No. 21-70544

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC; DR. SUNIL AGGARWAL, M.D., Ph.D; 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.

BRIEF OF AMICI CURIAE END OF LIFE WASHINGTON, EVERGREENHEALTH, THE WASHINGTON STATE PSYCHOLOGICAL ASSOCIATION, A SACRED PASSING, AND PARTICIPATING END OF LIFE CARE CLINICIANS AND RESEARCHERS IN SUPPORT OF PETITIONERS AND SEEKING REVERSAL OF THE DEA FINAL AGENCY ACTION

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, amici curiae End of Life Washington, EvergreenHealth, The Washington State Psychological Association and A Sacred Passing disclose that none of these entities has a parent corporation and that no publicly held corporation owns 10 percent or more of stock, as they are all nonstock entities.

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I. IDENTITY AND INTEREST OF AMICI CURIAE[1]

A. Organizational Amici

Amicus curiae ***End of Life Washington ("EOLWA")***[2] is a non-profit organization in Washington State that provides direct service, community education, and advocacy to ensure that Washington residents have access to a full range of end-of-life options, including excellent palliative care and, for those who qualify and choose it, medical aid in dying. Founded in 1988, EOLWA believes that a peaceful death should be within everyone's reach and that no one should face intolerable suffering at the end of life. In 2008, EOLWA drafted and sponsored Initiative 1000 which was passed by Washington voters and became in 2009 the Washington Death with Dignity Act. RCW 70.245. EOLWA continues to implement this law by working closely with 90 to 95% of all Washingtonians who exercise their right to medical aid in dying. EOLWA upholds the right to the full range of end of life choices through advocacy, education, and support.

To those ends, EOLWA issued a policy statement in 2020, supporting access to psilocybin as a palliative treatment for terminally ill patients suffering from

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[1] This Brief of Amici Curiae is filed pursuant to Fed. R. App. P. 29(a) as all parties consent to its filing. No counsel for any party authored this brief in whole or part, and no person or entity other than amici, their members, or counsel, made any monetary contribution for the preparation or submission of this brief.

[2] https://endoflifewa.org/ (last visited 5/5/21).

debilitating depression and anxiety. *See* APP-17–21. The statement observes, "A terminal cancer diagnosis is well-known to produce anxiety and depression (including suicidal ideation) in a significant number of individuals" and cites studies showing that psilocybin therapy "is effective in relieving emotional and existential distress at the end of life for 65-85% of terminally ill people in clinical trials, when it's administered properly." The statement further notes there are "no lasting negative effects and many significant and enduring positive benefits" associated with psilocybin therapy. EOLWA advocates for terminally ill patients to have access to psilocybin-assisted therapy as one option to help relieve suffering at the end of life.

Amicus curiae ***EvergreenHealth*** is an integrated two-hospital healthcare system that was formed in 1972 as a public hospital district. The main campus is located in Kirkland, Washington and includes a 318-bed medical center. EvergreenHealth has been recognized by Healthgrades as one of America's 100 Best Hospitals for the past five years (2017-2021). EvergreenHealth partners with Seattle Cancer Care Alliance to deliver comprehensive cancer care at the Halvorson Cancer Center on the Kirkland campus, and also includes EvergreenHealth Home Care Services, which provides Home Health, Behavioral Health, Hospice, and Palliative Medicine care.

Every day, EvergreenHealth Hospice provides care to over 500 patients and their families residing in communities across King and Snohomish counties, as well as to patients and families who come to the 15-bed Hospice Care Center on the Kirkland campus. The Palliative Medicine services provides specialized consultation and management for patients with life-limiting illnesses in both inpatient and outpatient settings. As a state and national leader in end-of-life care, EvergreenHealth is committed to providing patients with access to the highest-quality comprehensive medical care available. This commitment is informed both by an understanding of the critical role of evidence-based medicine in end-of-life care, and by the recognition of the degree to which mental, emotional, and spiritual distress contribute to the suffering of patients with terminal illness. It is because of this deep commitment that EvergreenHealth advocates for terminally ill patients to have access to psilocybin-assisted therapy.

Amicus curiae the ***Washington State Psychological Association (WSPA)*** is a nonprofit scientific and professional organization founded in 1947. WSPA represents more than 600 members and affiliates, including the majority of psychologists holding doctoral degrees from accredited universities.

The mission of WSPA is to support, promote and advance the education, science and practice of psychology in the public interest. Indeed, WSPA is recognized at the national level of psychology for its dedication to promoting the

public interest. Whenever WSPA attempts to promote the public interest, it relies upon the most recent scientific evidence to establish what actions would enhance the mental and behavioral health of Washington citizens. With those principles in mind, WSPA fully supports efforts to make psilocybin available under Right to Try laws to help relieve non-physical suffering experienced by many people with a terminal illness.

