When Off-Label Ketamine Meets Direct-to-Consumer Telehealth: Liability Risks and Ethical Responsibilities

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Aided by COVID-19–era regulatory flexibilities, direct-to-consumer telemedicine has expanded access to mental health care. Ketamine prescribed off-label for psychiatric conditions is increasingly marketed online and delivered at home through telehealth platforms. Taking a wrongful death lawsuit against a telehealth ketamine provider as a point of departure, the authors examine how combining off-label prescribing with on-demand delivery can strain clinical safeguards. Given the limited oversight of many telehealth platforms and the drugs they prescribe, responsibility and liability for patient safety rest heavily on clinicians. When off-label prescribing is combined with on-demand telehealth, the structures that sustain responsible care require support, including the capacity to sustain robust clinical relationships, monitoring, and accountability.

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On October 29, 2023, Phillip Ward, a 27-year-old man receiving off-label ketamine at home through the telehealth platform Mindbloom, was found dead in his bedroom (1). The official cause of death was ketamine toxicity (1). Two years later, Ward's parents filed a wrongful death lawsuit against the ketamine provider, pharmacy, and clinicians involved in his care, claiming that the death was a result of negligence.

The lawsuit alleges multiple breakdowns of responsible care: prescribing despite a history of substance use and cardiovascular risk; reliance on at-home monitoring tools that were misused or not used at all; and continued ketamine refills despite clear signs of patient disengagement, including missed mandatory checkups and failed payments. It is unclear how widespread the practices described in the Ward complaint are. The allegations remain to be proven at trial. Still, the lawsuit highlights broader ethical challenges related to off-label prescribing and direct-to-consumer telehealth that are increasingly common across health care.

OFF-LABEL PRESCRIBING

U.S. Food and Drug Administration (FDA) approval tends to lag behind clinical innovation, particularly in fields such as psychiatry, where patients with severe, high-risk disorders are often excluded from clinical trials (2). When FDA approval is sought, it is typically for a specific, well-defined indication. Once a drug has been approved, pharmaceutical companies may have limited incentives to seek additional indications because clinicians can prescribe it off-label for uses not specifically approved by the FDA. This includes use for different indications, doses, and populations.

Off-label prescribing of FDA-approved medications is common and legitimate (2). A 2006 study found that up to 21% of commonly used prescriptions were for off-label use, with rates rising to 96% for psychiatric disorders (3).

One reason off-label prescribing is important is that it allows clinicians to provide existing drugs to patients who would otherwise be unable to benefit from new and innovative uses. Ketamine is a clear example. Approved by the FDA as an anesthetic in 1970, it is now commonly prescribed for off-label use to address a wide range of psychiatric conditions, such as treatment-resistant depression, posttraumatic stress disorder, and obsessive-compulsive disorder (4). In 2019, the FDA approved the S-enantiomer of racemic ketamine—esketamine, trademarked as Spravato and delivered as a nasal spray—for treatment-resistant depression. Approval came with an FDA-mandated Risk Evaluation and Mitigation Strategy that required in-clinic administration and postdose

HIGHLIGHTS

- Ketamine prescribed for off-label use via telehealth platforms expands access but strains safeguards.
- Limited oversight in this area increases liability risks and clinicians' responsibility for patient safety.
- Safe ketamine care requires ongoing follow-up, monitoring, and clear accountability.

monitoring. However, these same safety requirements do not apply to off-label racemic ketamine—prescriptions of which rapidly increased after Spravato's approval, likely because of the significant price difference between Spravato and racemic generic ketamine (5).

Numerous case reports of poor medical and psychiatric outcomes, as well as instances of prescriber neglect or abuse predating the case against Mindbloom, suggest that ketamine use for non–FDA-approved indications carries risks that warrant caution (6). In October 2023, the FDA warned against the use of compounded ketamine products for psychiatric disorders (7). It stated that racemic ketamine is not approved for the treatment of any psychiatric disorder and noted that its use without proper medical supervision may expose patients to serious risks, including substance misuse, dissociation, psychiatric events, and respiratory depression, as well as cardiac and urinary issues.

