complex regulatory advice to high-stakes transactions and active litigation.

That approach allows the Skadden partner to assess risk quickly and proactively identify impact areas for a stable of clients that includes pharmaceutical and biotechnology companies, medical device manufacturers and genomic laboratories, among other healthcare industry participants.

For example, on the enforcement and investigation front, Florence's recent engagements include representing Purdue Pharma L.P. in connection with emerging developments relating to the marketing of opioid medications, including its successful resolution of U.S. Department of Justice civil and criminal investigations concerning the sale and marketing of opioid products.

In terms of regulatory/compliance work, Florence represented a major medical product



trade organization in drafting comments for submission to two FDA dockets while representing Veloxis Pharmaceuticals A/S, when it filed a federal action seeking to reverse the FDA's decision to delay approval of its new drug, Envarsus XR, based on marketing exclusivity given to an earlier-approved competing drug.

On the transactional front, Florence recently represented Dicerna Pharmaceuticals, Inc. in its \$3.3 billion acquisition by Novo Nordisk; Alcon in its \$355 million acquisition of the U.S. commercialization rights to the ophthalmic medication Simbrinza from Novartis; and Honeywell in its \$1.3 billion acquisition of Sparta Systems, a provider of enterprise quality management software for the life sciences industry, from New Mountain Capital and other stockholders. **MLW**

Achievements and professional activities

Hiring partner, Boston office, Skadden; member, Women's Initiatives Committee, Skadden; law clerk, Judge Colleen Kollar-Kotelly, U.S. District Court for the District of Columbia (2006-2008)

SUZANNE L. FILIPPI**Partner, Morgan, Lewis & Bockius
Boston**

With a focus on corporate transactions in the life sciences industry, Boston attorney Suzanne L. Filippi represents an eclectic lineup of major biotech players, including public entities, private companies and multinational pharmaceutical corporations.

Drawing on her deep life sciences industry knowledge, Filippi counsels clients in a wide range of corporate transactions, with a particular emphasis on complex license and collaboration agreements, co-commercialization/co-promotion matters, and mergers, acquisitions, and externalizations in the life sciences sector.

Filippi recently led a team of 40 lawyers from 11 Morgan Lewis offices across the globe over a six-month period as she represented Takeda Pharmaceutical Co. in a series of cross-border transactions with Oak Hill Bio Ltd., a newly formed clinical-stage rare disease therapeutics company.

The complicated transaction structure involved an asset sale of Takeda's TAK-607 program, a stock sale of a Takeda wholly owned German subsidiary, an exclusive license for Takeda's oral pKAL compound, and the negotiation of various equity and shareholder agreements, as well as a highly confidential negotiation with a public special purpose acquisition company (SPAC).

Filippi also recently represented Takeda in its agreement with Moderna and Japan's Ministry of



Health, Labour and Welfare (MHLW) to import and distribute an additional 50 million doses of Moderna's mRNA COVID-19 vaccine in Japan.

The deal, announced last summer, includes the potential to secure and supply vaccines for COVID-19 variants or booster products should they be successfully developed by Moderna and licensed by the MHLW.

Takeda previously announced a three-way agreement with Moderna and MHLW to distribute 50 million doses of the COVID-19 Vaccine Moderna Intramuscular Injection in Japan in 2021. With this latest agreement, Takeda will import and distribute the additional 50 million doses from as early as the beginning of 2022, totaling 100 million doses between the two agreements.

The agreement also includes the option to purchase another 100 million doses. **MLW**

Achievements and professional activities

Co-leader, Pharmaceuticals Working Group, Morgan, Lewis & Bockius; member, Life Sciences Planning Committee, Boston Bar Association

GREGG A. GRINER**Partner, Orrick, Herrington & Sutcliffe
Boston**

An accomplished transactional attorney and legal advisor, Gregg A. Griner has led hundreds of business ventures and developed long-lasting relationships with management teams and boards of directors over the course of a 30-year career.

Through his work as a partner at Orrick, Herrington & Sutcliffe — which recruited him about three years ago to help build out its life sciences practice and the corporate business practice in its Boston office — as well as other firms before that, Griner has developed, attending all board and committee meetings.

Griner also serves as outside general counsel for his clients and helps guide them in all aspects of their businesses. Meanwhile, he maintains deep global connections throughout the life sciences and technology industries.

Griner represents private and public life sciences companies, investors and underwriters. He leads clients through IPOs, private and public equity and debt offerings, acquisitions, joint ventures, strategic partnerships and licensing transactions and exits. He has represented one public life sciences company for 17 years, beginning with its second round of venture financing.

Among his representative projects, Griner represented Vanda Pharmaceuticals in



its IPO and follow-on public offerings and continues to represent the company in all corporate and corporate governance matters, capital markets and M&A work, as well as '34 Act filing matters.

Griner has also represented such leading life sciences investors as NEA, RA Capital, OrbiMed, Third Rock Ventures, F-Prime Capital, MPM Capital, Atlas Venture, Deerfield, Polaris, RTW Investments, Prospect Venture Partners and Venrock.