Amicus curiae **A Sacred Passing (ASP)** offers accessible death and dying education to individuals, community associations and medical organizations. The mission of ASP is to educate, collaborate, and share ways to be supportive educational companions for those studying to be death companions, death doulas, and for those who are dying and for those caring for them. ASP offers education both online and in-person, and the crew is primarily located in Duwamish tribal land (or Seattle, WA). A Sacred Passing's mission is to guide and assist people towards a more conscious dying experience, while honoring their individual autonomy.

A Sacred Passing advocates, alongside End-of-Life Washington (EOLWA), *et al.*, for terminally ill patients to have access to psilocybin-assisted therapy. A Sacred Passing works in communities to actively dismantle systems of power and oppression as they present in dying and death through providing relevant, factual and accessible education, non-medical care and advocacy, ensuring the inclusion of peoples from systematically marginalized communities. Our long term goal is to

deepen partnerships with medical practitioners and other community groups to provide care to people in their dying that speaks to what they want, elevating a return to whole person, community supported care. It is for all of these reasons that we advocate on behalf of an individual's "Right to Try," as codified in both federal and state law. *See* 21 U.S.C. § 360bbb, *et seq.*; RCW 69.77, *et seq.* In 2017, the Washington state legislature enacted its "Right to Try" legislation and correctly noted that terminally ill patients "should be permitted to pursue the preservation of their own lives by accessing available investigational drugs," and that decisions about the use of available investigational drugs should be made by each individual person with the consultation of their health care provider.

B. Individual Amici

The following individual amici are all distinguished end-of-life clinicians and researchers who join with the organizational amici to support the rights of terminally ill patients to access psilocybin-assisted treatment under the federal and Washington state Right To Try laws:

- ***Ira Byock, M.D.***, palliative care physician and Active Emeritus Professor of Medicine and Community & Family Medicine of the Dartmouth Geisel School of Medicine;

- ***Nick Gideonse, M.D.***, Associate Professor of Family Medicine, Medical Director, MAT Program and Kindred Hospice, Oregon Health & Science University Family Medicine at Richmond;
- ***Roland R. Griffiths, Ph.D.***, The Oliver Lee McCabe, III Professor in the Neuropsychopharmacology of Consciousness; Director, Center for Psychedelic and Consciousness Research; Professor, Departments of Psychiatry and Neuroscience, Johns Hopkins University School of Medicine;
- ***Matthew W. Johnson, Ph.D.***, The Susan Hill Ward Professor of Psychedelics & Consciousness Research, Johns Hopkins University School of Medicine, Department of Psychiatry and Behavioral Sciences;
- ***Mikhail Kogan, M.D.***, Medical Director, George Washington Center for Integrative Medicine, Associate Professor of Medicine, Associate Director of Geriatrics Fellowship, George Washington University, Founder and Executive Director of AIM Health Institute, 501(c)(3) organization aimed at providing whole health and integrative care for vulnerable and Medicaid recipients of greater D.C. area;
- ***Timothy Quill, M.D., FACP, FAAHPM***, Professor of Medicine, Psychiatry, Medical Humanities and Nursing, University of Rochester Medical Center; and

- ***Lisa R. Yeager MSW, LICSW, CPTR***, Washington State palliative care social worker.

II. INTRODUCTION

In *Advanced Integrative Medical Science Institute, PLLC, et al., v. U.S. Drug Enforcement Administration, et al.,* the Petitioners seek review of the Final Agency Action by the U.S. Drug Enforcement Administration ("DEA") that it had "no authority to waive" any of the requirements of the Controlled Substances Act ("CSA") to accommodate both Washington state and federal legislation allowing for the use of any medication, including those listed in Schedule I of the CSA, under certain very limited circumstances. *See* RCW 69.77, *et seq.*; 21 U.S.C. § 360bbb, *et seq.* (collectively, "Right To Try" or "RTT"). As Petitioners argue, the DEA's interpretation undermines the purpose of state and federal Right To Try laws, raises significant constitutional concerns, and is arbitrary and capricious. *See generally,* Petitioners' Opening Brief.

This Brief describes the practical and policy impacts of the DEA Final Agency Action. As a practical matter, the DEA's position is a complete barrier to the Right To Try medications listed in Schedule I of the CSA – even when those medications would otherwise meet the stringent criteria for terminally ill patients to use them under Right To Try. This virtually nullifies, without authority, state and federal Right To Try laws, when patients seek to use psilocybin. If the DEA does not create

a waiver or other functional pathway for manufacturers to distribute and for physicians to safely and appropriately administer Schedule I medications that satisfy the stringent requirements of the Right To Try statutes, terminally ill patients will be forced to endure unnecessary harm that the statutes were designed to prevent.

