No. 21-70544

In the United States Court of Appeals for the Ninth Circuit

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, DR. SUNIL AGGARWAL, MD, PHD, MICHAL BLOOM, AND ERINN BALDESCHWILER,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; MERRICK GARLAND, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL; AND D. CHRISTOPHER EVANS, IN HIS OFFICIAL CAPACITY AS ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

MOTION FOR LEAVE TO FILE BRIEF OF AMICUS CURIAE KATHY L. CERMINARA, SYLVIA LAW, THADDEUS POPE, AND ROB SCHWARTZ

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Pursuant to Federal Rules of Appellate Procedure 27 and 29, Kathy L. Cermina, Sylvia Law, Thaddeus Pope, and Rob Schwartz (the "Amicus Curiae") respectfully moves for leave to file the attached *amicus curiae* brief in support of Petitioners.

The Amicus Curiae state the following in support of this Motion:

1. The Amicus Curiae is a group of law professors and bioethicists who advocate for the protection and expansion of end of life liberties. The amicus curiae have an interest in this case because it sets a precedent for the analysis of experimental palliative treatment under Right to Try legislation, and as such impacts future analyses of similar end of life liberties.

2. Under Federal Rules of Appellate Procedure 29(a)(4)(E), the Amicus Curiae certify that no party's counsel authored the attached brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person – other than the amicus curiae, its members, or its counsel – contributed money that was intended to fund preparing or submitting the brief.

3. The Amicus Curiae's brief is timely because it was filed within seven days of the May 14, 2021 filing of the Petitioners' principle brief. Fed. R. App. P. 29(a)(6). The brief complies with Fed. R. App. P. 29(a)(5) because it is no more

than half the maximum length of 13,000 words authorized for the defendants-appellants' principle brief.

4. Counsel for Petitioners have consented to the filing of this *amicus* brief; counsel for Respondents has not.

5. The Amicus Curiae respectfully move that this Court grant leave to file the brief of amicus curiae submitted with this motion.

DATED: May 21, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

DATED: May 21, 2021

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I. INTRODUCTION

In recent years, the Federal government and a supermajority of states have enacted Right To Try ("RTT") laws for end of life care.[1] Pursuant to these laws, many terminally ill patients have benefited from receiving medications and treatment that have not yet been approved by FDA.[2] In some cases, terminally ill patients have lengthened their remaining lives and improved the quality of their remaining lives.[3] Despite these benefits, some legal scholars and bioethicists have raised concerns regarding RTT laws. These concerns include giving false hope to dying patients, harming patients by administering experimental drugs that have not been tested thoroughly, and providing potentially harmful drugs to patients who may lack capacity to make an authentic informed consent.[4] These concerns, however, are not pertinent to the present case, which involves a request to provide psilocybin therapy as palliative care for terminally ill patients. Since psilocybin will only be administered as palliative, rather than curative, care, there is no concern that patients may be misled into thinking they will be cured by psilocybin. Further, psilocybin, unlike newly synthesized experimental drugs, has been used by humans for centuries

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[1] Goldwater Institute, *Right to Try in Your State*, https://righttotry.org/in-your-state/ (last visited May 21, 2021).
[2] *See* Goldwater Institute, *Right to Try Is Working*, RIGHT TO TRY, http://righttotry.org/right-to-try-is-working/ (last visited May 19, 2021).
[3] *Id.*
[4] *See infra*, section IV.

without harm. The risks of taking psilocybin are minor, well understood, and easily controlled for by physicians. Psilocybin has one of the lowest risk profiles of any Schedule I drug, and its efficacy as an antidepressant and antianxiety agent have been well established.[5]

The Drug Enforcement Administration ("DEA") erred in refusing Petitioners' request to access psilocybin for relief of debilitating depression and/or anxiety, and this Court should vacate DEA's decision. The criticisms some have lodged against RTT laws simply do not apply in the present situation, where a well-known, safe and effective drug will be given solely as palliative care to patients facing the end of their lives.

This brief addresses the various criticisms legal scholars and bioethicists have made regarding the RTT movement and RTT legislation, including the Washington Right to Try Act (the "Washington Act"), and it explains why those criticisms are unfounded in the context of palliative use of psilocybin. This brief also sets forth the reasons why palliative use of psilocybin is an appropriate application of the Washington Act.

[5] *See infra*, Section II.

II. PSILOCYBIN IS A SAFE AND EFFECTIVE PALLIATIVE CARE DRUG.

Psilocybin, 4-phosphoryloxy -*N*,*N*- dimethyltryptamine, is a substance that occurs in nature in various species of mushrooms.[6] In the human body, psilocybin "rapidly metabolize[s] to psilocin, which is a potent agonist at serotonin 5-$HT_{1A/2A/2C}$ receptors, with 5-HT_{2A} receptor activation directly correlated with human hallucinogenic activity."[7] Since the 1960's, clinical studies have shown that critically ill patients treated with psilocybin described "psychospiritual epiphanies, often with powerful and sustained improvement in mood and anxiety as well as diminished need for narcotic pain medication."[8]

A 2011 pilot study conducted by researchers at the University of California Los Angeles and published in the Journal of the American Medical Association "demonstrate[d] that the careful and controlled use of psilocybin may provide an alternative model for the treatment of conditions that are often minimally responsive to conventional therapies, including the profound existential anxiety and despair that often accompany advanced-stage cancers."[9] Consistent with prior research, the study

[6] Charles S. Grob et al., *Pilot Study of Psilocybin Treatment for Anxiety in Patients with Advanced-Stage Cancer*, 68 ARCHIVES GEN. PSYCHIATRY 71, 71 (2011).
[7] *Id.*
[8] *Id.*
[9] *Id.* at 79.