Additionally, Griner represented the lead investors in the \$125 million cross-border pre-IPO financing of GH Research while also representing Schrodinger, Inc. in structuring the Nimbus Therapeutics joint venture with Atlas Venture.

He also represented TearScience in its acquisition by Johnson & Johnson. **MLW**

Achievements and professional activities

Member, Colorado state bar

WESLEY C. HOLMES

**Partner, Latham & Watkins
Boston**

With nearly 20 years' experience advising companies and banks on some of their most complex and sophisticated transactions, Wesley C. Holmes built a reputation as a leading healthcare lawyer not only in Boston, but in the U.S. and globally — one who invests himself not only in the matter at hand, but in the long-term success of the client.

Holmes has built that reputation by helping his clients at Latham & Watkins achieve their most ambitious objectives on broad range of transactions, including public securities offerings, high-yield debt offerings, M&A finance, and private and venture offerings.

In fact, just within the past year, Holmes has advised on more than 30 matters valued at more than \$14 billion.

Holmes's accomplishments include leading a team that represented P3 Health Partners, a patient-centered and physician-led population health management company, in its completed business combination with publicly traded Foresight Acquisition Corp.

Holmes also led the team that represented Altaris Capital in the sale of its portfolio company BK Medical, a designer and manufacturer of medical devices, to GE Healthcare, a subsidiary of General Electric.

That acquisition — reportedly GE's largest under Larry Culp, who has focused heavily on paying



down GE's debt since taking over as CEO in 2018 — will enable the company to expand its ultrasound business from diagnostics to surgical imaging.

Holmes represented Rapid Micro Biosystems, an innovative Massachusetts-based life sciences technology company providing mission critical automation solutions to facilitate the efficient manufacturing and fast, safe release of healthcare products, in its initial public offering of more than 9 million shares of Class A Common Stock listed on Nasdaq.

In addition, Holmes led the team that represented Sight Sciences, Inc. in its \$240 million IPO on Nasdaq. The growth-stage medical device company focuses on the development and commercialization of proprietary devices that target the underlying causes of the world's most prevalent eye diseases. **MLW**

M. MELISSA HUNTER-ENSOR

**Shareholder, Greenberg Traurig
Boston**

With a Ph.D. in neuroscience, a four-year post-doc at MIT, and thesis research that culminated in a first-author paper in the peer-reviewed journal Cell, M. Melissa Hunter-Enzor brings a wealth of scientific knowledge to her IP clients at Greenberg Traurig in Boston.

Hunter-Enzor leads a team that serves as outside counsel to such entities as Beam Therapeutics, Fate Therapeutics, MedImmune, the Broad Institute, Johns Hopkins University, and Aspira Women's Health. She focuses her practice on the IP and commercial needs of clients in the life sciences industry, encompassing pharmaceutical, biotechnology, chemical, agricultural, diagnostics and medical device companies.

In this capacity, Hunter-Enzor represents her clients throughout the entire business cycle, working with organizations that range from start-ups and universities to global pharmaceutical companies while handling everything from patent portfolio management and strategic alliances to litigation and pre-litigation strategy.

Hunter-Enzor also assists venture capital firms and other investors in assessing the IP risks of target investments and conducts IP patent and licensing due diligence in connection with life sciences technology transactions.

Hunter-Enzor's representative matters include her patent prosecution efforts for Aspira, a publicly traded company with an FDA-ap-



proved ovarian cancer diagnostic. Since 2016, the efforts of she and her team have resulted in more than 16 patents being granted to Aspira in more than 10 countries.

Hunter-Enzor has also represented Aspira in its IP due diligence in connection with a private placement funding round, while assisting with the re-branding of Vermillion Inc., as Aspira Women's Health and the trademarking of marks covering a number of its commercial products, including EndoCheck, Ova1, Overa and Ova1plus.

Meanwhile, on the litigation front, Hunter-Enzor successfully opposed two European patents on behalf of EnviroLogix while successfully opposing another patent in Australia. **MLW**

Achievements and professional activities

Office managing partner, Boston office, Latham & Watkins; recognition recipient, capital markets debt offerings, Legal 500 U.S.

Achievements and professional activities

Co-chair, Global Patent Prosecution Group and Boston Intellectual Property & Technology Group, Greenberg Traurig; chair, Boston Office Women's Initiative, Greenberg Traurig; board member, Cure Rare Disease; board member, Women Accelerators

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CONGRATULATIONS

Greenberg Traurig congratulates **Melissa Hunter-Enzor** on being named a **"Go To Lawyer"** for Life Sciences/Healthcare by Massachusetts Lawyers Weekly.



Melissa Hunter-Enzor
Shareholder

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LATHAM & WATKINS^{LLP}



We congratulate our colleague and friend

Wesley Holmes

for being selected as a 2022 Go To Life
Science Lawyer

LW.com

Latham & Watkins delivers innovative solutions to complex legal and business challenges around the world. From a global platform, Latham lawyers advise leading multinationals, boundary-pushing start-ups, and the investors and financial institutions that fuel them. The firm helps clients navigate market-shaping transactions, high-stakes litigation and trials, and sophisticated regulatory matters. Latham is one of the world's largest providers of pro bono services, steadfastly supports initiatives designed to advance diversity within the firm and the legal profession, and is committed to exploring and promoting environmental sustainability.