Psilocybin is a Schedule I controlled substance that is a highly promising palliative care medication. In recent years, multiple well-controlled studies demonstrated "significant efficacy and few adverse side effects" when psilocybin was administered as part of a therapy protocol for seriously ill patients. *See* APP-22–26, Ira Byock, M.D., FAAHPM, *Taking Psychedelics Seriously,* 21 Journal of Palliative Medicine 4 (2018) (hereinafter "Byock").[3] Psilocybin therapy may offer immediate and sustained relief to terminally ill patients for whom conventional psychiatric treatment and medications have been unable to sufficiently treat the depression and anxiety associated with an incurable disease. As Dr. Byock wrote, ***this relief may be life-extending.*** *Id.,* APP-23. Right To Try laws were designed to enable terminally ill patients to try potentially life-sustaining medications that would otherwise be unavailable, whether the medications sought treated a patient's physical or mental health.

[3] The medical articles, studies, position statement for EOLWA and declarations of terminally ill patients Susan Patz and John Borrow, M.D., cited in this brief are attached in the Appendix for the convenience of the Court.

The DEA's action here blocks all access under the Right To Try to highly promising psilocybin treatment. As a practical matter, manufacturers will not produce or distribute psilocybin for treatment, nor will physicians be able to administer psilocybin therapy, without a path to do so that protects them from prosecution. Although state and federal Right To Try laws were enacted to provide such a path, the threat of possible prosecution or sanctions by the DEA for producing, distributing or administering a Schedule I drug is so great that the DEA's Final Agency Action effectively eliminates this treatment option under Right To Try. Nor is the DEA's preferred approach – that physicians interested in administering psilocybin therapy do so as a "researcher" – a feasible alternative. Amici and their constituents, all terminally ill patients and the palliative care providers who treat them, cannot wait for months, if not years for more research studies to be established, just so that these drugs may be administered. Nor can they easily access the treatment under the FDA's existing Expanded Use program; Right To Try was specifically designed to provide an alternative option for accessing investigational drugs to other FDA pathways including Expanded Use. Terminally ill patients should be able to receive this promising and possibly life-extending treatment ***without delay***, through the streamlined access provided by Right To Try.

III. ARGUMENT

A. Congress, and the State of Washington Opened the Door to Investigational Treatment with the Right To Try.

"A fair reading of legislation demands a fair understanding of the legislative plan." *King v. Burwell,* 576 U.S. 473, 498, 135 S. Ct. 2480 (2015). With the Right To Try, Congress sought to eliminate barriers to treatment with investigational drugs for terminally ill patients. As a result, Right To Try "allows use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law," free from federal prosecution, provided that certain conditions are met. 21 U.S.C. § 360bbb-0a. The Food and Drug Administration ("FDA") described the law's purpose:

> This law provides a new pathway for patients to request, and manufacturers or sponsors to choose to provide, access to certain unapproved, investigational drugs, including biological products, for patients diagnosed with life-threatening diseases or conditions (as defined in § 312.81 (21 CFR 312.81)) who, as certified by a physician, have exhausted approved treatment options and who are unable to participate in a clinical trial involving the investigational drug.

APP-274–276*,* 85 Fed. Reg. 44803, 44805. The Right To Try placed the decision-making regarding access to investigational drugs, in the hands of the terminally ill patient and their treating provider, under stringent conditions. *See id.; see also* APP-27–28, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try (last visited 5/9/21). When those strict conditions are met, the Right To Try is permitted, without further government intervention.

Congress amended the Right To Try into the existing Food, Drug and Cosmetics Act ("FDCA"). Importantly, Congress prohibited any part of the Controlled Substances Act from being "construed as in any way affecting, modifying, repealing or superseding the provisions of the [FDCA]" ***including the Right To Try***. *See* 21 U.S.C. § 902. Congress's determination that the Right To Try prevails over any part of the CSA is presumed to be deliberate. *United States v. Motamedi*, 767 F.2d 1403, 1406 (9th Cir. 1985).

Similarly, the State of Washington concluded that "[p]atients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product or device receives final approval from the United States Food and Drug Administration." RCW 69.77.010. The law was designed to permit use of unapproved medications without any approval from the FDA. *See* APP-29–31, Final Bill Report on SSB 5035 (2017).[4] Importantly, the Washington Legislature did not exclude Schedule I medications from the definition of "investigational products" covered by the Washington Right To Try law. *See* RCW 69.77.020(4) ("'Investigational product' means 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

[4] http://lawfilesext.leg.wa.gov/biennium/2017-18/Pdf/Bill%20Reports/Senate/5035-S%20SBR%20FBR%2017.pdf?q= 20210511123405 (last visited 5/11/21).

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").[5] Psilocybin is covered by both the federal and Washington State Right To Try laws.

