



Denver, Colorado
September 20, 2025

Presented By

Daniel Sternthal

Shareholder | Houston, TX

Brad Cook

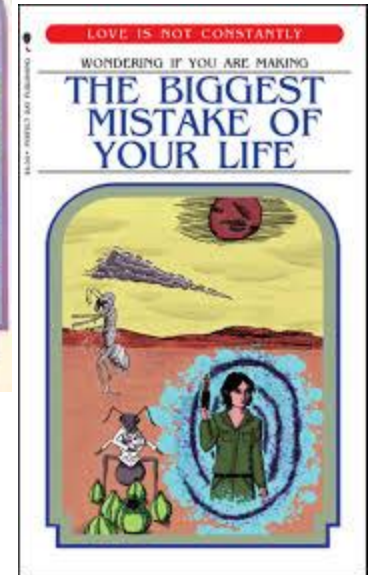
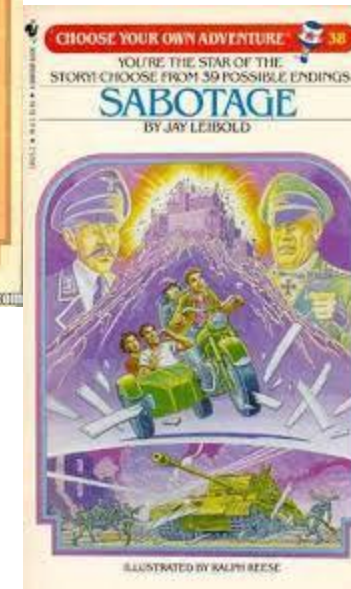
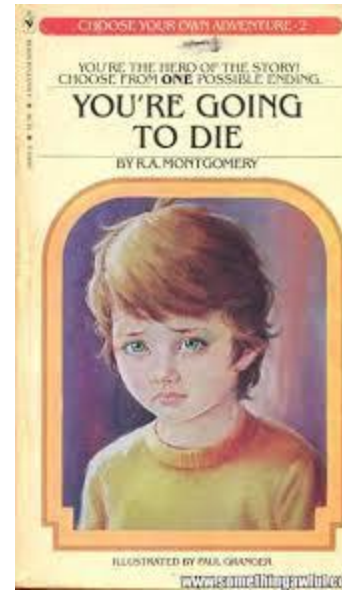
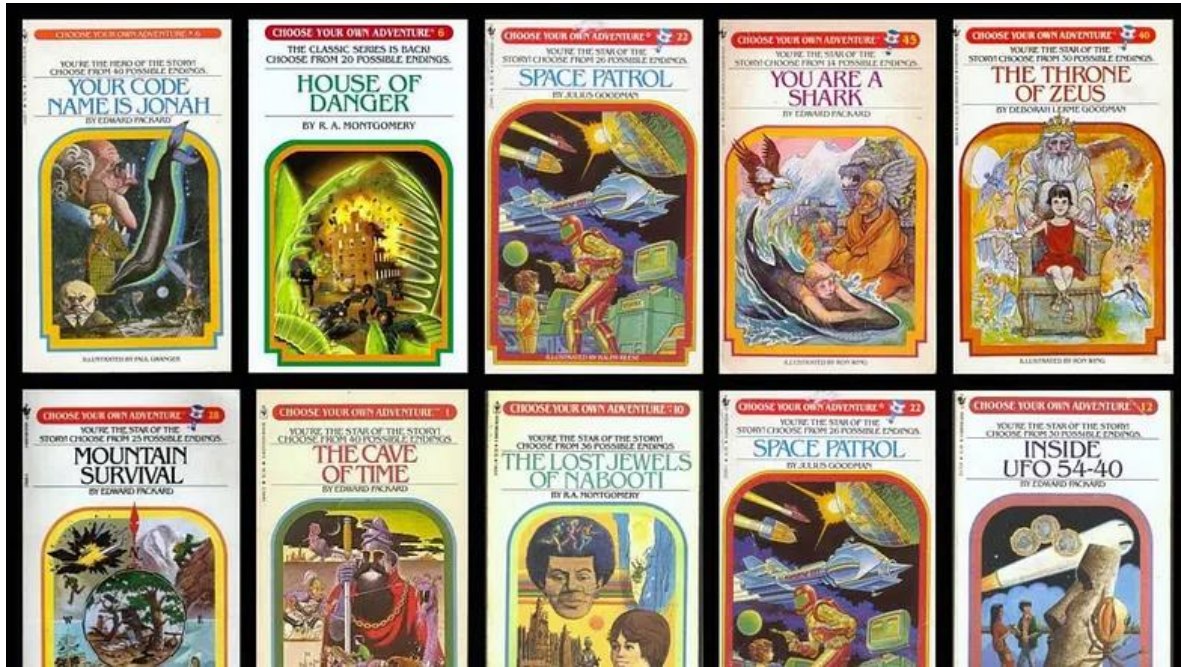
Associate | Houston, TX