AMY M. JOSEPH

Partner, Hooper, Lundy & Bookman Boston

As a member of the business department at Boston's Hooper, Lundy & Bookman, Amy M. Joseph advises health systems, academic medical centers, teaching hospitals, and a wide variety of other healthcare providers on a broad range of business and regulatory matters.

Joseph devotes a substantial portion of her practice to fraud and abuse compliance, counseling her clients on how to comply with federal and state anti-kickback and self-referral laws.

She also serves as lead deal counsel or regulatory counsel on mergers, acquisitions and other strategic affiliations.

Additionally, Joseph frequently advises both providers and health information technology companies in the digital health space, including compliance and reimbursement issues related to digital health.

Meanwhile, Joseph regularly works closely with health system and hospital compliance departments to advise prospectively on protocols and best practices, as well as assist with internal investigations and has received a certification in healthcare research compliance (CHRC).

Joseph has been a particularly valuable resource for clients since the start of the pandemic, helping them navigate the regulatory landscape to develop telehealth initiatives.

Such work included developing a 50-state analysis of COVID licensure waivers for a leading academic medical center; analyzing scope-of-practice and cor-



porate considerations across seven initial states for another academic medical center building a national telehealth network; and developing out-of-state telehealth policy across 15 states for academic medical center.

Joseph has also guided multiple VC-backed digital health companies in establishing "Friendly PC" arrangements to seamlessly scale across 50 states while regularly counseling multiple digital health companies through geographic expansion and financings.

Joseph is also a widely published author on telehealth and compliance and a sought-after speaker on a variety of health law issues, having spoken before the Massachusetts Hospital Association, Connecticut Hospital Association and California Orthopedic Association. **MLW**

SCOTT A. KAPLAN

Partner, Sidley Austin Boston

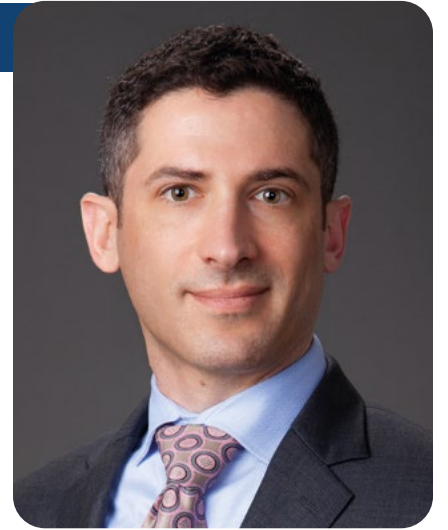
Before entering private practice, Scott A. Kaplan spent seven years as an enforcement counsel at the FDA, helping the agency resolve seizures, injunctions, administrative detentions and criminal prosecution while acting as counsel for compliance matters to the FDA's district offices.

That experience provided Kaplan first-hand knowledge on how to navigate the complicated ins and outs of drug and medical device regulatory issues and compliance.

At Sidley Austin, Kaplan puts that experience to work for some of the largest life sciences companies in the world, traveling anywhere in the world at a moment's notice to help a client through a crisis that could derail the manufacture of a critical drug.

For example, Kaplan recently led the response to data integrity issues found during an FDA inspection of a foreign active pharmaceutical ingredient (API) manufacturer. Kaplan's work led to an "acceptable" classification of the inspection, allowing the company to continue to export products to the U.S.

Following implementation of the remediation plan, the company hosted successful FDA inspections at its other facilities. In addition, through the internal investigation, the company was able to identify responsible individuals



and take appropriate personnel actions.

Kaplan also recently led an investigation into data falsification related to a client's acquisition of an Indian drug manufacturing facility.

The investigation uncovered significant misconduct prior to the acquisition, in breach of representations and warranties associated with the sale of the facility. Kaplan's follow-up negotiations with the selling party resulted in the sellers relinquishing an eight-figure amount held in escrow as part of the sale process.

In addition, Kaplan assisted the client with compliance integration and a remediation project to bring the facility into the client's global quality network and assure future compliance. **MLW**

Achievements and professional activities

Co-chair, Academic Medical Center/Teaching Hospital Working Group, Hooper, Lundy & Bookman; member, Fraud & Abuse Practice Group, Hooper, Lundy & Bookman; co-author, AHLA's "The Stark Law: Comprehensive Analysis and Practical Guide," seventh edition; co-author, telemedicine chapter, ABA's "Physician Law: Evolving Trends and Hot Topics"

Achievements and professional activities

Panelist, "Moving at Warp Speed: Are you ready to go to market?" (2020); presenter, Introduction to Drug, Biologics and Biosimilar Law and Regulation, Food and Drug Law Institute (2019); associate chief counsel for enforcement, FDA Office of the Chief Counsel (2009-2017); special assistant U.S. attorney (2015-2017); law clerk, Judge Helene N. White, 6th U.S. Circuit Court of Appeals



We congratulate our colleague **Amy Joseph** on being named a Go To Life Science/Health Care Lawyer by Massachusetts Lawyers Weekly. Well done Amy!