B. Psilocybin Therapy is a Promising Palliative Care Treatment that Qualifies for Use Under Right To Try.

Palliative care providers deliver specialized medical treatment to people living with serious, and often incurable, illness. The focus of palliative care is to improve the quality of life for patients and provide relief from the symptoms and stress associated with debilitating conditions. Palliative treatment seeks to provide relief from pain, anxiety and depression, and, in particular, the existential distress associated with a terminal illness. As many as 40% of cancer patients experience such clinically significant psychological distress that they meet the criteria for a mood disorder. *See* APP-32-48, 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 JOURNAL OF PSYCHOPHARMACOLOGY 1181-1197 (2016) (hereinafter "Griffiths"). Addressing the anxiety and depression of terminally ill patients is a key component of palliative treatment.

[5] Some other states specifically excluded Schedule I drugs from the scope of their Right To Try statutes. *See, e.g.,* Mo. Rev. Stat. § 191.480(2).

The tools that palliative care providers have to treat serious and debilitating mental health symptoms include psychological counseling and psychiatric medications. For some terminally ill patients, however, these conventional interventions are insufficient or ineffective to provide relief. *See* Byock, APP-23. Psychiatric medication may take too long to become effective, or may be determined to be ineffective. *Id.* Psychiatric medications may also have significant side effects that may be a serious concern for terminally ill patients. *Id.* Many palliative care providers look to psilocybin as a promising alternative when conventional treatment is not effective or appropriate. APP-49–51, Kelmendi, *et al.,* "*The role of psychedelics in palliative care reconsidered: A case for psilocybin*," JOURNAL OF PSYCHOPHARMACOLOGY 1-3 (2016) (hereinafter "Kelmendi"). Indeed, a host of recent studies show that it may be a safe and effective option for certain patients when administered properly.[6]

[6] Although potential adverse effects of psilocybin are well documented, treatment with psilocybin can be safe and effective when standard safety guidelines are followed. *See* APP-68-85, Johnson, et al., *Human Hallucinogen Research: Guidelines for Safety,* 22(6) JOURNAL OF PSYCHOPHARMACOLOGY 603-620 (2008). These include screening patients for medical or psychiatric contraindication, psychological preparation of patients before psilocybin administration, psychological support of patients during and after a psilocybin session, and treatment supervised by an appropriately trained clinician familiar with psilocybin treatment. *Id.,* APP-73–81.

C. Recent Studies Demonstrate the Potential for Psilocybin Therapy to Aid Terminally Ill Patients

In 2016, a randomized double-blind trial evaluated the impact of a single dose of psilocybin treatment on depression and anxiety in patients with a form of life-threatening cancer. *See* APP-52–67, 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 JOURNAL OF PSYCHOPHARMACOLOGY 1165-1180 (2016). No serious adverse events attributed to psilocybin were recorded. *Id.,* APP-62. The study concluded that even a single dose of psilocybin, administered under supportive conditions, was effective to decrease the symptoms of depression and anxiety, and to increase the quality of life of cancer patients. *Id.,* APP-62. Importantly for terminally ill patients, the effects were sustained at a review six months later. *Id.* In sum, the study revealed that even a single dose of psilocybin, administered in a supportive environment, can significantly improve the well-being of patients with a life-threatening disease. A second 2016 study revealed similar results. *See* APP-32-48, Griffiths.[7]

[7] Based upon these studies, psilocybin has been recommended for rescheduling under Schedule IV of the CSA. *See* APP-94–148, Johnson, et al., *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, NEUROPHARMACOLOGY 142 (2018).

Other studies confirm as much. In an earlier 2011 double-blind randomized controlled study, similar results were obtained, albeit with a smaller sample. APP-86–93, Grob, *et al.,* "*Pilot Study of Psilocybin Treatment for Anxiety in Patients with Advanced-State Cancer*," 68 ARCH GEN PSYCHIATRY, pp. 71-78 (2011). The participants experienced a significant reduction in anxiety at one and three months after the treatment. *Id.* No significant adverse events were identified. *Id.* In late 2020, a fourth randomized controlled study concluded that psilocybin therapy is effective at producing large, rapid, and sustained anti-depressant effects in patients with cancer and treatment-resistant depression. APP-149-157, Davis, *et al., Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial,* JAMA PSYCHIATRY (November 4, 2020) found at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2772630 (last visited 5/12/21). When the risks of psilocybin therapy are compared to the risks of conventional psychiatric medications, their safety profile appears to be quite strong. *See* Marks, Mason M., *Recent Development: Controlled Substance Regulation for the COVID-19 Mental Health Crisis,* 72 Admin. L. Rev. 649, 663-665 (Fall 2020) (hereinafter "Marks"). The "margin of safety" for psilocybin therapy is heightened because it is always administered with professional supervision according to a structured protocol. *Id.,* p. 665.

