HUSCH BLACKWELL

Kimberly I. Chew

SENIOR COUNSEL

THE LINK VIRTUAL OFFICE
PHONE: 510.768.0627
OAKLAND, CA*
PHONE: 510.768.0650
EMAIL: KIMBERLY.CHEW@HUSCHBLACKWELL.COM

OVERVIEW

Kimberly is a seasoned professional with a rich background in biotech research, leveraging her extensive experience to guide clients through the intricate landscape of clinical trials and academic research compliance.

Her experience extends to analyzing FDA regulatory exclusivity periods, providing regulatory analysis related to clinical trials such as Institutional Review Board's (IRB) scope of authority and safety reporting, and drafting suitability petitions to the Office of Generic Drugs, as well as conducting regulatory due diligence for SEC filings in the biotech sector. Kimberly's litigation skills extend to patent enforcement and defense and Hatch-Waxman (ANDA) litigation, further solidifying her role as a comprehensive advisor in the biotech and pharmaceutical industries.

"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

Industries

Education
Healthcare
Life Sciences

Services

Academic Medicine
Chemistry & Biotech
Clinical Research & Trials
Environmental
Environmental Remediation & Superfund
FDA Regulatory
Healthcare Regulatory & Compliance Counseling
Pharmaceutical Manufacturers
Pharmacy
Proposition 65
Psychedelics & Emerging Therapies

Kimberly's scientific background, including her 16-year tenure in research science, enhances her understanding of drug development, genomic studies, and medical conditions like cancer and muscular dystrophy. Her perspective as a research scientist turned attorney allows her to combine legal knowledge with scientific insight, offering clients a comprehensive view of their projects.

As co-founder of the firm's Psychedelic and Emerging Therapies practice group, Kimberly navigates the legal intricacies of psychedelic therapeutics and emerging medical technologies, such as regenerative stem cells. Her practice spans research and development, clinical trials, product liability, and controlled substances, and she is knowledgeable about both federal and state regulations. She is enthusiastic about the potential of AI tools in life sciences and their impact on intellectual property, compliance, and liability. She is also keenly aware of how mental health parity rules will shape the future of healthcare.

Kimberly's commitment to innovation and compliance extends to risk assessments, data integrity and management, and regulatory adherence. Her regulatory affairs certification underscores her dedication to industry standards, as she assists clients in navigating the intersection of law and biotech research. Known for her strategic insights and clear communication, Kimberly is a trusted partner for researchers, innovators, and clinicians and is adept at addressing complex issues in research and commercialization.

Experience

LIFE SCIENCES, HEALTHCARE, PSYCHEDELICS, & EMERGING THERAPIES

- Advised higher education client on federal regulations and California law governing who is able to prescribe, administer and dispense controlled substances under California law, information needed for DEA licensing requirements, and clinic licensing requirements for human studies involving psychedelic substances.
- Advised distributor as to the liability risks of importation of certain products as related to drug paraphernalia laws.
- Advised venture capital firm as to liability risks associated with proposals that could implicate international treaties on psychedelics.
- Advised author as to liability issues related to contract with publisher and drafted disclaimer language for author's book related to psychedelic-assisted therapy.
- Provided advisory services related to developing a ketamine clinical network.

Experience

- Assisted physician in navigating audit and investigation by Medicare Administrative Contractor (MAC) to seek a reduction in overpayment claims through analysis and rebuttal of technical and clinical positions of auditor.
- Prepared informed consent documents to comply with healthcare regulations for therapy practice utilizing new technology.
- Advised healthcare practitioner as to the liability risks involved with proposed harm reduction therapies.
- Represented mental healthcare practitioner to negotiate and resolve claims associated with a therapeutic instrument.
- Provided analysis of company drug discovery regulatory files in order to provide a due diligence evaluation that would enable potential investors to understand potential risks involved that could impact the business.
- Developed a comprehensive research data management policy for an R2 research university, addressing clear roles and responsibilities, data retention for verification, compliance, and intellectual property protection; secure storage, backup, encryption, and controlled access; procedures for archiving, transfer, destruction, and external access requests; protocols for PI departures; and training requirements for faculty, staff, and students.
- Advised a hospital research institute on regulatory compliance, conflict of interest management, and organizational structure for clinical trials, including analysis of reporting obligations to NIH and FDA, best practices for committee independence, financial services arrangements, and IRB operations to ensure research integrity and mitigate perceived or actual conflicts of interest.

