October 10, 2021

Dear Senator Murray,

Have you or someone close to you (friend, family member etc.) ever suffered mental and emotional distress as a result of a life-threatening, debilitating, chronic diagnosis, condition and/or illness? How comfortable are you with the reality of death and the process/stages of dying? Would you feel emotional ease and a deep sense of inner peace if you or a close family member received a life-threatening diagnosis and/or shortened life span? If you or someone close to you suffered from severe depression, anxiety, and suicidal ideation as a result of a life-threatening illness diagnosis or disabling condition, and your doctor could prescribe a medicine and/or therapeutic modality that holds promising potential to relieve, ameliorate, heal and/or cure symptomatic/clinical anxiety/depression, and/or otherwise maintain the quality and possibly quantity of life, would you prefer to have that option and choice available? Would you prefer to make that decision on your own behalf? If you were given a prognosis of 2 years or less to live and due to bureaucratic-red-tape the time you have been given is frustratingly-exhausted trying to access such medicine and therapies, would you consider that to be helpful or hurtful to your overall quality of life?

My name is Erinn Baldeschwiler. I am a 49-year old Washington native and resident, mother of two teenagers, Stage IV terminal cancer patient, and one of two patient petitioners in a lawsuit (AIMS et. al. v DEA) filed against the Drug Enforcement Agency (DEA) for the agency's denial to accommodate state and federal Right-To-Try (RTT) laws.

I am reaching out today to ask for your support in honoring the accommodation of state and federal RTT laws for end-of-life patients and palliative care professionals.

PERSONAL TIMELINE

In March of 2020, in line with the COVID-19 outbreak, I was diagnosed with Stage IV terminal breast cancer and given statistically 2 years to live, with the main goal of providing the highest quality of life for the time I have remaining. The sobering diagnosis and prognosis was unexpected and destabilizing. The thought of dying prematurely in conjunction with the likelihood of not seeing my children grow into adulthood was a devastating one-two punch to my overall mental and emotional well-being. The added emotional and mental toll my children, family and friends bear further exacerbates this pain and suffering.

In August 2020, I consulted with Dr. Sunil Aggarwal of AIMS Institute in Seattle to help ameliorate the anxiety and depressive symptoms of my life-threatening diagnosis. Traditional tools available to palliative care doctors are limited to temporary relief of physical pain and suffering of patients with the use of highly-addictive prescription opioid medications. At present, there remains a large gap in the palliative care toolbox to help patients relieve the emotional and mental distress that often accompanies a life-threatening diagnosis.

In October 2020, I was informed of state and federal Right-To-Try (RTT) legislation that allows access to investigational drugs for patients suffering from life-threatening illnesses. I was subsequently invited to join the effort for legal access to psilocybin as a promising medication and therapeutic modality for relief of end-of-life anxiety and depression.

On September 2, 2021, oral arguments were presented to a three-judge panel in the US Ninth Circuit Court of Appeals, Case No. 21-70544 AIMS v. USDEA. Petitioners and Amici argued RTT laws do not impede the DEA's role, as a regulatory agency, and the agency has the ability and duty to accommodate the discreet therapeutic use of Schedule I substances when those drugs have been proven safe but have not yet completed the FDA approval process as a prescribed medication.

It is now October 2021 - 12 months after joining the advocacy effort and 18 months after my diagnosis - and myself and other end-of-life patients are still waiting on a ruling from the court and/or response from the Department of Justice (DOJ) and DEA on how they play to accommodate RTT laws.

Why am I a part of this effort? Why are RTT laws crucial to end-life-patients and their palliative care physicians? Why should Congress fight for the RTT statutes it enacted?

Time. Highest quality of life. Justice.

End-of-life patients are in need of immediate relief, the highest quality of life possible, and access to promising investigational medicines awarded them under RTT laws.

TIME

End-of-life patients do not have the luxury of time - which is at the heart and intent of RTT laws - of waiting for FDA approval, court rulings, or stall tactics by government agencies. Patients are literally working against the clock and trying our best to live the most fulfilled life possible in the time we have remaining. The unnecessary exhaustion of time, energy, tax dollars, and resources being employed by the DOJ and DEA to willingly obstruct legal access to investigational medicines awarded under state and federal RTT laws is a colossally inhumane waste of time that serves to unjustly proliferate and prolong the mental and emotional anguish of end-of-life patients and their loved ones. It is simply an unacceptable response to the petitioners request for accommodation under RTT laws. Additionally, the DOJ is asking that the Court dismiss this case on grounds of - in my opinion - legal semantics over the interpretation if "guidance" in this instance counts as "final action" by the agency. This is a legitimate case that requires legitimate consideration in an expeditious fashion. This argument is a further waste of time and I am sharing with you the critical aspects of this case and what it means to those facing the end-of-life.