The reported benefits described in these studies are consistent with the reports from palliative care patients themselves. In a recent case study, four cancer patients described their experience with psilocybin treatment. *See* APP-158–163, Malone, *et al., Individual Experiences in Four Cancer Patients Following Psilocybin-Assisted Therapy,* 9 FRONT. PHARMACOL. 256 (April 3, 2018). Each described the different ways in which access to this treatment improved their lives and health. Each case study revealed decreased anxiety and increased sense of purpose in life after psilocybin treatment. *See, e.g.,* p. 4 (Tom: "I don't have a fear of death … I am more interested in life now than ever before"); p. 5 (Brenda: "I feel more contented and happy about my place in the world in all the things I'm doing"). Indeed, in the 2016 Griffiths study (APP-32–48), over two-thirds of the participants ranked the single dose of psilocybin therapy among the most meaningful experiences of their lives. Marks, p. 659.

D. Palliative Care Professionals Support the Use of Psilocybin Therapy under Right to Try laws.

Many palliative care providers are cautiously optimistic that psilocybin therapy will provide a critical tool missing from their toolbox – a treatment that will ease the anxiety and depression associated with the end of life. *See* APP-49–51 (Kelmendi). Many hope that this treatment will, in fact, extend the lives of their

patients by reducing suicidality and the desire for medical aid in dying.[8] This possibility unites palliative care providers who support and oppose "medical aid in dying" treatment. *See, e.g.,* APP-164-166, Timothy E. Quill, MD, MACP, FAAHPM, "Statement Supporting Oregon's Measure 34, the Psilocybin Service Initiative Enabling Access for Palliative Care in Terminally Ill Patients.". For example, Dr. Byock, a staunch opponent of medical aid in dying, wrote in 2018 that palliative care physicians should consider the therapeutic use of psychedelic medications, including psilocybin, for patients for whom conventional treatment has been unsuccessful:

> Palliative care clinicians and teams also encounter patients whose misery is rooted in emotional, social, existential, or spiritual distress. Cancer, heart failure, liver failure, and amyotrophic lateral sclerosis (ALS) or motor neuron disease are among the diseases that can result in a progression of personal losses: Of feeling in control. Of taking care of one's self. Of contributing to others. Of enjoyment. Of meaning and purpose. Ultimately, some ill people say they have lost any reason to go on living.
>
> People who are incurably ill and living with progressive disease-related disabilities can experience anxiety, depression, and demoralization. Therapy alone and drug treatments for such syndromes are often insufficient. Medications for depression may take weeks to become effective or prove ineffective. Antidepressants and anxiolytics carry side effects that can include mental slowing and confusion. These adverse effects are particularly common and hazardous in patients with advanced physical illness, who are also at risk of polypharmacy,

[8] Medical aid in dying, which has been legal in Washington since 2008, allows qualified, terminally ill adults to request a prescription for medication that will hasten their death after satisfying multiple strict requirements.

> multidrug interactions, and concomitant disequilibrium and falls. When nonphysical suffering persists despite prudent approaches, published, evidence-based guidelines are limited.

APP-23 (Byock). Dr. Byock predicted that use of psilocybin, in carefully supervised, structured settings, might ease the suffering of patients in this situation, and could extend their lives. Put simply, patients who feel less depressed and anxious about their terminal diagnosis, may live longer, either through improved mental and physical health or a possible delay in seeking medical aid in dying. *Id.,* APP-25 ("A person with severe depression, who has a coexisting serious, life-threatening physical condition, may feel that his or her quality of life is not worth living and may forgo arduous, but potentially life-saving treatments"); APP-167–176, Calder, Abigail E., "*Psilocybin and the Will to Live*," PSYCHEDELIC SCIENCE REVIEW (May 6, 2021) ("[A] cancer diagnosis increases someone's risk of suicide four-fold") (hereinafter "Calder"). For this reason, Dr. Byock advocates that psilocybin therapy be "legitimately cast as a ***right to try*** issue." *Id.* (emphasis added). By effectively decreasing depression and anxiety and increasing the desire for life in terminally ill patients, psilocybin treatment may have an even greater life-saving effect than other medications typically considered under the Right To Try laws. *See id.*

Similar opinions were elicited from a recent study of 17 palliative care experts. *See* APP-177–188, Beaussant, *et al., Defining the Roles and Research*

Priorities for Psychedelic-Assisted Therapies in Patients with Serious Illness: Expert Clinicians' and Investigators' Perspectives, JOURNAL OF PALLIATIVE MEDICINE (2020). The study found three consistent themes expressed by the experts: (1) there is a significant unmet clinical need for relief from depression and anxiety among patients with serious illness; (2) existing interventions (such as psychiatric medications and therapy) are limited and not effective for some; and (3) psilocybin therapy may have a rapid impact on reducing distress associated with a life-threatening disease. *Id.,* APP-182. And, as demonstrated by the individual Amici listed here, all distinguished and experienced clinicians and researchers, there is significant support for pursuing the use of therapeutic psilocybin by palliative care professionals.

E. Patients Need this Palliative Care Option.

Most importantly, patients facing the end of life have the right to try psilocybin treatment, since it may relieve suffering, improve the quality and prolong the quantity of their life. End of Life Washington represents the interests of these patients, including Susan Patz and James Borrow, M.D.