found that psilocybin was well tolerated, with "no untoward cardiovascular sequelae" and only minor elevations of heart rate and blood pressure.[10]

In a 2016 randomized double-blind study conducted by researchers at Johns Hopkins University and published in the Journal of Psychopharmacology, "[n]o serious adverse events attributed to psilocybin administration occurred."[11] The study also found that "psilocybin ([at a dose of] 22 or 30 mg/70 kg) produced large decreases in clinician- and self-rated measures of depressed mood and anxiety, along with increases in quality of life, life meaning, and optimism, and decreases in death anxiety."[12] These positive outcomes resulted from a single dose, and they were sustained at a 6-month follow-up, with "about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety."[13]

In a 2019 study conducted by researchers at the Institute of Psychiatry, Psychology and Neuroscience at King's College London and published in *Psychology Today* "show[ed] no serious adverse effects related to administering regulated doses of psilocybin in a controlled setting with one-on-one support from a

[10] *Id.* at 76.
[11] Roland R. Griffiths et al., *Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial*, 30 J. PSYCHOPHARMACOLOGY 1181, 1187 (2016).
[12] *Id.* at 1181.
[13] *Id.*

specially trained therapist."[14] The study also determined that psilocybin at 10 or 25 mg doses induced "transient psychedelic experiences".[15]

These and other studies show that, in research spanning nearly 60 years, psilocybin has been shown to be safe, well tolerated, and effective in reducing depression and anxiety, particularly in patients facing end of life.

III. BACKGROUND OF RIGHT TO TRY LAWS

In 2017, the state of Washington enacted its RTT law.[16] The law recognizes that "the process for approval of investigational drugs … often takes many years," and patients with terminal illnesses frequently do not have the luxury of waiting until an investigational drug obtains final approval from FDA.[17] In light of this recognition, Washington legislators unanimously voted to approve access to investigational drugs for "patient[s] with a terminal illness in consultation with the patient's health care provider."[18]

In 2018, following the enactment of the Washington RTT law as well as the enactment of RTT laws by many other states,[19] the United States Congress enacted

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[14] Christopher Bergland, "*Psilocybin: Four Important Takeaways from a Clinical Trial*," PSYCHOLOGY TODAY, available at: https://www.psychologytoday.com/us/blog/the-athletes-way/201912/psilocybin-four-important-takeaways-clinical-trial.
[15] *Id.*
[16] WASH. REV. CODE ANN. § 69.77 *et seq*. (2017).
[17] WASH. REV. CODE ANN. § 69.77.010 (2017).
[18] *Id.*
[19] Goldwater Institute, *supra* note 1.

a Federal RTT law.[20] The Federal RTT law carved out a statutory exception to FDA's safety/efficacy requirements for premarket approval under § 355.[21] The Federal RTT law provides an exemption to § 355's premarket approval requirements for unapproved investigational drugs that have successfully completed Phase 1 safety trials, but that have not yet completed Phase 2 or 3 trials. Under certain conditions, this exemption permits distribution of unapproved drugs for therapeutic use in patients facing end of life who have exhausted approved treatment options.[22]

RTT laws give terminal patients the right to try investigational, unapproved drugs for which only safety, and not efficacy, has been established. Terminally ill patients who have exhausted approved treatment options face drastically different risk/benefit tradeoffs than other patients. Federal and a supermajority of state lawmakers have determined that the potential benefits of allowing such patients access to experimental treatment outweighs the risks in many situations.

Despite the sweeping enactment of RTT legislation around the country, some resistance to RTT laws continues to exist. Critics of RTT laws have argued that providing patients with access to investigational drugs can harm patients – physically, emotionally, and even financially. The amicus curiae do not comment in this brief on the merits of such criticisms generally. Rather, they argue that such

[20] *See generally* 21 U.S.C. § 360bbb (2018).
[21] 21 U.S.C. § 360bbb-0a (2018).
[22] 21 U.S.C. § 360bbb-0a(b) (2018).

criticisms do not apply in the present situation, where doctors and patients have sought access to psilocybin – a safe, effective and well known drug – solely for palliative care.

IV. CRITICISMS OF RTT LAWS DO NOT APPLY IN THE PRESENT CASE

As set forth below, the criticisms some legal scholars and bioethicists have made to RTT laws do not apply in the present case, where a centuries-old, well-known, safe and efficacious drug will be administered solely as palliative care to assist terminally ill patients in coping with the anxiety and depression accompanying their end of life situations.

A. The Palliative Use of Psilocybin Does Not Prioritize Efficiency Over Safety.

Some critics of RTT laws have argued that they prioritize drug distribution over safety. In the case of psilocybin, however, these concerns are not applicable, given its centuries-long safety record .

1. Criticisms in the Literature

One of the major criticisms of RTT legislation like the Washington Act focuses on the supposed trade-offs such legislation makes between access and safety. While proponents of RTT legislation argue for efficient access to potentially life-saving treatments, detractors have come forward with concerns about granting vulnerable patients access to drugs without more information about certain drugs' safety. Although some supporters of RTT legislation may feel the Food and Drug

Administration's ("FDA") regulatory process for approving drugs arbitrarily denies patients access to experimental treatments that could save lives, critics feel this legislation strikes the wrong balance between these battling concerns of speed and safety.