Background

- Ketamine, traditionally known for its anesthetic properties, is continues to gain traction as a treatment for depression and other mental health conditions.
- However, its use in therapeutic settings brings forth complex legal considerations, raising questions about FDA approval, insurance coverage, state regulations, and ethical practices.
- Goal for this brief talk is to highlight some of the more significant legal issues.



Choose Your Own Adventure



Shifting Landscape – 2024 – 2025 and Beyond



Inquiry Seeks Source of Ketamine That Caused Matthew Perry's Death

FDA, VA, and DEA

- Feb. 16, 2022 Compounding Risk Alert involving compounded ketamine nasal spray
- Oct. 10, 2023 Warning about potential risks associated with compounded ketamine for psychiatric disorders
- June 27, 2024 Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest
- January 1, 2025 – Veteran Health Affairs Clinical Determination and Indication for Intravenous Ketamine for Treatment Resistant Depression
- January 14, 2025 DEA 3rd Extension of Covid Telehealth Flexibilities
- January 17, 2025 DEA Proposed Rules regarding telehealth treatment involving controlled substances – Comment Period closed in March (6,475 comments)
- January 21, 2025 Allows standalone use of Spravato

FDA Guidance on Ketamine Usage

FDA Approval

- While ketamine is FDA-approved as an anesthetic, its use for mental health conditions remains "off-label," meaning it is not specifically approved for these purposes. However, the FDA recognizes the potential therapeutic benefits and is actively reviewing its use in specific settings, like treatment-resistant depression.

Clinical Trials

- To support ketamine's expanded use, the FDA is encouraging and overseeing clinical trials to gather more robust evidence about its safety and efficacy for mental health conditions.

Commercialization and Privatization of Ketamine

- KETARx – FDA approved it in August for use in surgical pain management, aims to address issues with compounded ketamine, such as quality concerns and shortages. Plans to expand KETARx's therapeutic applications to include mental health, neurological disorders, and other pain conditions
- NRX-100 – NRx has developed a proprietary, patentable formulation of ketamine that will be far closer to a physiologic pH (7.35 to 7.45) versus generic Ketamine that requires a pH of 2.0. Physicians can still prescribe the old generic formulation, but prescribers outside of hospitals will be forced to ketamine from compounding pharmacies, which the FDA cautions against. Moreover, once there is a legally labelled form of IV ketamine on the market, it becomes illegal for a compounding pharmacy to dispense compounded ketamine in similar dosage and route of administration.

Reimbursement from Insurance Payers

Coverage Limitations

- Insurance coverage for ketamine therapy is inconsistent, as payers may not cover off-label uses or may have specific protocols and requirements.

Prior Authorizations

- Many insurers require prior authorization before covering ketamine therapy, adding complexity to the treatment process.

Out-of-Pocket Costs

- Patients may face significant out-of-pocket expenses, even if their insurer partially covers ketamine therapy.

DOJ Guidance Diversion Control

UNITED STATES OF AMERICA,
Plaintiff,
v.
KENNETH IWAMASA,
Defendant.

UNITED STATES OF AMERICA,
Plaintiff,
v.
ERIK FLEMING,
Defendant.

UNITED STATES OF AMERICA,
Plaintiff,
v.

JASVEEN SANGHA,
aka "the Ketamine Queen," and
SALVADOR PLASENCIA,
aka "Dr. P.,"
Defendants.

UNITED STATES OF AMERICA,
Plaintiff,
v.
MARK CHAVEZ,
Defendant.

- Ketamine Queen plead guilty; Sentencing December 10th. She was last of five charged in the Perry death



State Regulatory Considerations

State Variations

- Regulations regarding ketamine therapy vary widely by state. Some states have specific guidelines for its use in psychiatric settings, while others have more relaxed or undefined regulations.
- Texas – September 2025 Stakeholder Meeting regarding non hypnotic low dosage Ketamine
- Alabama – August 2025 Position Statement

Licensing Requirements

- Physicians prescribing ketamine for mental health purposes must meet specific licensing requirements and adhere to state-specific regulations.
- How CRNAs, PAs, APRNs, RNs fit in.