Like the patient Petitioners in this matter, Ms. Patz is a terminally ill patient who desperately seeks relief from her treatment-resistant depression and anxiety and is eager to try psilocybin. *See* ER-10–17, ER-18–23. Ms. Patz suffers from late-stage amyotrophic lateral sclerosis (ALS), known by many as Lou Gehrig's disease.

APP-11–16, Patz Decl., ¶ 3.[9] It is a fatal disease for which there is no cure and involves progressive and inexorable loss of a patient's bodily function and integrity, while their mental state remains fully intact. *Id.* Her prognosis is one to two years. *Id.*

Ms. Patz has experienced the kind of debilitating physical losses described by Dr. Byock that have now led to other serious psychological losses. *See* APP-23 (Byock). At first, she experienced some loss of physical control which has now spread to the point where she can no longer stand or walk. APP-12, Patz Decl., ¶ 4. This physical loss severely constrains Ms. Patz's life and she can no longer enjoy activities that gave her joy and satisfaction. *See id.,* ¶ 5. She can no longer garden, drive a tractor, swim, or cook, all activities about which she was passionate. *Id.* She has also lost her career as a cardiac care nurse which gave her a "tremendous sense of purpose." *Id.,* ¶ 6. Ms. Patz describes the depression she now experiences as

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[9] Consideration of similar declarations to those filed herein is often permitted. In *Webster v. Reproductive Health Services,* 492 U.S. 490, 109 S. Ct. 3040 (1989), an amicus brief filed with the Supreme Court included numerous declarations by women who had experienced legal and illegal abortions. More recently, the Ninth Circuit and U.S. Supreme Court considered amicus briefs containing such declarations of surviving family members of terminally ill individuals who desired to hasten their deaths. *See Compassion in Dying v. State of Washington,* 79 F.3d 790, 834 n. 126 (9th Cir. 1996), *rev'd, Washington v. Glucksberg,* 521 U.S. 702, 117 S. Ct. 2258 (1997); *Oregon v. Ashcroft,* 368 F.3d 1118 (9th Cir. 2004), *aff'd, Gonzales v. Oregon,* 546 U.S. 243, 126 S. Ct. 904 (2006). As in the above cases, the declarations filed here in the Appendix to the brief contain first-hand information by persons intimately familiar with the issues presented to the Court.

"constant and severe." *Id.* ¶ 7. She feels as if she has been at "rock bottom" for more than two and a half years and has contemplated suicide more than once. *Id.* She has tried conventional psychiatric treatment and medications but they have not provided her with sufficient relief. *Id.,* ¶ 13.

Ms. Patz does not want to continue in this manner, and she would like to try psilocybin treatment:

> I want to experience joy during the time I have left. I want to enjoy the company of my family and friends. I want to appreciate my home and my animals. I want to find pleasure in things like reading and food again. I want to stop crying so much.
>
> …
>
> I want to try this treatment. I don't want to keep living in this deep, dark place where my mind has been stuck for the past two-and-a-half years. I don't want to spend the last year or two of my life feeling isolated, depressed, and suicidal. I am desperate to try something that will work, something that will enable me to experience joy and pleasure again. ***If the Right-to-Try laws don't allow someone like me the chance to try something that may help alleviate my suffering, then what good are they***?

Id., ¶¶ 12, 14 (emphasis added). Ms. Patz is not seeking psilocybin treatment for recreational purposes. She advocates for its use in a controlled setting, under the care of her palliative care clinician, with proper protocols for patients like her at the end of life, for whom conventional treatment has been unsuccessful. *Id.,* ¶ 14. That is the precise situation Right To Try laws were designed to address.

Similarly, Dr. Borrow, a retired radiologist, is diagnosed with Stage 4 Leimyosarcoma, a rare cancer that attacks the smooth muscles that line organs throughout the body. APP-6–10, Borrow Decl., ¶ 4. Dr. Borrow's condition is also terminal. *Id.,* ¶ 4. Dr. Borrow experiences significant, debilitating anxiety related to his condition. *Id.,* ¶ 5 ("At times I feel hammered and overwhelmed by this unexpected diagnosis"). As a physician he read with great interest the recent studies and articles on psilocybin and believes that it is a medical treatment that will provide him with significant benefit: "I am eager to try this treatment, as I believe it may help me to integrate my terminal diagnosis with what time I have left so that I can live the rest of my life to the fullest, as well as provide relief from the anxiety I experience." *Id.* Dr. Borrow hopes that the treatment will improve his life so significantly that his life will be prolonged and he may avoid medical aid in dying. *Id.,* ¶ 6. Dr. Borrow has tried to participate in research studies of psilocybin but has not identified any study for which he is eligible. *Id.,* ¶ 7