For example, some critics have pointed out that the RTT path to experimental treatment fails to address the concerns illuminating the RTT movement in a holistic manner. According to Sylvia Zaich, the RTT Movement has accused the FDA process of being "broken".[23] But, instead of proposing a different framework or attempting to remedy the process's pitfalls in the existing framework of the law, RTT supporters "decided the easier path was pre-approval access legislation that cut-out the FDA."[24] According to Zaich, safety and efficacy of drugs are important concerns that cannot simply be eliminated from consideration because patients are "frustrated" with the approval process.[25] Zaich points out that Phase 1 Clinical Testing does not guarantee a drug's safety, and that many drugs that pass Phase 1 are later determined to be unsafe.[26] Moreover, according to Zaich, allowing patients to bypass testing and approval via RTT does not just expose patients to potentially harmful, unsafe drugs – it also reduces the number of individuals available for

[23] Sylvia Zaich, *An Examination of the Right to Try Act of 2017 and Industry's Potential Path Moving Forward*, 92 S. CAL. L. REV. 331, 360 (2019).
[24] *Id.*
[25] *Id.* at 361.
[26] *Id.*

clinical trials and directly exacerbates the complained-of lag between development and approval.[27]

Brandon Brown, Camerin Ortiz, and Karine Dube likewise criticize RTT legislation's use of Phase 1 testing as a bellwether for a particular treatment's safety. In evaluating the pros and cons of RTT laws, these authors point out that the clinical trial and review process currently in place at the FDA "took more than 50 years to establish in order to ensure that pharmaceuticals are safe for their intended use[.]"[28] According to Brown, et al., the FDA process "is an effective method that weeds out most ineffective or dangerous drugs." As such, these authors argue that RTT laws are "hypocritical" in that they rely on the FDA's Phase 1 testing results to determine toxicity and possible side effects, but decline to utilize the FDA's subsequent phases which ensure drugs have been "rigorously tested" and "deemed safe for widespread use."[29] Like Zaich, these authors point out that, while a large number drugs pass Phase 1 testing, many will be later eliminated for safety and/or efficacy concerns.[30] As a result, Brown, Ortiz, and Dube contend that RTT legislation may not adequately "protect the integrity and safety of the drug development process[.]"[31]

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[27] *Id.*
[28] Brandon Brown et al., *Assessment of the Right-to-Try Law: The Pros and Cons,* 59 J. NUCLEAR MED. 1492, 1492 (2018).
[29] *Id.*
[30] *Id.*
[31] *Id.*

2. Safety Concerns Do Not Warrant The DEA's Denial Of Psilocybin in the Present Case.

Those who criticize RTT legislation based on safety concerns primarily have focused on Phase 1 testing's inability to conclusively establish safety and efficacy and the prioritization of efficient access to drugs over those concerns, as well as the impact of thinning the available pool of candidates for potentially life-saving treatments. In the case of palliative use of psilocybin in terminal cancer patients, however, none of these concerns is applicable.

First, the concerns about safety and efficacy in the context of Phase 1 experimental treatments are inapplicable in the context of psilocybin, because psilocybin is not a new drug; it has been safely used for many decades. Indeed, hallucinogens have been used by indigenous cultures in sacramental and healing contexts for millennia.[32] In the 1950s and 1960s, hallucinogens were studied in the context of basic clinical research, therapeutic clinical research, and for use as incapacitating agents in soldiers.[33] Although initial research focused on hallucinogens as agents of warfare, subsequent research began to include "more preparation and interpersonal support during the period of drug action," resulting in fewer adverse psychological reactions and increased reports of positively-valued

[32] Matthew W. Johnson et al., *Human Hallucinogen Research: Guidelines for Safety*, 22 J. PSYCHOPHARMACOLOGY 1, 3 (2008).
[33] *Id.* at 4.

experiences.[34] Through years of study, researchers have found that hallucinogens "possess relatively low physiological toxicity, and have not been shown to result in organ damage or neuropsychological deficits."[35] Hallucinogens also "are not typically considered drugs of dependence in that they do not engender compulsive drug seeking" and are not associated with withdrawal syndrome.[36] While a potential risk of hallucinogen administration is prolonged psychosis, "it is unknown whether the precipitation of psychosis in such susceptible individuals represents a psychotic reaction that would have never occurred in the absence of hallucinogen use, or whether it represents an earlier onset of a psychotic break that would have inevitably occurred."[37] These cases are also extremely rare and almost non-existent in the case of psilocybin.[38]

Overall, psilocybin has been administered in numerous clinical situations without any significant safety issues. For example, a recent study investigating the feasibility, safety, and efficacy of psilocybin in patients with treatment-resistant depression found "no serious or unexpected adverse" reactions.[39] Another study of

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[34] *Id.*
[35] *Id.* at 6.
[36] *Id.* at 7.
[37] *Id.* at 8.
[38] *Id.*
[39] Robin L. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment-Resistant Depression: An Open-Label Feasibility Study*, 3 LANCET PSYCHIATRY 619 (2016).

psilocybin as a treatment for anxiety and depression in patients with life-threatening cancer also confirmed no serious adverse events.[40] The same results on safety of psilocybin were reported in a 2011 study exploring the safety and efficacy of psilocybin in patients with advanced-stage cancer and reactive anxiety.[41] In summary, studies of psilocybin – particularly when it is used in patients with anxiety and depression under controlled settings – have resulted in resounding consensus of the drug's safety. Further, psilocybin is generally considered not to be addictive.[42]

There are also a myriad of studies demonstrating psilocybin is effective in treating depression and anxiety. The 2011 study that administered moderate doses of psilocybin to patients with advanced-stage cancer and anxiety "revealed a positive trend toward improved mood and anxiety."[43] A study of psilocybin use in patients with treatment-resistant depression – which is common in cancer patients – resulted in "markedly reduced" depression symptoms, as well as "[m]arked and sustained

