HUSCH BLACKWELL



# Kimberly I. Chew

**SENIOR COUNSEL**


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## OVERVIEW

Kimberly is a scientist-turned-attorney who helps life sciences innovators bring cutting-edge therapies to patients while navigating the complex legal and regulatory frameworks governing biomedical innovation. Her background in research science gives her a practical understanding of the scientific, operational, and funding realities facing biotechnology companies and academic researchers as they advance new therapies toward clinical use.

As co-founder and co-leader of the firm's Psychedelics & Emerging Therapies practice, she guides clients through every stage of

## Industries

Education
Healthcare
Life Sciences

## Services

Academic Medicine
Chemistry & Biotech
Clinical Research & Trials
FDA Regulatory
Healthcare Regulatory & Compliance Counseling
Pharmaceutical Manufacturers
Pharmacy
Psychedelics & Emerging Therapies

> *"Kimberly has represented our company for a number of years, streamlining defense. After taking the matter over from another law firm, she kept us up to date on what was going on and kept costs contained. Kimberly is the best attorney that I have worked with."*
>
> — Bud Krohn, Former President, Automotive Consumer Lending Company

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development, from clinical trial agreements and research collaborations to regulatory compliance and enforcement matters. She represents drug developers, biotechnology companies, and startups, often helping new ventures address early-stage challenges such as corporate formation, trademarks, and governance by collaborating with firm colleagues to deliver integrated legal solutions tailored to each client's goals and stage of development.

In the emerging therapies space, Kimberly advises on evolving legal frameworks surrounding psychedelic therapeutics and other novel medical technologies, including regenerative stem cell therapies. She works with clinics and clinicians to develop best practices, prepare informed consent and operational documents, comply with state regulations, and navigate investigations by medical boards or enforcement agencies. She also counsels on clinic ownership and operational structures, helping clients achieve regulatory compliance while supporting their business objectives.

Her work spans research and development, clinical trials, product liability, and controlled substances regulation at the federal and state levels. She closely tracks emerging life sciences issues, including the growing role of artificial intelligence (AI) in regulatory review, and presents on how federal agencies use AI to analyze regulatory data. Kimberly also advises clients on best practices when deploying AI internally, working with vendors, or interacting with agencies that use AI-driven tools.

Her practice includes advising on FDA regulatory issues across a range of health-related products and services, with a particular focus on matters at the intersection of wellness and regulated medical products. Kim regularly helps clients assess when a product or service may begin to implicate drug or device regulatory considerations—work that draws directly on her scientific background, especially where clinical or development factors are involved. She advises on FDA regulatory exclusivity periods, clinical trial regulatory issues such as Institutional Review Board (IRB) authority and safety reporting, and suitability petitions before the Office of Generic Drugs. Kim also conducts regulatory due diligence for biotech SEC filings and has litigation experience in patent enforcement and defense, as well as Hatch-Waxman (ANDA) litigation.

Kimberly draws on 16 years of experience in research science, including roles in academia and four startup ventures, to understand the scientific and operational realities clients face. She appreciates the pressures of funding cycles, publishing requirements, and protecting intellectual property, and understands the priorities of small biotech companies building and safeguarding patent portfolios, as well as academic researchers balancing the desire to share discoveries with regulatory and commercialization realities.

A trusted partner for researchers, innovators, and clinicians, Kimberly listens attentively to clients' challenges, anticipates potential obstacles, and helps prioritize resources and legal spend while managing risk and delivering high-quality, efficient work. Known for her strategic insight, practical guidance, responsiveness, and approachable manner, she communicates clearly, meets clients where they are, and ensures they feel supported and confident in their decisions.

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# Experience

### LIFE SCIENCES, HEALTHCARE, PSYCHEDELICS, & EMERGING THERAPIES

- Advised academic medical centers, hospital pharmacies, and research organizations on Drug Enforcement Administration (DEA) registration, storage, dispensing, destruction, and transfer of controlled substances in clinical trials, including protocol-specific compliance and regulatory documentation.
- Provided guidance on principal investigator accountability, sponsor-institution relationships, and regulatory and ethical standards under Food and Drug Administration (FDA), International Council for Harmonisation Good Clinical Practice (ICH GCP), and Office for Human Research Protections (OHRP) requirements for clinical research contracting, including tri-party agreements and Corporate Practice of Medicine compliance.
- Advised on FDA regulatory pathways for medical devices, including 510(k) clearance, Investigational Device Exemption (IDE) requirements, expanded access programs, and emergency use provisions; provided guidance on device importation, labeling compliance under 21 CFR Part 801, informed consent for unapproved devices, and clinical trial agreements for multi-site device studies involving novel technologies.
- Led regulatory compliance and patient notification strategy for the closure of a hospital-based stem cell bank, including Health Insurance Portability and Accountability Act (HIPAA) compliance, patient communications, and risk mitigation for disposition of cell therapy products.
- Drafted and negotiated complex multi-site clinical trial agreements, data sharing arrangements, and asset purchase agreements for biotechnology companies and healthcare organizations, addressing regulatory compliance, privacy, intellectual property (IP), compensation, and risk mitigation.