The reasons Dr. Borrow and Ms. Patz seek psilocybin treatment echo those of the patient Petitioners, both of whom are diagnosed with serious, advanced, and life-threatening conditions. As Petitioner Baldeschwiler wrote, "[t]he prospect of dying soon and not being here to watch my children grow up, and to nurture them to adulthood causes me severe anxiety and depression, which conventional therapy has not ameliorated." ER-19, ¶ 4. "It is my hope that therapy facilitated with psilocybin

will allow me to obtain relief from the debilitating anxiety and depression I endure." ER-20, ¶ 9. Petitioner Bloom seeks psilocybin treatment for similar reasons: "I have experienced a lot of suffering from unrelieved anxiety and depression" that she believes "psilocybin assisted therapy could improve." ER-12–13, ¶¶ 7, 9. The organizational amici count as their constituents many other patients who would consider psilocybin therapy under Right To Try, should the DEA's Final Agency Action be reversed and a clear and timely path for terminally ill patients be established for this treatment.

F. All Requirements of Right To Try Are Met By Petitioners.

There is no dispute that psilocybin therapy, as proposed by Dr. Aggarwal, meets the requirements of Right To Try. ***First,*** the medication has completed an FDA-approved Phase I clinical trial. *See* 21 U.S.C. § 360bbb-0a(a)(2)(A); APP-189–209, Michael W. Jann, *Psilocybin Revisited: The Science Behind the Drug and Its Surprising Therapeutic Potential*, 38 PSYCHIATRIC TIMES 3 (Mar. 9, 2021). ***Second,*** the drug is not approved or licensed under the FDCA or the Public Health Services Act. *See* 21 U.S.C. § 360bbb-0a(a)(2)(B). ***Third,*** psilocybin is under investigation in a clinical trial and is the subject of an active IND application. *See* 21 U.S.C. § 360bbb-0a(a)(2)(C); *see* APP-210–273, Psilocybin Investigator's Brochure, Usona Institute, https://www.usonainstitute.org/wp-content/uploads/2020/08/Usona_Psilocybin_IB V3.0_08.31.2020_cc.pdf, p. 10 (last

visited 5/11/21). And ***fourth,*** the medication is actively under development and production, and not subject to a clinical hold.[10] *See* 21 U.S.C. § 360bbb-0a(a)(2)(D). *See also* RCW 69.77.020(4).

Nor is there any dispute that the patient Petitioners are "eligible" under the Right To Try. *See* 21 U.S.C. § 360bbb-0a(a)(1); ER-10–17, ER-18–23. Petitioners Bloom and Baldeschwiler are terminally ill cancer patients who seek treatment with psilocybin therapy from Dr. Aggarwal and who have completed the Right To Try Informed Consent document required under RCW 69.77.020. *See* ER-15–17; ER-22–23; Dkt. No. 9-2, ¶ 9. Dr. Aggarwal is willing to obtain any required authorization identified by the DEA that is consistent with the directives of Right To Try and the time and treatment constraints of his patients. ER-27, ¶ 10. As explained below, the DEA's suggestion that Dr. Aggarwal obtain a waiver from prosecution as a "researcher" is unworkable, and inconsistent with Right To Try laws, which allow for ***therapeutic use*** of investigational drugs.

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[10] In any event, under Right To Try, the manufacturer of psilocybin, not the FDA or DEA, determine if these criteria are met. APP-274-276, 85 Fed. Reg. 44,803, 44805 ("[A] manufacturer or sponsor is in the best position under the Right To Try Act to determine if an investigational drug meets these criteria…. FDA is not proposing to make determinations about whether a particular investigational product is an eligible investigational drug under the Right To Try Act").

G. The DEA's Proposed Researcher Waiver is Not An Alternative To Right To Try.

In response to Dr. Aggarwal's request for authorization or registration from the DEA to obtain psilocybin, the DEA refused to recognize a path for legal possession of psilocybin pursuant to the Right To Try laws. Instead, the DEA suggested that Dr. Aggarwal apply for a DEA Schedule I researcher registration to conduct research with psilocybin. ER-9, citing to 21 U.S.C. § 823(f), 21 C.F.R. §§ 1301.18, .32. If granted, the DEA advised that Dr. Aggarwal could then petition for a grant of an exemption from prosecution. *Id.,* citing to 21 C.F.R. § 1316.24(b). That is the only option provided by the DEA for Dr. Aggarwal to support his patients' efforts to use psilocybin without threat of prosecution.

The DEA's approach would defeat both the letter and the spirit of the Right To Try laws. As noted above, the purpose of the Right To Try was to streamline the process for terminally ill patients to obtain investigational medications for therapeutic use without governmental interference. *See* § III.A., *supra.* The DEA's Final Agency Action, however, directs Dr. Aggarwal to obtain multiple governmental authorizations as a "researcher" before he can support his patients' treatment with psilocybin under Right To Try. Put simply, the DEA's approach would re-impose government regulation on the Right To Try process, despite the directives of both Congress and the Washington Legislature. This defeats the

explicit purpose of Right To Try – to create a timely, informed and easily accessible pathway to investigational medication outside of the DEA and FDA.