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WILLIAM M. MANDELL**Partner, Pierce & Mandell
Boston**

Boston attorney William M. Mandell, founding member and co-managing partner of Pierce & Mandell in Boston, has more than 35 years' experience in health and business law representing healthcare systems, medical and dental practices, and health professionals of all kinds in regulatory, transactional and corporate matters.

Mandell's work on behalf of clients includes mergers and acquisitions, practice startups, transitions, buy-ins and buy-outs, regulatory compliance and health reform-driven initiatives such as ACOs, among many other areas of the healthcare system.

Mandell also represents nonprofit organizations, corporate executives, startups, and small and family businesses.

Beyond his busy practice, Mandell is the author of several publications on health law, including *Managing Relationships with Industry: A Physician's Compliance Manual*, the "Physicians" chapter of the *Massachusetts Health and Hospital Law Manual* and *Making Sense of the Stark Law: Compliance for the Medical Practice*, published by the Massachusetts Medical Society.



Additionally, Mandell is active in the healthcare bar, having served as co-chair of the Boston Bar Association's Health Law Section.

He is also a sought-after panelist and speaker at continuing education programs not only for the bar, but for other professional associations, including the Massachusetts Medical Society, the Yankee Dental Conference and Massachusetts Continuing Legal Education.

Mandell has served on the adjunct faculty at Suffolk University Law School and, in his spare time, trains for and runs half-marathons. **MLW**

Achievements and professional activities

Co-managing partner, Pierce & Mandell; past co-chair, Health Law Section, Boston Bar Association; adjunct faculty, Suffolk University Law School; member, advisory board, Owen M. Kupferschmid Holocaust/Human Rights Project, Boston College Law School; president, Eddie & Alyce Mandell Memorial Scholarship Fund, Inc.; national board member, UAspire; co-author, chapter on "Physicians," *Massachusetts Health and Hospital Law Manual*; annual presenter, "Representing Physicians & Other Health Care Providers," Massachusetts Continuing Legal Education

KRISTIN G. MCGURN**Partner, Seyfarth Shaw
Boston**

As a labor and employment attorney with a special focus on healthcare and life sciences organizations, Boston attorney Kristin G. McGurn helps her clients maintain healthy workforce cultures, strategically assisting them as they navigate the employment life cycle from onboarding to separation.

The Seyfarth Shaw partner also guides clients to innovative contractual terms and cutting-edge policies to enhance employee relations and contain risk while utilizing innovative technology tools and methods of service delivery to better support them.

Specifically, McGurn has helped clients through her early involvement in Seyfarth's process mapping for arbitrations, wage-and-hour litigation and audits and leave management, while also developing a technology-enabled questionnaire to assess the exempt classification of workers for health care providers, medical technology companies and government contractors.

McGurn is also an experienced labor and employment litigator who helps clients in the healthcare and pharmaceutical industries navigate state and federal discrimination and wage-and-hour claims, as well as claims brought under the Family and Medical Leave Act and Americans with Disabilities Act.

Recently, McGurn successfully represent-



ed a Massachusetts hospital in a high-profile lawsuit challenging its vaccination policies. She also recently represented a health care provider in a class action claim alleging wage and hour violations for unpaid overtime and 24-hour weekend shifts.

McGurn has spent the past two years advising health systems and pharmaceutical companies on policies and regulations related to the COVID-19 pandemic, including government shutdown orders, health and safety guidance, and safe operations protocols.

McGurn co-chairs her firm's Health Care, Life Sciences & Pharmaceuticals Group and is a leader in bar activities, serving as vice-chair of the American Health Lawyers Association's labor and employment practice group. **MLW**

Achievements and professional activities

Co-managing partner, Boston office; co-chair, Health Care, Life Sciences & Pharmaceuticals Group; co-leader, Engagement Working Group; vice-chair, Labor & Employment Practice Group, American Health Lawyers Association; member, American Bar Association College of Labor and Employment Lawyers

TIMOTHY M. MCCRYSTAL**Partner, Ropes & Gray
Boston**

The co-chair of the healthcare practice group at Ropes & Gray in Boston, Timothy M. McCCrystal has been advising healthcare and life sciences companies and investors on cutting-edge regulatory matters and transactions for more than 30 years.

Most recently, McCCrystal has been counseling clients impacted by the COVID-19 pandemic on operational preparedness and business continuity planning, among other issues. Additionally, McCCrystal has been advising clients on novel regulatory issues related to the expansion of telehealth to improve access to care.

McCCrystal's practice also involves structuring and negotiating health care affiliations, mergers and acquisitions, joint ventures, hospital-physician relationships, medical practice acquisitions and formation and reorganization of multi-institutional healthcare systems.