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[40] Stephen Ross et al., *Rapid and Sustained Symptom Reduction Following Psilocybin Treatment for Anxiety and Depression in Patients with Life-Threatening Cancer: A Randomized Controlled Trial*, 30 J. PSYCHOPHARMACOLOGY 1165, 1176-77 (2016).
[41] Charles S. Grob et al., *supra* note 7.
[42] Tanya Lewis, "John Hopkins Scientists Give Psychedelics the Serious Treatment," SCIENTIFIC AMERICAN, https://www.scientificamerican.com/article/johns-hopkins-scientists-give-psychedelics-the-serious-treatment/ (last visited May 21, 2021); Griffiths et al., *supra* note 12.
[43] Lewis, *supra* note 42.

improvements in anxiety and anhedonia[.]"[44] A recent study that administered psilocybin to cancer patients with clinically significant anxiety and depression resulted in "rapid, robust and enduring anxiolytic and anti-depressant effects in patients with cancer-related psychological distress."[45] A clinical trial of psilocybin-assisted therapy in patients with major depressive disorder demonstrated psilocybin "was efficacious in producing large, rapid, and sustained antidepressant effects in patients with major depressive disorder."[46]

The overwhelming weight of evidence demonstrates that psilocybin is safe, fast-acting, and extremely effective in treating symptoms of depression and anxiety in cancer patients. As such, concerns about skipping Phase 2 and 3 testing should not be a significant barrier to granting access to this treatment under RTT legislation.

Similarly, concerns about decreasing the available pool of candidates for clinical trials, and therefore preventing other patients access to life-saving treatments, are not applicable here. First, significant clinical trials on the safety and efficacy of psilocybin already have been conducted. To the extent additional testing must be performed for psilocybin to progress through the FDA approval process, a terminal cancer patient's palliative use of psilocybin will not prevent others' access

[44] Carhart-Harris et al., *supra* note 39.
[45] Ross et al., *supra* note 40.
[46] Alan K. Davis et al., *Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial*, 78 J. AM. MED. ASSOC. PSYCHIATRY 481, 482 (2021).

to "life-saving" experimental treatments. This is because psilocybin is intended for palliative, end-of-life care for terminal cancer patients. As such, stalling the approval process will not impact other patients' access to any life-saving treatment. In addition, the safety and efficacy of psilocybin in treating depression and anxiety can be tested in other pools of patients – such as individuals with anxiety or depression unrelated to cancer, or non-terminal cancer patients experiencing anxiety and depression. Utilizing these other groups of potential patients promotes terminal patients' "right to try" a clinically effective treatment that could drastically improve their quality of life without adversely affecting any other patient pools.

B. The Administration of Psilocybin as Palliative Care To End Of Life Patients Does Not Give Them False Hope.

Critics of RTT laws have cited concerns that granting patients special access to experimental treatments may provide false hope of recovery. These concerns are not applicable to the use of psilocybin in this case, however, because the treatment would be used palliatively and would not be administered as a life-saving treatment.

1. Criticisms in the Literature.

Another common criticism of RTT legislation faults it for giving terminal patients false hope of recovery. According to these critics, allowing patients to bypass the normal FDA process and gain access to experimental treatments, which have not undergone more rigorous testing, gives terminal patients a false expectation that the treatment will be life-saving.

Zaich is one such critic. Citing a report which demonstrates that advertisements for FDA-approved medications can "have misleading effects on people's perceptions of their individual outcomes," Zaich argues it is "reasonable to think that patients' perceptions could be equally skewed about investigational drugs[.]"[47] Because "investigational drugs are often touted as 'revolutionary' at medical meetings by the manufacturers, tweeted as 'groundbreaking' by physicians and reported as 'life-saving' by media, as compared to the current treatment option[,]" Zaich argues allowing patients access to experimental treatments in this manner gives patients unrealistic expectations of their likelihood of being cured.[48]

Brown, *et. al.* have likewise criticized RTT legislation for inflating terminal patients' expectations. According to these authors, "there may be misunderstanding of experimental drugs and their likely success rates[.]"[49] Brown, Ortiz, and Dube argue this misunderstanding could lead "[t]erminally ill patients who feel as if they are running out of time" to be "swayed by the false hope provided by an experimental procedure[.]"[50] These authors point out that the false hope created by RTT legislation could exacerbate the legislation's existing problems created by limited patient understanding of the safety and efficacy of experimental therapies.[51]

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[47] Zaich, *supra* note 23, at 363.
[48] *Id.* at 363-64.
[49] Brown et al., *supra* note 28, at 1492.
[50] *Id.*
[51] *Id.*

Michelle J. Rubin and Kristin R.W. Matthews likewise focus on RTT legislation's unintended consequence of inflated hopes, and the effect this can have on terminal patients' decision-making processes. According to Rubin and Matthews, "[t]he chance to access investigational drugs can naturally raise the hopes of patients and families[.]"[52] However, when this hope turns out to be a "false hope", Rubin and Matthews point out that this increased access ends up "causing more stress in a terminally ill patient's life."[53] The interplay between false hope and incomplete information is also relevant to Rubin and Matthews, who argue that "Right to Try laws can perpetuate the idea that an experimental drug is worth the risk and potential danger, despite the fact that 85% of experimental drugs fail during clinical trials."[54]

2. Palliative Use of Psilocybin Does Not Create False Hope.

Critics of RTT argue that, because many experimental drugs are touted as "revolutionary" or "groundbreaking", granting terminal patients special access to these drugs outside of the FDA process may further inflate their expectations that the experimental treatment will cure them or save their lives. However, psilocybin has not been touted as a "cure" or "life-saving" treatment for cancer; the patients requesting access to psilocybin in these circumstances seek to use it palliatively for