Corporate Practice of Medicine Concerns

Ownership Restrictions

- In many states, non-physicians cannot own or control medical practices, posing challenges for businesses providing ketamine therapy.

Physician Control

- To comply with corporate practice of medicine laws, ketamine clinics must ensure that physicians have ultimate control over medical decision-making.

Legal Compliance

- Navigating corporate practice of medicine regulations requires careful legal consultation to ensure compliance with state-specific rules.

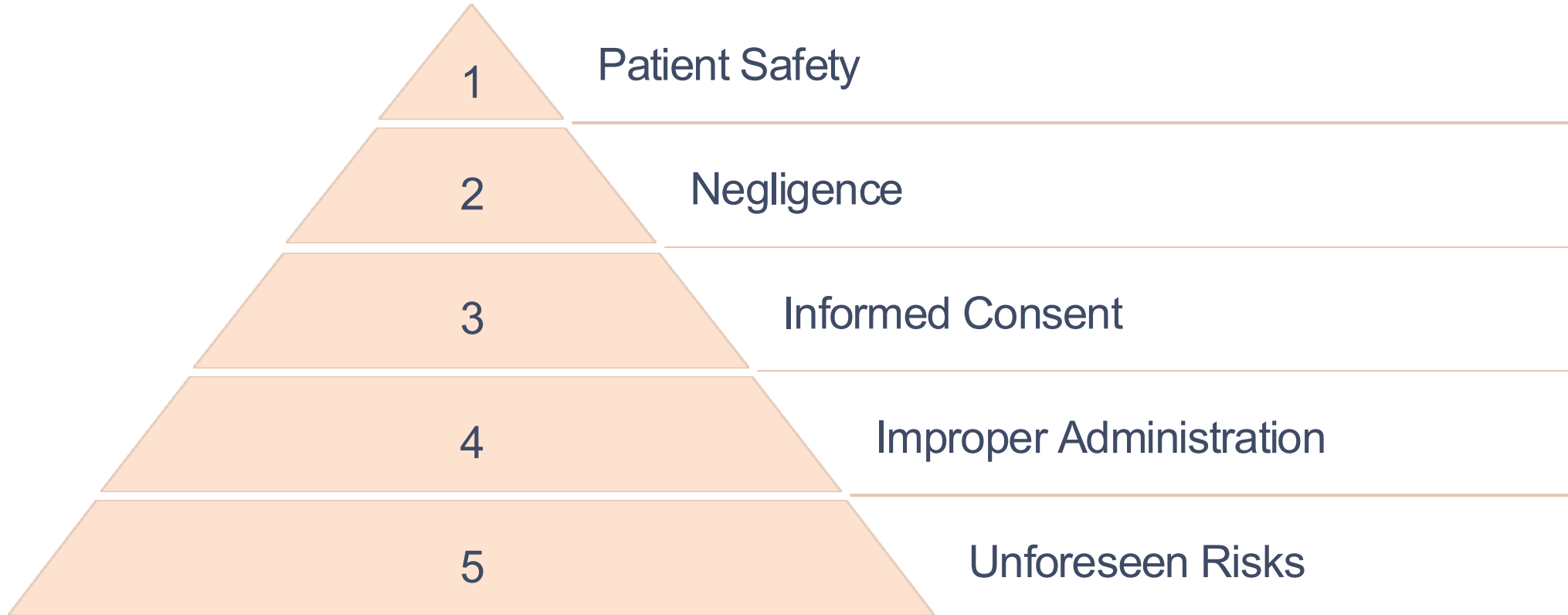
Online Direct to Consumer



- Telemedicine platforms are increasingly used for delivering ketamine therapy, offering patients convenience and access to treatment from home.
- Insurance payers are developing guidelines for covering telemedicine-based ketamine therapy, which can vary significantly based on the insurer and plan.

Board Investigation

Recent Lawsuits and Court Cases



Recent lawsuits related to ketamine therapy highlight the need for strict adherence to best practices and legal compliance. Cases have centered around patient safety, informed consent, and potential negligence in administering the drug.

Best Practice for Ketamine Therapy

1

Informed Consent

Patients must receive thorough information about the risks and benefits of ketamine therapy, including its potential side effects.