Additionally, McCCrystal has expertise in structuring innovative value-based healthcare arrangements and initiatives and has experience in privacy and cybersecurity, regularly advising clients on the full array of data privacy, protection and security matters relating to the HIPAA privacy and security rules.

McCCrystal's recent accomplishments include advising Harvard Pilgrim Health Care in its combination with Health Plan Holdings (formerly



Tufts Health Plan), representing the joining of two iconic non-profit healthcare companies.

The combination closed on Jan. 1, 2021, after receiving all regulatory approvals and new organization will provide coverage to more than 2 million members in every segment of the market.

Meanwhile, McCCrystal represented LifeStance Health Group, one of the nation's largest providers of outpatient mental healthcare, in its \$720 million initial public offering.

This was a particularly challenging task because of the sudden pandemic, which necessitated advising the company on moving its services to a virtual environment, rolling out a telehealth and digital healthcare platform nationally, while also assuring compliance with a patchwork of state and federal laws and regulations. **MLW**

Achievements and professional activities

Co-chair, health care practice group, Ropes & Gray; panelist, "Innovative Business Models in the Emerging Value-based Health Care Landscape," "Will Value-based Care Save the Health Care System?" Conference at Harvard Law School; presenter, "Emerging Trends in Health Care Joint Ventures," AHLA Annual Meeting

ANDREW J. MERKEN**Partner, Burns & Levinson
Boston**

Burns & Levinson partner Andrew J. Merken has spent more than 30 years building a career as a leading local corporate healthcare/life sciences attorney.

A founding co-chair of its life sciences group, which he started in order to represent emerging and growth-stage life sciences companies in the lower middle market (up to \$100 million in revenue), Merken brings deep experience across the entire lifecycle of health care and life sciences companies, from startup to venture capital funding to third party collaborations to exit or IPO.

In that capacity, Merken has advised and represented countless life sciences companies, VC investors and investment banks, helping them lead day-to-day operations, finance their growth, build their businesses and exit when the time is right.

Merken's cases and projects include IPOs, follow-on public offerings, sell-side and buy-side M&A transactions and/or SEC compliance for numerous local and national publicly traded life sciences companies. His clients have included including Biogen, Sonoma Pharmaceuticals, Myriad Genetics, Harvard Bioscience, ARIAD Pharmaceuticals, Indevus Pharmaceuticals, Charles River Laboratories, Paradigm Genetics, Seragen, PLC Systems, Macrochem Corpo-



ration, Variagenics, Telor Ophthalmic Pharmaceuticals and Creative Biomolecules.

He also recently represented Boston Technology Research Corporation in its recent \$15 million Series A Preferred Stock financing by new investors Insight Partners and existing investors LRVHealth, New Stack Ventures and JumpStart Capital.

Merken is currently representing Hampstead Hospital, a 111-bed mental health and substance abuse facility, in its sale to the State of New Hampshire. The sale, which is being championed by the governor of New Hampshire and is expected to close in spring 2022, should enable the state to address a shortage of beds available for mental health and substance abuse patients, particularly children. **MLW**

Achievements and professional activities

Co-chair, Life Sciences Group and Securities Group, Burns & Levinson; chair, 2018 Venture Capital and Private Equity Conference, Boston Bar Association; past co-chair, Business Transactions Section and Corporate Law Committee, Boston Bar Association; member, board of directors, Penn Club of Boston; member, audit committee, Combined Jewish Philanthropies; member, Tufts University Alumni Council

KEVIN S. PRUSSIA

**Partner, WilmerHale
Boston**

As an experienced litigator, WilmerHale partner Kevin S. Prussia brings his life sciences and technology clients extensive experience in major disputes involving intellectual property and commercial matters.

Prussia's experience comprises every aspect of trial and appellate practice, including bench and jury federal trials, International Trade Commission investigations, Patent Trial and Appeal Board proceedings, and appeals to both the U.S. Court of Appeals for the Federal Circuit and the Supreme Judicial Court.

Prussia has handled challenging witness examinations and oral arguments for clients in high-stakes litigations and has successfully tried cases to verdict while counseling numerous other clients through complicated settlement discussions.

He was a key member of the WilmerHale team that secured a decisive trial victory for clients Bristol-Myers Squibb Company and Pfizer Inc. in Hatch-Waxman litigation over patents covering the blockbuster drug Eliquis, which is used to treat and reduce the risk of blood clots and strokes in patients.

Prussia also served as a leading team member in WilmerHale's representation of Genentech in IP litigation over its \$7 billion-per-year



drug, Herceptin, one of the first humanized antibodies approved by the FDA and the standard of care for an aggressive form of breast cancer.

Several manufacturers sought approval for their biosimilar versions of Herceptin and challenged Genentech's patents via IPRs. After successfully defending several IPR challenges and litigating these actions for years, Genentech reached favorable settlements with each challenger.