[52] Michelle J. Rubin & Kristin R.W. Matthews, *The Impact of Right to Try Laws on Medical Access in the United States*, 66 BAKER INST. POL'Y REP. 1, 8 (2016).
[53] *Id.*
[54] *Id.*

increased quality of living as they approach end of life. As such, it is unlikely that concerns over patients' false expectations that their lives will be saved by experimental drugs could apply in this context. And, in fact, petitioners' declarations demonstrate their lack of false expectations, as both patients have declared under penalty of perjury that they are aware they have a "very limited quantum of time to live."[55]

The concern over false expectations is likewise ameliorated by the Washington Act's requirements for informed consent, which require a physician to provide "[t]he potentially best and worst outcomes of using the investigational product and a realistic description of the most likely outcome."[56] This requirement ensures that physicians temper expectations by clearly indicating that psilocybin will not cure the patient's cancer or save his or her life, and that the patient will most likely still perish from the terminal cancer. Moreover, because physicians have access to years of studies demonstrating the specific safety and efficacy of psilocybin, and its use in terminal cancer patients, the concern that lack of information about experimental drugs could be exacerbated by this false hope is

[55] *Declaration of Michael Bloom, in Support of Motion for Expedited Review*, D.E. 19, ¶ 3; *Declaration of Erin Baldeschwiler, in Support of Motion for Expedited Review*, D.E. 19, ¶ 3.
[56] WASH. REV. CODE ANN. § 69.77.050(2)(d) (2017).

unfounded here. Instead, physicians can use that information to appropriately inform patients and temper their expectations.

False hope simply is not a valid concern with regard to the administration of psilocybin to terminally ill patients, where the treatment does not create an expectation that the patient's underlying condition will be cured and patients are adequately informed of that fact.

C. Terminal Patients Can Give Informed Consent to Palliative Use of Psilocybin Under the Washington Act.

Some critics of RTT laws have contended that it is impossible to give informed consent to experimental drug treatments. However, given the extensive information available about psilocybin, and the specific standards for consent provided by the Washington Act, this is not a significant concern in the present case.

1. Criticisms in the Literature.

Some opponents of RTT legislation have raised red flags regarding the impact of these laws on informed consent. According to these critics, because there is not sufficient information about the safety of drugs accessed through RTT laws, and because many terminal patients have no other feasible treatment options, it is effectively impossible for patients selecting treatments available through RTT to give truly informed consent to the risks and consequences of such treatments.[57]

[57] Brown et al., *supra* note 28, at 1492.

According to Brown, et. al., the lack of informed consent is a major negative consequence of RTT legislation. These authors assert that a patient's understanding of a drug, its potential consequences, and the purpose of an experimental trial are critical to obtaining informed consent.[58] That being said, they state that consent forms "are often confusing, written in a way that is difficult to understand, and contain highly technical terms at great length, which can result in patients missing or misunderstanding the gist of the experiment."[59] According to Brown, Ortiz, and Dube, given the high expectations terminal patients place upon experimental treatment, and lack of other viable options to cure their illness, the "false hope" provided by an experimental drug could cause a terminal patient to cast aside his or her concerns about negative effects, consequences, or lack of information.[60]

Rubin and Matthews are likewise doubtful of terminal patients' ability to provide informed consent to experimental treatments under these circumstances. According to Rubin and Matthews, RTT laws "assume that patients and physicians can adequately identify experimental drugs that will help them and assess the risk benefit threshold themselves."[61] This assumption, they argue, fails to address the fact that clinical testing data is often proprietary and not available to physicians,

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[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] Rubin et al., *supra* note 52, at 8.

meaning that patients and physicians "might not have the necessary information to make a fully informed decision[.]"[62] Because of this information gap, physicians "may be unable to offer an accurate assessment before the drug passes Phase 2 or 3 clinical trials, leaving the patient potentially uninformed while consenting to receive the intervention[.]"[63] Rubin and Matthews also argue that, without the FDA's intervention, there is no guarantee that consent forms used under RTT laws will be accurate or comprehensive.[64]

Like Rubin and Matthews, Brenda Lin is also concerned that lack of FDA oversight impact may negatively impact the quality of informed consent. Lin argues that "Right to Try laws bypass IRB review of treatment protocol and do not establish informed consent standards."[65] According to Lin, while RTT legislation "does explicitly require that the eligible patients provide written informed consent to the investigational drug treatment," these laws' silence "as to the criteria the informed consent must meet" prevents "patient autonomy" and "truly informed decisions."[66] Lin also points out that, even if RTT laws did include adequate criteria, "[g]enuine informed consent is particularly difficult to attain in the experimental treatment

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[62] *Id.* at 9.
[63] *Id.* at 10.
[64] *Id.*
[65] Brenda Lin, *Federal Right to Try Act: Heightened Informed Consent and Price Regulation Measures Will Improve Quality, Autonomy, and Exploitation Issues*, 16 HASTINGS BUS. L. J. 207, 214 (2020).
[66] *Id.* at 215-16.

context because even the physician may not know how safe or effective the treatment is."[67]

Overall, Lin's argument reflects concerns about two principles promoted by informed consent: quality of care and individual autonomy. According to Lin, "informed consent is meant to safeguard against poor quality health care, amongst other dangers."[68] Lin suggests that "[t]he act of informing patients encourages physicians to carefully consider their decisions while practicing medicine."[69] Without adequate informed consent, Lin warns, "patients may lose autonomy by making decisions without fully understanding the proposed treatment or its full benefits and risks."[70]

2. Patients Can Provide Informed Consent to the Palliative Use of Psilocybin.

As noted in Section I.C, those who criticize RTT legislation for its inability to enable informed consent from patients have several related concerns. First, critics are concerned that patients and their physicians do not have sufficient information about the safety and efficacy of experimental drugs to provide truly informed consent to the treatment they are receiving, as well as its risks and consequences. Second, they are concerned that the informed consent required by RTT legislation

[67] *Id.* at 216.
[68] *Id.* at 219.
[69] *Id.*
[70] *Id.* at 220.

lacks clear criteria and/or standards. And third, critics are concerned that the lack of informed consent could affect the quality of the patient's treatment or undermine the patient's exercise of individual autonomy. In the context of palliative use of psilocybin under the Washington Act, however, these concerns are unfounded.