Off-label prescribing operates in an ethical gray area that places a heavy responsibility on clinicians to ensure safe care (8, 9). Although the FDA regulates drugs, and the U.S. Drug Enforcement Administration (DEA) enforces rules against diversion, both agencies take a hands-off approach to clinical practice. Safe off-label prescription thus depends largely on the clinician's own medical judgment, which should be guided by sound scientific evidence, documented medical practice, and a desire to benefit the patient (9).

HOW ON-DEMAND KETAMINE STRAINS SAFEGUARDS

Ketamine is increasingly delivered through on-demand telehealth models that raise particular challenges for safe and responsible care. These platforms advertise directly to patients online, connect patients with clinicians who prescribe ketamine, arrange delivery by compounding pharmacies, and support at-home use under virtual supervision. The platforms expanded rapidly in the United States during and after the COVID-19 pandemic (5) as in-person mental health care declined and telehealth expanded. A growing number of telehealth start-ups also emerged around this time to offer online assessments, therapy, and prescription medications marketed directly to consumers (10). For controlled substances like ketamine, temporary DEA policies during the pandemic (which have since been extended) aided this expansion, in part, by relaxing long-standing requirements for in-person medical evaluations prior to prescription (5).

Although on-demand care has made off-label ketamine prescriptions more accessible, more convenient, and, in some cases, more affordable, it has also reoriented care in ways that may strain safeguards (11). For example, the FDA restricts off-label advertising by pharmaceutical companies, but it does not regulate advertising by online telehealth platforms that market directly to consumers. Several platforms have been found to make misleading claims about safety and efficacy, failing to disclose the off-label status of treatment or key risks, such as addiction potential (12). Advertising by some of these platforms blurs the line between medical treatment and wellness, suggesting efficacy for many purposes, from curing depression and supporting spiritual growth to healing heartbreak and bolstering creativity. This framing confuses consumers and patients and complicates the understanding of legitimate medical use in off-label ketamine prescribing.

As with other contexts of direct-to-consumer telemedicine (10), many individuals seeking ketamine through on-demand care may have already determined that ketamine is the treatment that best suits their goals, medical or otherwise. In addition to their encounters with direct-to-consumer marketing, they may be encouraged to self-diagnose and self-treat with off-label ketamine by so-called carefluencers: social media personalities who share health and wellness advice online (13). Although the many options that are readily available online appear to support patient autonomy by providing validated, self-administered diagnostic instruments, these same online applications leave patients vulnerable to misinformation and misdiagnosis in the absence of a bona fide medical assessment.

Even when off-label prescribing is used for appropriate medical indications, risk may be compounded when screening procedures are narrowly focused on eligibility rather than suitability. Screening for on-demand care is often solution oriented, focusing less on whether the treatment is the best option for the patient's medical problem and more on identifying contraindications that would exclude them from receiving it (14). This narrowed focus may discourage broader conversations that situate treatment decisions within a more comprehensive understanding of a patient's medical history, treatment goals, and potential alternatives.

On-demand care can introduce communication difficulties into the clinician-patient relationship and fragment care (11), making it difficult to establish the rapport necessary for clinicians to contextualize risks and recalibrate treatment decisions over time. In addition, on-demand platforms may not ensure continuity of care with a single clinician throughout treatment or with a patient's existing or past medical providers. As a result, clinically relevant information, such as medical records, may be incomplete or conflicting.

Finally, commercial pressures often exist in opposition to the ethics of appropriate medical care, further straining existing safeguards (10, 11). On-demand care is often offered through digital mental health start-ups whose survival depends on attracting consumers and expanding the number and types of prescriptions they provide. This model can shift priorities away from patients and providers and toward consumer demand and company interests (11). Clinicians may be pressured to shorten appointment times and increase patient volume while feeling compelled to meet consumer demands. These pressures may make it harder to engage in the patient-centered deliberation necessary to ensure proper informed consent, heightening liability risk.