Beyond his work for WilmerHale clients, Prussia maintains a busy civil rights pro bono practice and represents a class of individuals in a high-profile immigration case against the U.S. Department of Homeland Security. **MLW**

Achievements and professional activities

Member, Litigation/Controversy Department, IP Litigation Practice Group and Management Committee, WilmerHale; member and former president, board of directors, ACLU of Massachusetts; member, advisory board, Center for Law, Brain and Behavior at Massachusetts General Hospital; member, dean's advisory council, College of Arts and Science at NYU; part-time faculty member, Boston University School of Law

JOHN C. SERIO

**Partner, Withersworldwide
Boston**

As both a registered patent attorney and a pharmacist, John C. Serio brings his clients a first-hand knowledge of the pharmaceutical industry as well as the broader life sciences and healthcare sectors.

An IP partner at Withersworldwide, Serio specializes in representing pharmaceutical, biotechnology, nutraceutical and medical device companies with patent prosecution, licensing and litigation matters. Serio also has extensive expertise in food and drug law involving pharmaceuticals and medical devices, and is a recognized expert on direct-to-consumer advertising of pharmaceuticals.

In that capacity, life sciences and healthcare companies turn to Serio for a wide variety of regulatory issues, including the conduct of clinical studies, manufacturing, preparation and filing of regulatory documents, FDA regulatory compliance and FDA enforcement matters.

Serio has a multilateral understanding of complex scientific principles and drug development within the pharmaceutical industry — expertise he shares as an accredited speaker with the American College of Pharmaceutical Education and as regular speaker and writer on pharmaceutical issues.

In addition to his patent law work, Serio provides assessment and counsel concerning cross-border transactional matters related to pharmaceutical and medical device patent portfolios and regulatory strategy, and assists



clients with all aspects of product development and approval of drugs and medical devices.

He managed and directed the FDA submission and approval of an Emergency Use Authorization petition (EUA) for a COVID 19-related medical device, allowing the client to market its bio-containment device to protect healthcare professionals in the treatment of patients having infectious disease.

Serio also developed an extensive patent portfolio for a laboratory robotics company acquired by a leading multi-national diagnostic company, while also managing litigation on behalf of a Fortune 500 client seeking to enforce of its medical device portfolio, an engagement that resulted in a successful settlement.

He also successfully represented a pharmaceutical company in a False Claims Act matter, which resulted in a dismissal. **MLW**

Achievements and professional activities

Accredited speaker, American College of Pharmaceutical Education; member, Greater Boston Chamber of Commerce Life Sciences Alliance; member, Boston Patent Law Association; member, Boston Bar Association

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Withers congratulates



John Serio

on being recognized by
Massachusetts Lawyers Weekly as a
“Go To Life Science and Health Care
Lawyer.” Congratulations to John
and all of this year’s honorees!

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MELISSA M. THOMPSON

**Partner, Robinson & Cole
Boston**

Melissa M. “Lisa” Thompson has established herself as a valuable advisor to companies, senior management and boards of directors in the healthcare, life sciences and technology sectors, while also distinguishing herself as an active mediator and arbitrator.

As a partner and member of Robinson & Cole's Health Law Group, Government Investigations, and Data Privacy + Cybersecurity Team, Thompson handles matters ranging from corporate law, commercial contracting and government audits to clinical research law and institutional review boards.

Thompson also has experience representing clients on issues involving privacy and security, including HIPAA, reimbursement, Medicare and Medicaid, state and federal surveys and termination actions, managed care disputes, pharmacy and compounding laws, fraud and abuse, Stark Law, and antikickback and federal program exclusions.

She also has experience with U.S. Food and Drug Administration compliance and regulatory matters, product recalls, FDA citizen petitions and appeals, medical device and pharmaceutical labeling reviews, advertising and marketing compliance, drug and medical device reimbursement, clinical research agreements, and commercial contracting. On the technology sector side, Thompson counsels clients on privacy and security, software



licensing, data use agreements, information exchange system agreements, and regulatory requirements.

Thompson's representative achievements include prevailing in both individual and consolidated reimbursement appeals cases in front of administrative law judges for the U.S. Department of Health and Human Services on behalf of a national hospice provider.

Additionally, she has negotiated settlements with the U.S. Department of Justice, Centers for Medicare & Medicaid Services and state Medicaid in termination and enrollment actions.

Thompson is an active arbitrator and mediator on the panel of the American Health Law Association and the Health Care, Life Sciences and Commercial panels of the American Arbitration Association. **MLW**

Achievements and professional activities

Member, Dispute Resolution Council, American Health Law Association; member, arbitration and mediation panels, American Health Law Association; member, Master Mediator Panel, American Arbitration Association; member, advisory committee, Boston International Arbitration Council; member, Chartered Institute of Arbitrators; member, Dispute Resolution Section, American Bar Association

KATHLEEN M. WILLIAMS

**Partner, Nutter
Boston**

When life sciences companies, research institutions and investors turn to Nutter partner Kathleen M. Williams for guidance on complex legal issues, they not only retain the services of a seasoned patent attorney, but a scientist with a Ph.D. in molecular biology and biochemistry from Brown University.

As chair of Nutter's life sciences practice group, Williams brings her science background to bear on complex patent interferences before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, as well as in inter partes reviews.