First, patients and physicians have access to sufficient information about the safety and efficacy of psilocybin to provide informed consent to this treatment. As discussed above in Section II.A, there are decades of information about the safety and efficacy of psilocybin in treating anxiety and depression.[71] There also are multiple clinical trials that have focused, in particular, on the efficacy of psilocybin in treating emotional conditions cancer patients face at end of life. These studies have found no significant adverse effects, the consequences and potential side effects of psilocybin are minor and well-documented, and there is ample material on which a physician can advise a patient when weighing the potential pros and cons of using psilocybin palliatively.[72] As such, lack of informed consent is of limited relevance to the present case.

Likewise, Washington state law and the Washington Act ensure truly informed consent is given before an experimental drug is administered. Under the Washington doctrine of informed consent, "a health care provider has a fiduciary

[71] *See, e.g.*, *supra* Section IV.A.2.
[72] *Id.*

duty to disclose relevant facts about the patient's condition and the proposed course of treatment so that the patient may exercise the right to make an informed health care decision."[73] And the Washington Act clearly enumerates the criteria for an effective informed consent, including disclosure of numerous information relating to the patient's condition, approved treatments, possible courses of action, outcomes, and side effects.[74] The Washington Act's informed consent requirements meet the standard enumerated by the Washington Supreme Court, and they adequately address concerns voiced by critics about clarity of informed consent standards. As such, concerns about the quality of informed consent received from terminal cancer patients seeking psilocybin treatment in Washington state are sufficiently addressed by the Washington Act.

Because physicians have sufficient information to evaluate psilocybin as a palliative treatment for anxiety and depression in terminal cancer patients, and the Washington Act provides clear criteria for obtaining truly informed consent from patients, concerns about the impact of informed consent on quality of care and individual autonomy are unwarranted. Given the amount of information available to physicians about psilocybin, and standards for effective administration of psilocybin

[73] *Stewart-Graves v. Vaughn*, 170 P.3d 1151, 1155 (Wash. 2007).
[74] WASH. REV. CODE ANN. § 69.77.050(2) (2017).

treatments, quality of care will not be compromised when psilocybin is administered under the supervision of a trained clinician.

While concerns regarding informed consent may be relevant to certain treatments and certain aspects of RTT legislation, palliative use of psilocybin under the Washington Act does not involve lack of adequate informed consent.

D. Manufacturer And Physician Liability Is Not A Concern With Psilocybin, Particularly In The Present Case.

Given the long history of psilocybin use, there is no significant risk of physician malpractice of manufacturing defects, particularly with regard to the administration of psilocybin to terminally ill patients for palliative care. Accordingly, concerns that patients will be deprived of the opportunity to sue doctors and manufacturers are not warranted in the case of psilocybin.

1. Criticisms in the Literature.

Some commentators have raised concerns that RTT laws allow manufacturers of experimental drugs, and the physicians who prescribe them, to avoid liability to patients for death or injuries caused by such drugs. They note that "Right to Try has a provision that says if something terrible happens, nobody — the doctor, pharmacist or the drug company — can get sued by that patient or their heirs."[75] Under Section

[75] *See* Jennifer Byrne, *Right to Try: A 'Well-Intentioned' but 'Misguided' Law*, HEMONC TODAY (Mar. 10, 2020), https://www.healio.com/news/hematology-oncology/20200303/right-to-try-a-wellintentioned-but-misguided-

561B of the Federal RTT Act, an "eligible patient" may use an "eligible investigational drug" ("EID") exempt from certain parts of the FDCA and FDA regulations, and "no liability in a cause of action shall lie" against a manufacturer, sponsor, prescriber, or dispenser providing EIDs to an eligible patient that complies with Section 561B.[76] As a result, some commentators have concluded that the risks to patients, particularly patients from marginalized groups, outweigh the benefits of providing EIDs to terminal patients in end-of-life situations.[77]

2. Palliative Use Of Psilocybin In End Of Life Situations Does Not Raise Issues Of Manufacturer And Physician Liability.

While these concerns may be relevant for certain types of EIDs, particularly new drugs that offer hope for a cure from a terminal illness, they are not relevant in the case of psilocybin when used only for palliative care in confirmed end-of-life situations. Unlike new, experimental drugs, psilocybin has been used for centuries.[78] Studies of psilocybin "show it frequently falls at the end of the scales with the least

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law#:~:text=Right%20to%20Try%20also%20includes,investigational%20drugs%20to%20their%20patients.

[76] 21 U.S.C. § 360bbb-0a (2018); 21 U.S.C. § 360bbb-0a, PL 115-176, 132 Stat. 1372 (May 30, 2018).

[77] Byrne, *supra* note 75.

