HUSCH BLACKWELL

Natasha V. Sumner

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OVERVIEW

A co-founder and co-leader of the firm's Psychedelics and Emerging Therapies Practice Group, Natasha advises clients on the regulatory matters inherent in new drug development. She also advises behavioral health clients on compliance matters.

After witnessing individuals close to her struggle with mental health issues for which no effective treatments exist, Natasha has come to care deeply about behavioral and mental health. She is personally invested in supporting behavioral health providers and ensuring compliance with state and federal parity laws, as well as in helping developers get new behavioral health drugs to the public.

Natasha has experience working with the Health Insurance Portability and Accountability Act (HIPAA), 42 CFR Part 2, and other federal and state privacy requirements as well as federal and state laws pertaining to behavioral health and the practice of medicine. She regularly advises healthcare providers on risk management, particularly in the areas of privacy and security and fraud, waste, and abuse, and she creates compliance programs that address both business and legal concerns. Natasha approaches these matters from a holistic, top-down perspective, ensuring organizational wide involvement in assessing and addressing risks. She also assists clients with navigating the complexities of managed care contracts and has counseled many providers on Section 1557 of the Affordable Care Act.

With great personal passion for the promise of psychedelics and other new drugs, Natasha is well-versed in historical and current psychedelic research, including

Industries

Education
Healthcare
Life Sciences

Services

Cannabis
Chemistry & Biotech
Clinical Research & Trials
FDA Regulatory
Healthcare Regulatory & Compliance Counseling
Licensing & Tech Transfer
Pharmaceutical Manufacturers
Pharmacy
Psychedelics & Emerging Therapies

FDA-approved studies on MDMA and psilocybin use for mental health and end-of-life issues, the legalization and decriminalization of psylocibin in numerous cities and states, and biotech and pharmaceutical research. She's enthusiastic about the potential of these drugs to treat and potentially cure a variety of mental health needs, and she's fascinated by the drug development process. Natasha is motivated to help clients help the world, and she's equally dedicated to ensuring that underrepresented communities have access to new treatments.

Natasha supports clients throughout the entire process of drug development, from early research to clinical trial permission to final approval for supplying a drug to the public. She has assisted clients in securing the necessary approvals to research controlled Schedule 1 substances, advised on the establishment and launch of studies and formal clinical trials, and assisted with new drug applications to the FDA. Natasha has a particular interest in the research and clinical trial processes—she was first bitten by the psychological research bug as an undergraduate psychology major, and she enjoys nothing more than diving deep into a client's project and considering confounding factors and the challenge of adequate placebos. Her experience includes work with the country's leading researchers on MDMA.

Natasha's dedication to and passion for the behavioral health world set her apart, and she is highly knowledgeable about current research and the science behind it. Clients value her great desire to learn and her eagerness to understand as much as possible about their drug developments and the research that drives them.

Experience

- Researched and drafted briefing on federal preemption issues on behalf of leading global medical device manufacturer surrounding pharmaceutical and healthcare products.
- Represented injured plaintiff in claim involving natural product misbranded in violation of Food, Drug, and Cosmetic (FD&C) Act resulting in a successful settlement.
- Counseled product manufacturer client in all stages of litigation including utilizing a novel medical defense whether a newly discovered genetic mutation (BAP1) was the sole cause of decedent's cancer.
- 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.

Experience

- Advised business on current state and federal drug paraphernalia laws and liability issues related to psychedelic substances.

Recognition

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

Education

- J.D., Santa Clara University School of Law
  - *Santa Clara Law Review*, editor
  - Moot Court Best Oral Advocate
  - Best Brief Awards
- B.S., University of California, Davis
  - Psychology major, Biology minor

Admissions

- California
- U.S. District Court, Central District of California
- U.S. District Court, Eastern District of California
- U.S. District Court, Northern District of California

Community Leadership

On a pro bono basis, Natasha first chaired a trial representing a plaintiff prisoner in a Section 1983 case, resulting in a $30,000 verdict. Natasha has also represented pro bono clients in matters regarding developmental disability educational rights in the state of Texas; immigration and asylum based on sexual orientation; and work with the Promise of Justice Initiative (PJI), a project dedicated to helping heal injustices and injuries caused by non-unanimous jury convictions in Louisiana.

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

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