Additionally, Williams frequently handles intellectual property due diligence for corporate acquisitions, investments, licenses, and initial public offerings.

Among Williams' many notable engagements, she counsels Kymab (Sanofi) — a U.K.-based clinical-stage biopharmaceutical company that is developing a deep pipeline of novel human antibody-based therapies — in all aspects of the company's intellectual property strategy, including patent prosecution and freedom to operate.

Williams serves as outside IP counsel to f-Star Biotechnology Limited, another U.K.-based biopharma, on IP strategy, as it develops its immuno-oncology bispecific antibody therapeutics. f-Star's powerful platform enables the discovery of novel bispecific anti-



bodies, which are selected for their potential to transform the treatment of cancer. She also counsels Boston-based Inozyme Pharma, Inc., on its intellectual property strategy as it develops novel medicines for treatment of rare mineralization disorders.

In addition to providing strategic IP advice to such organizations, Williams is representing three different seed companies on patent creation and management, patent prosecution and commercialization. These seed companies are at the forefront of several innovative technologies in the fields of molecular diagnostics and have the potential to transform cancer research.

Williams is a frequent presenter at industry conferences, where she discusses patents, biotechnology and cutting-edge intellectual property issues. **MLW**

Achievements and professional activities

Chair, Life Sciences Practice Group, Nutter; "Life Science Star," LMG Life Sciences; panelist, BioEquity Europe 2022

MELISSA A. WONG

**Partner, Holland & Knight
Boston**

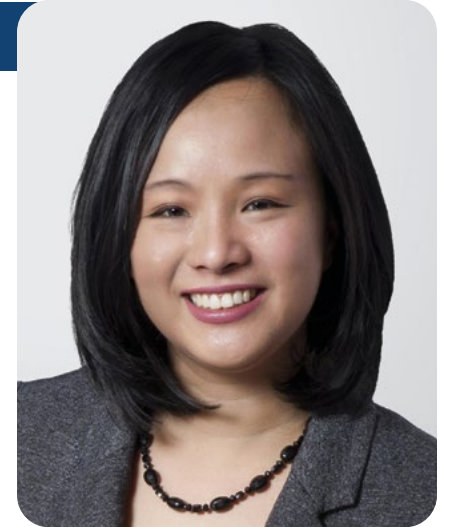
As a partner in Holland & Knight's Boston office and a member of its national Healthcare & Life Sciences Industry group, Melissa A. Wong has spent more than a decade carving out a special niche in managed care and federal healthcare programs like Medicare and Medicaid, as well as prescription drug coverage and reimbursement issues.

Wong's clients include health plans and managed care organizations, pharmaceutical and medical device manufacturers, pharmacy benefit managers, public-private state Medicaid agencies, third-party administrators and utilization review entities, insurance brokers and field marketing organizations.

She also represents traditional healthcare providers and suppliers, including physician groups and pharmacies.

In serving such clients, Wong advises clients on mergers and acquisitions, client services transactions, private equity investment, representations and warranties insurance underwriting, lending arrangements, government and payor audits and investigations, and interactions with federal and state government agencies.

Additionally, she counsels pharmaceutical manufacturers, pharmacy benefit managers and other stakeholders on drug coverage, pricing and reimbursement matters and emerging trends in the field, including the growing use of value-based purchasing arrangements.



Wong also has experience in the development and implementation of many companywide compliance programs tailored to Managed Medicare and Qualified Health Plan compliance obligations.

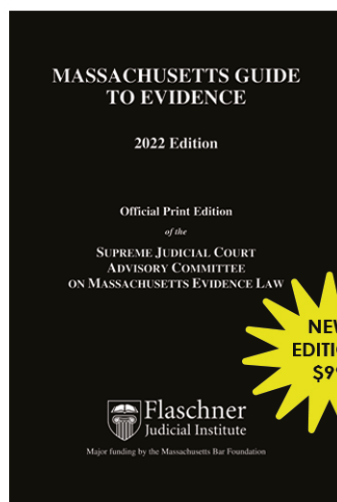
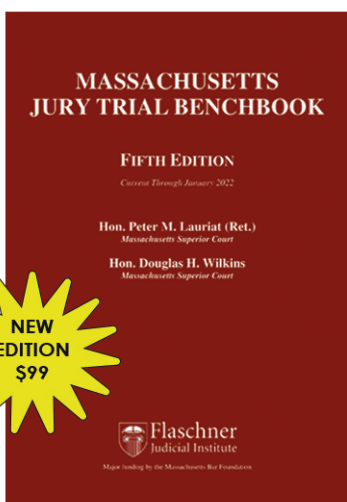
She has represented Medicare Part D sponsors before the Centers of Medicare and Medicaid Services and state departments of insurance, and has handled hearings before an administrative law judge on various regulatory and administrative issues.