2

Medical Screening

A comprehensive medical evaluation is crucial to rule out any pre-existing conditions that might contraindicate ketamine use.

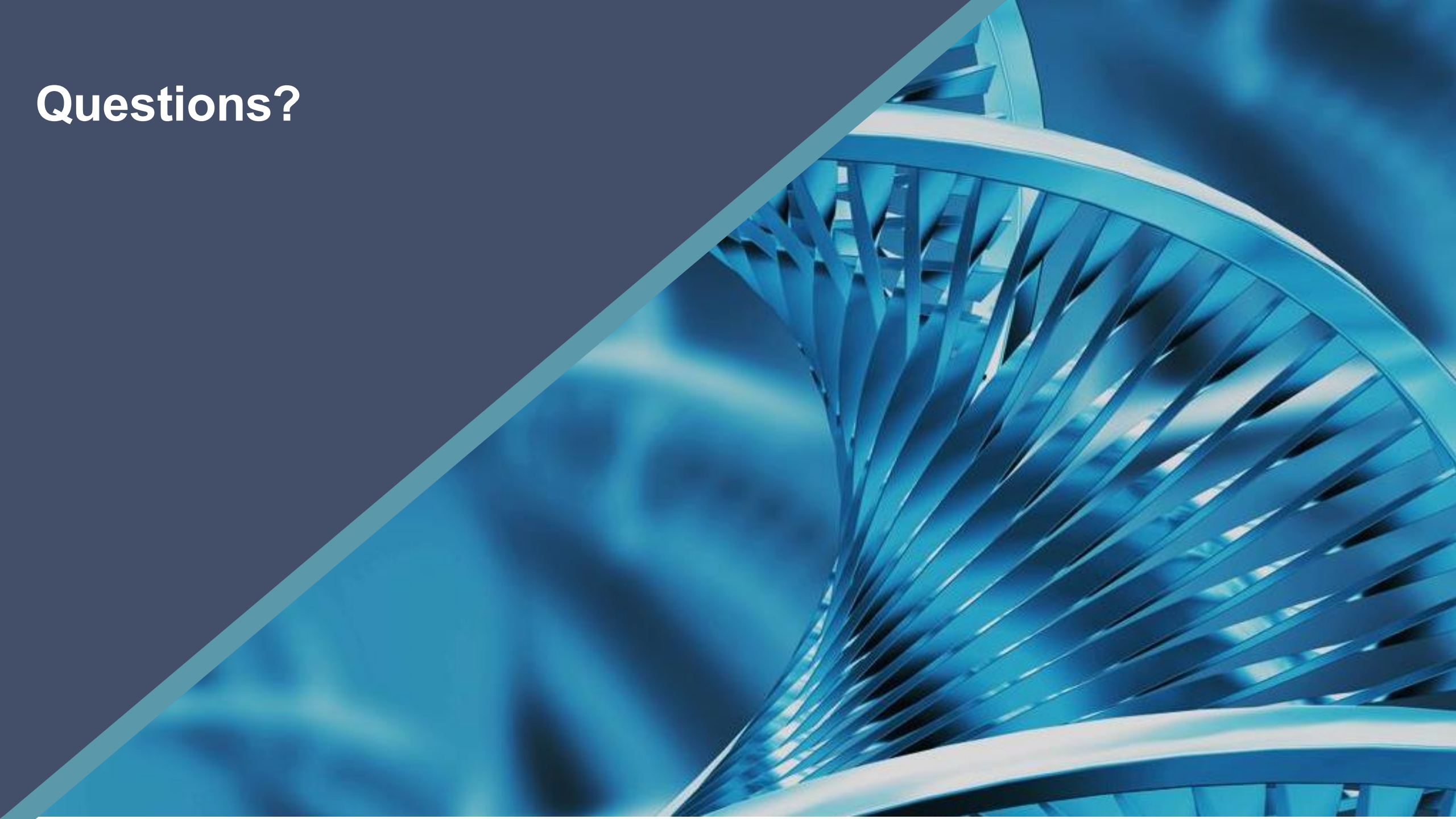
3

Dosage and Administration

Ketamine therapy should be administered by qualified healthcare professionals who are trained and experienced in its safe and effective use.



Questions?



Contact Information



Daniel Z. Sternthal
Shareholder / Houston
713.222.4034

dsternthal@munsch.com



Bradley A. Cook
Associate / Houston
713.222.1466

bcook@munsch.com