[78] *See* Matthew W. Johnson & Roland R. Griffiths, *Potential Therapeutic Effects of Psilocybin*, 14 J. AM. SOC'Y EXPERIMENTAL NEUROTHERAPEUTICS 734, 734-740 (2017) (noting that psilocybin has been "used for centuries as sacraments within indigenous cultures").

harm to users and society".[79] "Psilocybin also is lowest in the potential for lethal overdose as there is no known overdose level."[80] Studies of psilocybin show that it is well tolerated by patients, with little, if any, potential for "serious or unexpected adverse events".[81] Adverse events generally are limited to transient anxiety during drug onset, transient confusion or thought disorder, mild and transient nausea, and transient headache.[82] Recent clinical examinations of psilocybin have indicated that it is not hazardous to physical health.[83] "Psilocybin mushrooms have low toxicity, and death from an overdose is very rare. One survey in 2016 found that out of more than 12,000 users who took psilocybin, only 0.2% reported emergency medical treatment.[84] That rate is 5 times lower than MDMA (Ecstasy), LSD, and cocaine."[85]

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[79] *Reclassification Recommendations for Drug in 'Magic Mushrooms'*, JOHN HOPKINS MED. (Sept. 26, 2018), https://www.hopkinsmedicine.org/news/newsroom/news-releases/reclassification-recommendations-for-drug-in-magic-mushrooms.

[80] *Id.*

[81] Carhart-Harris et al., *supra* note 39.

[82] *Id.*; *see also* James Rucker et al., *Psilocybin Administration To Healthy Participants: Safety And Feasibility In A Placebo-Controlled Study*, COMPASS PATHWAYS (2019) https://compasspathways.com/wpcontent/uploads/2020/04/COM100945_ACNP_Rucker_ePoster_withoutQR-1.pdf (finding that psilocybin "was well tolerated in healthy participants").

[83] Charles S. Grob et al., *supra* note 7.

[84] Olivia Solon, *Study Finds Mushrooms Are the Safest Recreational Drug*, GUARDIAN (May 24, 2017, 6:18 PM), https://www.theguardian.com/society/2017/may/23/study-hallucinogenic-mushrooms-safest-recreational-drug-lsd.

[85] *Can You Die from Taking Too Many Psychedelic Shrooms?*, DESERT HOPE TREATMENT CTR. (May 22, 2020),

Given that the risk of an adverse event from psilocybin is so small, the possibility that a patient who took psilocybin (or his or her heirs) may be deprived of the right to sue a manufacturer or physician due to harm from psilocybin is remote, at most. The risk of unredressed harm is further reduced given that, in the present case, psilocybin will only be used for palliative care in patients who have confirmed terminal illnesses and have provided informed consent to treatment.

E. Psilocybin Patients are Not Likely to Be Vulnerable to Financial Exploitation by Practitioners and Insurance Companies.

Unlike other RTT drugs, the cost of psilocybin is modest. There is little, if any, concern that psilocybin patients will be taken advantage of financially.

1. Criticisms In The Literature.

Some commentators who oppose RTT laws have voiced concerns that patients prescribed experimental drugs in end-of-life scenarios may be taken advantage of financially. They argue that "Right to Try laws do not require manufacturers or insurance companies to pay for the investigational drug or device; the financial

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https://deserthopetreatment.com/hallucinogens/psychedelic-mushroom-addiction/overdose/ (citing Olivia Solon, *Study Finds Mushrooms Are the Safest Recreational Drug*, GUARDIAN (May 24, 2017, 6:18 PM), https://www.theguardian.com/society/2017/may/23/study-hallucinogenic-mushrooms-safest-recreational-drug-lsd; *Psilocybin Mushrooms Fact Sheet*, DRUG POL'Y ALL. (Jan. 2017), https://drugpolicy.org/sites/default/files/Psilocybin_Mushrooms_Fact_Sheet.pdf).

burden is placed on patients and their families. This stipulation unintentionally leads to a small, financially privileged group that has access to the drug."[86]

2. There Is Little, If Any, Concern That Psilocybin Patients Will Be Taken Advantage Of Financially.

In the case of psilocybin, there is little risk that patients will be taken advantage of financially. The cost of psilocybin is modest (less than $200 per treatment), particularly when compared to other RTT drugs.[87,88] Further, psilocybin is typically administered in a single (or sometimes a double) dose, with no need for ongoing treatment.[89] In a Johns Hopkins study, patients were administered two doses of psilocybin, together with supportive psychotherapy. Most patients experienced rapid improvement, and half of the study participants achieved remission within four weeks.[90] Accordingly, unlike expensive experimental drugs that may need to be

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[86] Rubin et al., *supra* note 52, at 8 (citing J. Jacob, *Questions of Safety and Fairness Raised as Right-To-Try Movement Gains Steam*, 314 J. AM. MED. ASSOC. 758 (2015)).

[87] Manufacturers' pricing information indicates that a typical dose of psilocybin of approximately 20 to 30 milligrams would cost $171. *See Psilocybin*, ORGANIX INC., https://organixinc.com/tryptamines/psilocybin (last visited May 19, 2021).

[88] In contrast to psilocybin, other drugs that have been administered under RTT laws are dramatically more expensive. For example, peptide receptor radionuclide therapy (PRRT), a chemotherapy regimen, may cost as much as $55,000-75,000 per patient, with some patients requiring multiple regimens. https://link.springer.com/article/10.1007/s11154-020-09608-y.

[89] Ross *et al.*, *supra* note 40, at 1175.

[90] *Psychedelic Treatment with Psilocybin Relieves Major Depression, Study Shows*, JOHN HOPKINS MED. (Nov. 4, 2020), https://www.hopkinsmedicine.org/news/newsroom/news-releases/psychedelic-treatment-with-psilocybin-relieves-major-depression-study-shows.

administered over a prolonged period of time, psilocybin can be administered at a modest cost in a short period of time, and positive results can be achieved without the need for ongoing pharmaceutical treatment. Under these circumstances, there is little risk of financial harm to patients.

