HUSCH BLACKWELL

Kimberly I. Chew

SENIOR COUNSEL

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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 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.
- 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.

Experience

- 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.
- 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.

Experience

- 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.
- 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.

Experience

- 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.
- 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.

Experience

- 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.
- 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

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

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