WHAT RESPONSIBLE CARE REQUIRES

By combining off-label prescription with on-demand delivery, ketamine providers have quickly expanded access to this drug, especially for patients who may not have benefited from existing mental health treatments. Because both off-label and on-demand care operate in regulatory gray zones, much of the responsibility for patient safety falls on clinicians.

The clinical relationship is the foundation of safe and effective health care. Responsible care depends on clinicians' capacity to develop a rapport with patients, to understand their medical history and goals, and to talk openly about uncertainty and risk. In on-demand telehealth settings, where medications like ketamine are prescribed off-label, this type of care requires more than a single intake visit; it depends on a continuous relationship between the patient and provider that includes protected time for conversation and clear expectations for follow-up.

During these conversations, clinicians should communicate the off-label status of treatment, the reduced oversight inherent in at-home use, the lack of definitive evidence of benefit, and how these constraints may shape what treatment can realistically offer. These conversations are particularly important when patients seek ketamine for goals that extend beyond well-established indications. Responsible off-label, on-demand ketamine care requires structures that preserve a clinician's capacity to exercise ongoing, context-sensitive judgment rather than reducing care to episodic or checklist-driven encounters.

Clinical monitoring of patients is essential. At-home monitoring tools, virtual check-ins, and scheduled assessments support safety only when patients choose to engage and clinicians consistently review and respond to the information. Regular follow-up must be expected rather than optional. Missed appointments must trigger clear responses on the part of the clinician, and points at which treatment is reassessed or paused must be defined. When oversight is lacking, opportunities to detect rising risks may be missed. Without these safeguards, monitoring risks becomes symbolic rather than truly protective.

Finally, responsible care depends on clear structures of accountability. Patients who seek out telehealth platforms that offer off-label ketamine need to know who is responsible for their treatment. Clinicians need to preserve the ability to intervene when concerns arise. On-demand platforms may fragment responsibility across providers or separate prescribing from follow-up and coordination with existing care, leaving all involved vulnerable to claims of negligent treatment. Without clear accountability, treatment may continue despite red flags.

Clinicians have a legally enforceable, fiduciary duty to use their competence and skills to benefit their patients. This duty is breached when they deviate from accepted standards of care by failing to provide the level and type of care that reasonably competent and qualified clinicians would deliver under similar circumstances. If such a breach results in injury or death, the clinician may be held liable for professional negligence. As care delivery models expand beyond traditional in-office settings, clinicians must continue to be held to the same standards of care to ensure patient safety.

Beyond individual clinicians, relevant professional societies also have an obligation to more judiciously self-regulate in this space. This includes providing guidance on best practices, supporting data collection on safety and outcomes, and working with regulatory bodies to ensure appropriate oversight (15).

CONCLUSIONS

The allegations in *John and Linda Ward v Mindbloom* (1), assuming they are ultimately proven in court, show what can happen when the structures that sustain responsible care break down. The plaintiffs described treatment that continued despite missed appointments, incomplete monitoring, and signs of disengagement. If accurate, these claims raise questions about how responsible clinical judgment was sustained under such conditions. Although the case has yet to be formally resolved, it highlights how protocols alone can be insufficient to guarantee ethical and safe care.

Off-label prescribing has long relied on careful professional judgment. Fragmented, consumer-facing platforms may complicate the exercise of that judgment. When the conditions that support sound clinical judgment break down, lapses in care may be seen as failures of reasonable clinical judgment and increase liability risk. At a minimum, responsible off-label, on-demand ketamine care requires a continuous clinical relationship, meaningful monitoring and follow-up, and clear structures of accountability.

Beyond ketamine care, challenges in off-label prescribing reflect a moment at which innovation in health care is advancing within rapidly expanding commercial and digital systems. COVID-19–era regulatory flexibilities expanded access to care by relaxing in-person requirements for the prescribing of controlled substances through telehealth platforms. They also exposed gaps in oversight that are still being worked out.

Expanding access to new treatments is important. But preserving the clinical relationships, institutional supports, and regulatory structures that make those treatments safe and ethical is essential.

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