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.

Prior to embarking on her legal career, Kimberly dedicated 16 years to the field of research science, contributing significantly to government agencies and biotech companies. Her journey began as a lab manager, where she not only supervised experimental design but also conducted groundbreaking experiments for the Human Genome Project. Her diverse skill set includes performing small animal surgeries for immunological studies, contributing to the drug development pipeline, and publishing prolifically in peer-reviewed scientific journals. Kimberly's scientific knowledge spans genomic studies/analysis, gene expression studies, tissue grafting,

"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
Healthcare Regulatory & Compliance Counseling
Pharmaceutical Manufacturers
Pharmacy
Proposition 65
Psychedelics & Emerging Therapies

DNA extraction, and genomic sequencing, all aimed at addressing medical conditions such as breast cancer, glioblastoma, and muscular dystrophy.

With a unique perspective gained from her experience in biotech startups, Kimberly seamlessly combines legal acumen with scientific insight. She comprehends the complexities of drug development, technology licensing, and clinical trials, offering clients a comprehensive understanding of their projects from both perspectives. Passionate about fostering innovation and improving lives, she serves as a problem solver and regulatory compliance advisor for those engaged in the research and commercialization of novel therapies.

As the co-founder and co-lead of the firm's Psychedelic and Emerging Therapies practice group, Kimberly is particularly inspired by the potential of psychedelic therapeutics to address mental health conditions like PTSD. She skillfully navigates the legal intricacies surrounding these therapies, providing guidance through the clinical trial process at both state and federal levels.

Kimberly's legal practice extends beyond psychedelics, encompassing emerging medical technologies such as regenerative stem cells. Her experience includes advising on research and development, clinical trials, product liability, environmental matters, and legal issues related to controlled substances. She navigates laws such as the Controlled Substances Act, healthcare regulations, and DEA licensing, demonstrating proficiency in handling federal and state agency inspections.

In addition to her regulatory focus, Kimberly supports litigation related to novel therapies and is qualified to address allegations of research compliance. As a trusted advisor, Kimberly is exceptionally qualified to navigate intricate issues related to research integrity, ensuring ethical conduct and regulatory adherence in a variety of contexts. Her background allows her to assist with issues relating to root cause investigations and corrective actions, research integrity, risk assessments and mitigation strategies, privacy, data management and data security issues in research, drug diversion concerns, research compliance auditing, compliance considerations for decentralized clinical trials, various regulatory requirements, and guidelines, covering FDA operations, product development, pharmacology/toxicology, and Good Clinical Practices.

Kimberly is knowledgeable about Document Management Systems, Quality Management Systems, Good Documentation Practices, and technical writing techniques, and the importance of Good Laboratory Practices (GLP) regulations. She holds a certificate in regulatory affairs, showcasing her proficiency in Good Manufacturing Practices, GLP, and data integrity. This credential reflects her commitment to staying at the forefront of industry standards, in order to assist clients in navigating the complex intersection of law and biotech research. Her multifaceted skill set, combined with a nuanced understanding of the legal and ethical dimensions of research, positions her as a trusted partner for researchers, innovators, and clinicians alike, whether addressing issues of research misconduct, international collaborations, or decentralized clinical trial.

Knowledgeable and energetic, Kimberly is known for identifying key strategies in challenging cases, then easily communicating those ideas to clients and legal teams in order to proceed with the best solutions.

Experience

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.
- 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.

Experience

- 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.
- 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.

Experience

- 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.

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 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.

Recognition

- *National Law Journal*'s Emerging Therapies/Life Sciences Trailblazers
- The Global Top 200 Psychedelic Lawyers, Policy & Regulation Experts, 2023

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.

2023 Pro Bono Achiever