V. PSILOCYBIN IS AN APPROPRIATE APPLICATION OF WASHINGTON'S RTT ACT

A. Washington's RTT Act Does Not Exclude Schedule I Substances.

Under the Washington Act, "[a]n eligible patient and his or her treating physician may request that a manufacturer make an investigational product available for the treatment of the patient."[91] An "investigational product" refers to a "drug, biological product, or device that has successfully completed phase one and is currently in a subsequent phase of a clinical trial approved by the United States food and drug administration assessing the safety of the drug, biological product, or device under section 505 of the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 355."

Psilocybin clearly meets this criteria, as it has completed Phase 1 testing and is currently in subsequent FDA testing.[92] Indeed, FDA's Proposed Rule on the federally enacted RTT legislation vests the manufacturer with authority to determine

[91] WASH. REV. CODE ANN. § 69.77.030(1) (2017).
[92] *See* Michael W. Jann, *Psilocybin Revisited: The Science Behind the Drug and Its Surprising Therapeutic Potential*, 38 Psychiatric Times (Mar. 9, 2021).

whether a drug constitutes an eligible investigational drug.[93] And, the definition of an "investigational product" encompasses all such drugs, biological products, or devices that have made it past Phase 1 clinical trials. Denying terminal cancer patients access to psilocybin merely because it is classified as a Schedule I substance would be an arbitrary exclusion that is unsupported by the text of the legislation. Unlike certain other states, such as Missouri, that have explicitly excluded Schedule I substances from their RTT Acts, the Washington Act contains no such exemption.[94]

Because the Washington Act does not exclude Schedule I substances, and psilocybin otherwise meets the criteria for an investigational product, palliative access to psilocybin is an appropriate application of the Washington Act.

B. Psilocybin Fills an Important Palliative Care Gap.

Terminal cancer patients should be granted access to psilocybin through the Washington Act because psilocybin addresses a long-standing palliative care gap, and it promotes individual autonomy and advances the life-saving and life-enhancing missions of RTT legislation.

The purpose of RTT legislation is to recognize the human dignity and individual autonomy of terminal patients by allowing them to access investigational

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[93] Food and Drug Administration, Annual Summary Reporting Requirements Under the Right to Try Act, 85 Fed. Reg. 44803 (July 24, 2020) (to be codified at 21 C.F.R. pt. 300).

[94] *See, e.g.*, MO. STAT. 191.480(2) (West 2020).

drugs and treatments that have the potential to be life-saving or life-enhancing.[95] Although psilocybin is used palliatively and is not itself intended to cure cancer, by addressing a persistent gap in palliative care, palliative use of psilocybin advances the goals of human dignity and individual autonomy. Moreover, the improved quality of life that can result from palliative use of psilocybin promotes RTT's life-saving and life-enhancing goals, particularly in states that authorize Aid in Dying ("AID"), by giving patients a more meaningful and legitimate choice between continuing to battle their terminal illness and choosing physician-assisted suicide.

While numerous drugs and treatments have been developed to address the physical ailments that accompany terminal cancer, there are little to no effective treatments for the extreme psychological toll that terminal cancer takes. "Enduring" and "clinically significant anxiety and/or depressive symptoms" are common in cancer patients.[96] Existing pharmacotherapeutic and psychosocial therapies are of limited efficacy in terminal cancer patients, and terminal cancer patients often experience high depression relapse rates and significant side effects after use of these therapies.[97] But, in terminal cancer patients, psilocybin has "produced rapid and sustained anxiolytic and anti-depressant effects . . . decreased cancer-related

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[95] *See* Goldwater Institute, *Facts About Right to Try*, RIGHT TO TRY, https://righttotry.org/facts-about-right-to-try/ (last visited May 20, 2021).
[96] Ross et al., *supra* note 40, at 1176.
[97] *Id.*

existential distress, increased spiritual wellbeing and quality of life, and was associated with improved attitudes towards death."[98] And, unlike other available treatments, the positive effects of psilocybin on state of consciousness can be felt for "months to years[.]"[99]

Given the lack of effective treatments for enduring, clinically significant anxiety and depression in cancer patients, psilocybin is an appropriate application of the Washington Act that fills this mental health-focused palliative care "gap." By improving terminal patients' quality of life and attitudes toward death, palliative use of psilocybin allows cancer patients to accurately assess their desires and outcomes for end of life treatment and care and make truly autonomous decisions on how to live the remainder of their lives. The importance of providing terminal patients the opportunity to treat their mental health symptoms and improve their quality of life is especially important in states such as Washington, where legislation authorizing AID has been passed.[100] Without effective options for addressing cancer patients' severe mental health symptoms, patients could be forced into a choice between enduring severe depression and anxiety in their final days or selecting AID. Preventing access to this important palliative treatment will not promote safety; instead, many patients may opt for aid in dying by necessity, and not by true choice.

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[98] *Id.* at 1177.
[99] *Id.* at 1166.
[100] WASH. REV. CODE ANN. § 70.245 *et seq.* (2009).

Given the great degree of autonomy terminal cancer patients have been given in Washington, it is important for these patients to have access to all safe and effective options in order to ensure decisions are made that promote a patient's free will and dignity. Because palliative use of psilocybin is safe, effective, and promotes this individual autonomy and dignity, it is an appropriate application of the Washington Act.

VI. CONCLUSION

For all of the foregoing reasons, the Court should grant the relief requested in Petitioners' Brief, including granting the Petition for Review, vacating the DEA's Final Determination, and instructing DEA to promptly accommodate RTT and provide directions to licensed practitioners on how to obtain approval from DEA necessary to obtain schedule I drugs for therapeutic use consistent with RTT laws.

DATED: May 21, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5) because this brief contains 7,070 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word Times New Roman 14-point font.

/s/ Bradley C. Graveline

CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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