Beyond her busy practice, Wong is a leader in both the American Health Law Association and the Asian American Lawyers Association of Massachusetts, and chairs the board of directors of Massachusetts Asian and Pacific Islanders for Health, a nonprofit organization promoting health access and outreach to Asian-American communities in Massachusetts. **MLW**

Achievements and professional activities

Vice chair of educational programming and leadership team member of the Payers, Plans and Managed Care Group, American Health Lawyers Association; board secretary and board director, Asian American Lawyers of Massachusetts; member, Hiring Committee, Holland & Knight

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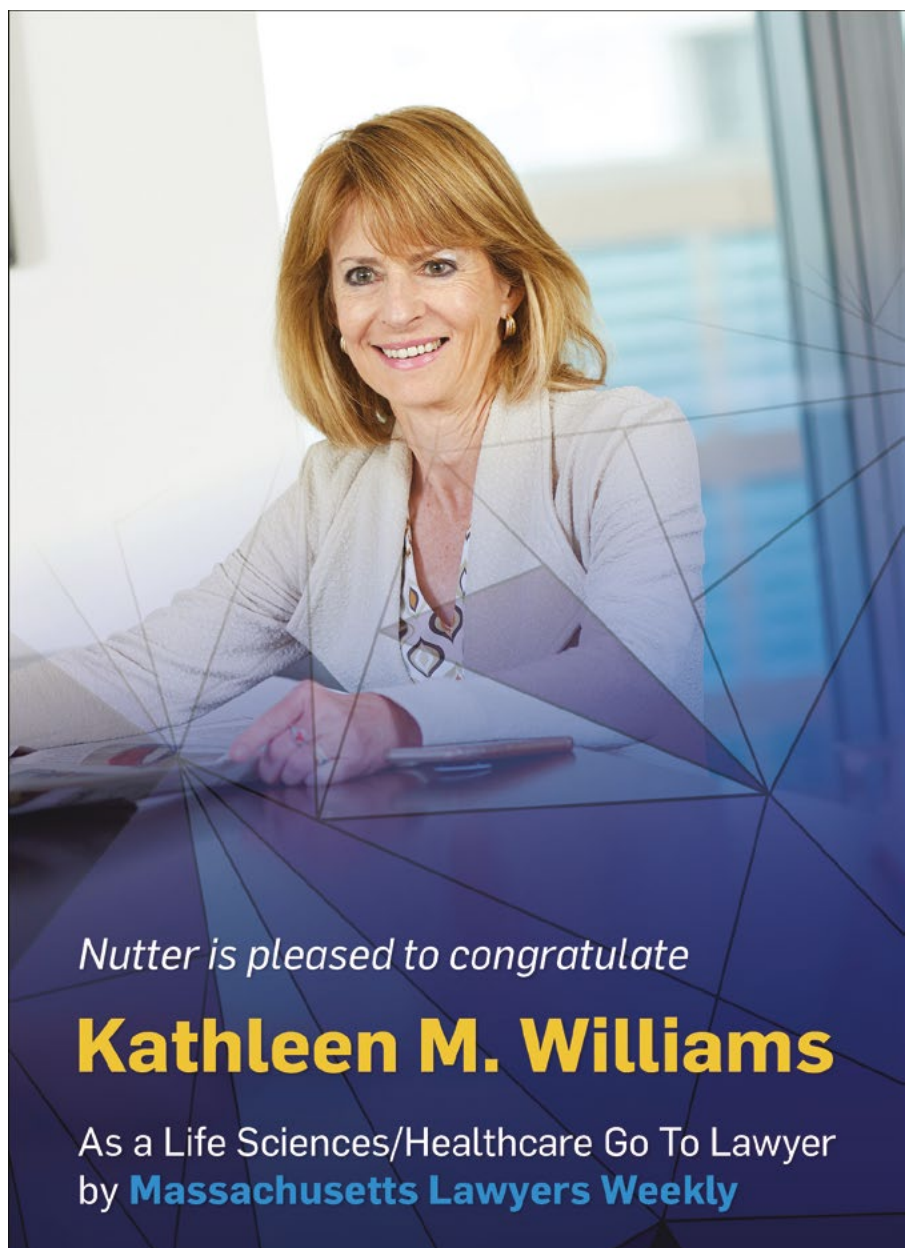
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Pierce & Mandell congratulates

WILLIAM M. MANDELL

on being named a

“Go To Health Lawyer” by

Massachusetts Lawyers Weekly.

Bill Mandell is a founding member and co-managing partner of the firm. He has over 35 years of experience representing health systems, hospitals, medical and dental group practices, MSOs and DSOs, physicians, dentists, mental health/substance abuse practices, and other health care practitioners in regulatory transactional and corporate matters on all aspects of health and business law.

PIERCE & MANDELL, P.C.

Since our founding in 1995, Pierce & Mandell, P.C. attorneys have provided high-quality legal service to large and small companies, professional practices, non-profit organizations and individuals. Every lawyer in our firm is committed to helping our clients achieve their business and personal goals by providing expert and cost-effective legal advice and service. Our team includes eleven lawyers with decades of experience as litigators, negotiators who are skilled in conflict resolution, and business advisors with a proven ability to solve all types of complex legal problems.

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