DEA's preferred approach is akin to a "Single-Patient IND" application[11] for treatment for psilocybin, similar to what was tried in the 1990s related to compassionate use of marijuana. *See* Pet. Opening Brief, p. 24. The FDA/DEA "work around" was ineffective then, (*see id.*) and will not work to provide terminally ill patients with timely and effective access to psilocybin treatment now. The DEA's suggestion would force Dr. Aggarwal through two time-consuming bureaucratic procedures, during which he would have to reshape the therapeutic use of psilocybin for his patients into a "research" framework. This is the very problem that Congress sought to fix with Right To Try.

Nor could Dr. Aggarwal and his patients with terminal cancer simply join existing research studies in order to obtain psilocybin treatment. There are few existing studies of psilocybin that are actively recruiting participants in the United States. *See* APP-277–279 (identifying clinical studies of psilocybin currently recruiting participants in the United States) found at: https://clinicaltrials.gov/ct2/results?term=psilocybin&recrs=a&map_cntry=US (last visited 5/18/21). Presently, none are in Washington state. *Id.* Even if there were an

[11] "IND" stands for Investigational New Drug.

available, accessible study, the Petitioner patients may not meet the particular characteristics required for the study. *See* APP-280-299, *Expanded Access and Right to Try: Access to Investigational Drugs,* Congressional Research Service, March 16, 2021, p. 3.

The only possible alternative to Right To Try for Petitioners is through the FDA's Expanded Access Program. *See* APP-300-332, "Investigational Drugs: FDA and Drug Manufacturers Have Ongoing Efforts to Facility Access for Some Patients," U.S. General Accounting Office, Report to Congressional Committees, September 2019, p. 2. Under that program, a physician must be approved by the DEA as a Schedule I researcher and then be approved by an Institutional Review Board and the FDA. *See* APP-333-337, Usona Institute, "Expanded Access Policy: Single-Patient Expanded Access," https://www.usonainstitute.org/expandedaccess/ (last visited 5/18/21). Dr. Aggarwal's experience with Expanded Access is revealing. He had previously sought a Schedule I medication for patients in urgent need through Expanded Access. ER-27, ¶ 10. Despite his efforts, no access to the medication was provided. "In my experience, Expanded Access was an unworkable process for my terminally ill patients with an urgent need for an eligible investigational drug." *Id.* Neither Dr. Aggarwal nor his terminally ill patients have the time necessary to navigate these complex administrative procedures at the very end of life. And, in any event, Congress intended Right To Try as an alternative

avenue for access to investigational drugs. If upheld, the DEA's final agency action would foreclose the path Congress created with Right To Try by forcing physicians back into the unworkable Expanded Access program.

H. The DEA's Action May Have the Unintended Effect of Shortening Patients' Lives.

In Washington, terminally ill patients are empowered to seek medical aid in dying in order to advance the time of death. *See* RCW 70.245, *et seq.* Under Washington law, patients like the Petitioners, Dr. Borrow and Ms. Patz may request, obtain and self-administer controlled substances to hasten their death. RCW 70.245.020. Some may seek aid in dying medications because they cannot find relief from the depression and anxiety they experience related to their terminal condition. *See, e.g.,* APP-15, Patz Decl., ¶¶ 12, 14. The Washington Legislature approved Right To Try to address this very situation – those times when terminally ill patients do not have the "luxury of waiting" for governmental approvals. *See* RCW 69.77.010. In sum, if Petitioners can take controlled substances to hasten their death, they should also be authorized access to controlled substances that are shown to relieve anxiety and depression, so that they may live their lives to the fullest while they can.

IV. CONCLUSION

This Court should direct the DEA that the Controlled Substances Act cannot "affect, modify, repeal, or supersede" the Right To Try. As requested by Petitioners,

the DEA's Final Agency Action must be overturned and the case remanded to the DEA, to establish a functional pathway for terminally ill patients and their palliative care providers to access psilocybin therapy without threat of prosecution.

RESPECTFULLY SUBMITTED this 21st day of May, 2021.

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CERTIFICATE OF COMPLIANCE FOR BRIEFS

9th Cir. Case No. 21-70544

I am an attorney for Amici Curiae End of Life Washington, EvergreenHealth, The Washington State Psychological Association, A Sacred Passing, and Participating End of Life Care Clinicians and Researchers.

This brief contains **6,441 words,** excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this Amici Brief complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).

DATED: May 21, 2021.

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CERTIFICATE OF SERVICE

I hereby certify on May 21, 2021, I electronically filed this Amicus Brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF System. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

DATED: May 21, 2021, at Seattle, Washington.

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