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## Experience

- Advised companies and research organizations on federal and state regulatory requirements for testing, manufacturing, and distributing psilocybin and other controlled substances, including DEA licensing, Controlled Substances Act (CSA)compliance, and navigation of Oregon and Colorado state frameworks.
- Counseled nonprofit organizations and foundations in the life sciences sector on governance, conflict of interest policies, board structure, and real estate transactions, including conflict waivers and compliance strategies for dual-role board members and trust/foundation transactions.
- Advised healthcare and digital health companies on regulatory compliance, informed consent, service agreements, and risk management for innovative therapies, telehealth, and emerging technologies, including compliance with the No Surprises Act and FDA guidance.
- Represented life sciences and healthcare clients in complex litigation, including Abbreviated New Drug Application (ANDA)/patent litigation, regulatory disputes, and risk mitigation strategies.
- Developed and implemented research data management and privacy policies for universities and research institutes, addressing data retention, secure storage, IP, compliance, and faculty and staff training.
- Provided strategic guidance on regulatory, privacy, and risk mitigation issues for venture capital firms (VCs), biotechnology companies, and healthcare innovators, including due diligence, IP, FDA/DEA compliance, and structuring of investment and operational models in emerging therapies.
- Advised on patient access to investigational drugs and devices under the federal Right to Try Act and Expanded Access Program, including regulatory analysis, clinical trial coordination, and guidance on FDA requirements for investigator-initiated studies.

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## Experience

- Advised compounding pharmacies, clinics, and investors on DEA registration, CSA compliance, and FDA regulatory risks for compounded drugs, including glucagon-like peptide-1 (GLP-1)receptor agonists, peptides, and Schedule III–V controlled substances; provided guidance on record-keeping, dispensing, destruction, and risk mitigation for innovative therapy models.

### AS RESEARCH SCIENTIST

- Served as laboratory manager, leading research and development laboratories for genomics and regenerative biology companies in the generation of higher quality differential gene expression profiling based database products and services offered to biotech and pharmaceutical clients for their drug and biomarker discovery and validation efforts across various disease areas. The database products were used for academic research and clinical medicine.
- Characterized and mapped genes to human chromosome 19 in a high-throughput manner utilizing laboratory instrumentation and analysis of genomic databases for Human Genome Project.
- Developed assays and processes utilizing laboratory instrumentation to examine gene expression in various health conditions in order to identify likely candidates for therapeutic intervention including microarrays, restriction enzyme differential display and qRT-PCR for gene expression analysis, standardized RT-PCR, and fluorescent DNA sequencing for breast cancer, Unverricht-Lundborg disease (a form of epilepsy), myotonic dystrophy, and cataractogenesis.
- Performed small animal surgeries to graft human immunological tissues into mice for efficacy testing of anti-viral treatments includingimmunohistochemical testing and characterization.
- Performed genetic engineering; supervised cloning and construction of cDNA libraries to support sequencing of human genome.

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## Experience

- Offered analysis and interpretation of sequence database hits using algorithms such as BLAST (basic local alignment search tool) and FASTA to compare subject nucleotide sequences with a database of sequences.
- Identified competitive start-up products and services and opportunities for in-licensing of technologies for genomics/molecular diagnostics based disease intervention testing and monitoring for the early detection and prediction of human cancers and mental illnesses.
- Worked in R&D related to stem cells derived from adult adipose tissues; developed and characterized stem cell lines (human and murine mesenchymal cells); characterized skeletal muscle derived stem cells into cardiomyocytes. Project sought to differentiate the cells into cardiac cells.
- Identified, assessed, and evaluated strategic genomics technologies including microarray, sequencing, or PCR based pharmacogenomic/genetic analysis platforms.
- Drafted standard operating protocols relating to assays, cell handling and propagation, and tissue culture laboratory procedures.

## Recognition

- *Chambers USA*, Psychedelics Law, Nationwide, 2025-2026
- *National Law Journal*'s Emerging Therapies/Life Sciences Trailblazers
- Top 200 Global Psychedelic Lawyers and Policy & Regulatory Experts, 2023-2026

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## Education

- J.D., Golden Gate University
  - Top 10%
  - CALI Award, professional responsibility
  - Moot Court Board
  - Environmental Law Moot Court Board
  - Asian-Pacific Law Association
  - Witkin award for Real Property, highest grade in course
- B.S., University of California, Davis
  - Biological Sciences
  - Laboratory research assistant – asbestos fiber imaging in lung tissue

## Admissions

- California
- U.S. District Court, Central District of California
- U.S. District Court, Northern District of California
- U.S. Court of Appeals, Ninth Circuit

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*Contact Kim to set up an in-person consultation by appointment in the Oakland office.

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