Experience

- Advised a nationally recognized cancer center on confidentiality, regulatory compliance, and risk management for clinical trial safety reporting and audits, including analysis of disclosure obligations to IRBs and sponsors; development of legal strategies to protect sensitive safety reports; review of clinical trial agreements and confidentiality provisions; recommendations for audit preparation, stakeholder alignment, and records management; and guidance on best practices for electronic medical record corrections and documentation.
- Assisted in ANDA litigation involving patent infringement and invalidity claims, including legal research and drafting on induced infringement, claim construction, and direct infringement standards; analyzed expert testimony, trial evidence, and regulatory data; evaluated arguments regarding label language and real-world prescribing practices; and contributed to post-trial briefing and strategy for noninfringement and invalidity defenses.
- Advised international technology company on federal and state regulatory requirements for testing, producing, and distributing psilocybin products, including DEA registration, Controlled Substances Act compliance, federal drug paraphernalia laws and provided guidance on licensing, security, and legal risks, related to state-specific regulatory frameworks and licensing in Oregon and Colorado.
- Advised Contract Research Organization on DEA and FDA regulatory requirements and procedural steps for conducting Schedule I clinical trials, including detailed analysis of federal and state (Virginia, Illinois, Texas) licensure processes, DEA registration (Form 225), site and background check protocols, and documentation requirements.
- Advised on patient access to investigational drugs and devices under the federal Right to Try Act and Expanded Access Program, including regulatory analysis of eligibility criteria, identification and evaluation of clinical trial opportunities, coordination with advocacy groups and clinical trial networks, and guidance on informed consent and FDA requirements for investigator-initiated studies.

Experience

- Advised company on federal and state regulatory requirements for home-based administration of ketamine and other controlled substances, including DEA registration, scope of practice for healthcare providers, FDA guidance on compounding, liability risks, and compliance strategies for innovative mental health and wellness service models.
- Advised on, drafted, and negotiated complex multi-party research consortium and clinical trial agreements for a large, multi-institutional clinical trial, including analysis and revision of terms related to regulatory compliance, intellectual property, data sharing, biological samples, indemnification, audit/inspection rights, and publication.
- Advised a digital health company on regulatory compliance, service agreements, and informed consent documentation for a platform involving psychedelic survey tools and assessments and advised on issues related to Controlled Substances Act and data privacy risks, HIPAA compliance, intellectual property and copyright issues, corporate governance, and best practices for data sharing and user disclosures in emerging legal environments.
- Advised a ketamine clinic on regulatory compliance and risk mitigation, including comprehensive review and revision of informed consent forms, patient agreements, policies and procedures, licensure requirements, scope of practice, telehealth protocols, employment and referral arrangements, and compliance with federal and state laws (including the No Surprises Act and FDA guidance) for ketamine, Spravato, weight loss, and peptide therapies.
- Advised a healthcare practice on operational and corporate compliance, including state referral and fee-splitting laws, corporate practice of medicine requirements, informed consent documentation for HRT and ketamine therapy, telehealth privacy compliance, financial arrangements with supplement vendors, and risk mitigation strategies for DEA and FDA regulatory adherence.
- Supported complex patent litigation involving alleged infringement of multiple patents, including claim analysis, discovery strategy, document review, confidentiality designations, motion practice, and damages assessment.

Experience

- Advised a foreign medical device manufacturer on regulatory and business risk management for U.S. market entry, including assessment of insurance requirements for device importation and distribution.
- Advised a psychedelic biotech company on the negotiation and revision of a letter of intent and related asset purchase terms for a patent portfolio sale, including analysis of deal scope, milestone payments, patent estate definitions, joint ownership, licensing considerations, and feedback on proposed revisions from prospective acquirers to protect client interests and ensure transaction clarity.
- Advised an educational and coaching business on regulatory compliance, corporate formation, intellectual property, and risk management, including review of workshop and marketing materials for potential issues related to the unauthorized practice of psychology, drafting disclaimers and service agreements, addressing copyright and trademark issues, developing website terms and privacy policies, and guiding on employment, insurance, and data privacy obligations.
- Represented a pharmacy in responding to a Board of Pharmacy disciplinary complaint, including analysis of records, development of a factual timeline, research of applicable disciplinary grounds, and drafting of the formal response to regulatory authorities.

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.

Experience

- 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.
- 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.

Experience

- Drafted standard operating protocols relating to assays, cell handling and propagation, and tissue culture laboratory procedures.

PRODUCT LIABILITY AND TOXIC TORT

- Advised business in advance of a planned product launch in the United States as to compliance and liability issues with federal and state controlled substance laws and product liability issues.
- Serves as national coordinating counsel for asbestos client, managing the discovery program.
- Counseled manufacturer and retail clients on regulatory compliance issues and in defense of lawsuits involving California's Proposition 65, which requires warnings to Californians about significant exposures to chemicals that allegedly cause cancer, birth defects or other reproductive harm.
- Assisted in defense of product manufacturer in a class action suit requiring detailed analysis of voluminous evidence related to the manufacturer's product recall.

ENVIRONMENTAL

- Audited client facilities and operations and update environmental management programs to ensure compliance with applicable environmental health and safety regulations.
- Negotiated reduced settlements in regulatory enforcement actions.
- Represented family dry cleaning business in federal and California Department of Toxic Control Substances (DTSC) allegations of groundwater contamination and related cleanup costs. Argued for equitable allocation in consideration of nearby fuel retailer with underground storage tanks.
- Represented manufacturer when DTSC inspections identified alleged environmental violations related to electroplating process; remedies included training and hazardous waste storage policy upgrades.

Experience

- Represented component part manufacturer when DTSC inspection revealed alleged violations including chemical processing, hazardous waste storage and recordkeeping. Remedies included policy and training upgrades.
- Advised out-of-state trucking company regarding diesel emissions in an enforcement action brought by the California Air Resources Board.

Recognition

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

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

---

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

Chambers USA 2025 - Kimberly Chew