Peter B. Gonick, WA Deputy Solicitor General representing Amicus of WA State (Amici States include WA, AZ, DE, IL, MI, MN, OH, OR, and the District of Columbia), agreed in court saying, "The wildfire of passing this legislation across the nation and in Congress is almost unheard of. They express the recognition that allowing patients who may not have time to wait for [final] FDA approval to receive [investigational] treatments. The average time for Phase I to FDA approval is 7-10 years, and Congress and the 41 states determined that was just too long for some patients suffering life threatening illnesses."

In its amici brief, End Of Life Washington (EOLW) et. al. states, "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."

HIGHEST QUALITY OF LIFE

"Highest quality of life." Those are the words that are as fresh in my mind as the very moment my oncologist uttered them after informing me there was no cure to my illness and the best we could hope for is the highest quality of life for the limited time I was given.

From a patient's perspective, "highest quality of life" is a personally subjective definition. For myself, that means creating as many memories with loved ones before I pass, having a deep-sense of inner peace, and a feeling of purpose to my life. The last thing I want is to fear death, feel hopeless, or have an impulse to end my life prematurely. The testimonies of fellow-end-of-life-study-participant-patients have provided me immense hope that psilocybin (or other investigational psychedelic) therapy offers promising medical use as a means of maintaining and possibly improving the quality and potentially extending the quantity of my life.

Study participants have been quoted as saying,

> "The most glorious part was [psilocybin therapy] made me feel more comfortable with living, because you're not afraid of dying."
>
> "I felt so beautiful. I felt like I'd never felt before. My sense of being loved, being worthy of love, of being cared for, of being important to someone. It's huge."
>
> "I don't have a fear of death ... I am more interested in life now than ever before."
>
> "I feel more contented and happy about my place in the world in all the things I'm doing."

In her book *Your Psilocybin Mushroom Companion*, Michelle Janikian reports, "a main theme for many of the participants in [clinical] trials is realizing how important their relationships are, how their response to their illness is negatively affecting the people they love, and that they want to spend the last chapter of their lives enjoying the presence of others. It helps people live until they die. Not just lie in their beds, feeling sorry for themselves and preoccupied with pain."

The reported benefits described in [clinical] studies are consistent with the reports from palliative care patients themselves. Janikian's book highlights recent studies, as also referenced in End of Life Washington's Amici brief filing to the court, "[A] landmark study [came] out in 2011 for the use of psilocybin for end-of-life anxiety. At UCLA, psychiatrist Charles Grob and his team gave 12 terminally ill cancer patients who also had clinical anxiety due to their diagnosis administered a "moderate" dose of psilocybin. Their findings were also positive, with a significant reduction in anxiety for three months and increase in mood for over six. The study has since been replicated with positive results at NYU and Johns Hopkins and it's been cause for many in the psychedelic community to question the way we die in Western Society. Bill Richards is quoted as saying, "It could transform palliative care and hospice care dramatically in the next few years. It's a very exciting frontier."

The amici brief filed by prominent end of life care organizations, palliative care physicians, researchers, bioethicists, and professors address the need to add psilocybin therapy to the palliative care toolbox in relieving anxiety, depression and improving patient's quality and extended quantity of life. They agree psilocybin is an appropriate application of Washington's RTT Act.

Psilocybin addresses a long-standing palliative care gap [SEC V Part B], 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 drugs and treatments that have the potential to be life-saving or life-enhancing. [REF: https://righttotry.org/facts-about-right-to-try/] 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. [REF: Law+Prof Amici Brief]

By effectively decreasing depression and anxiety and increasing the desire for life in terminally ill patients, psilocybin treatment may have an even greater lifesaving effect than other medications typically considered under the Right To Try laws. [REF: EOLW brief]

JUSTICE

In its initial denial (in February 2021) to accommodate access to psilocybin under RTT law, the DEA refers to the Controlled Substances Act (CSA) enacted in 1970 under the Nixon administration, citing it as a Schedule I controlled substance and deemed to "hold high potential for abuse and no accepted medical use in the U.S.". As a federal agency of unelected officials, the DEA's interpretation of this fifty-year-old act is in gross misalignment with modern clinical research and present-day intent of federal, state and local elected officials who enacted RTT laws and decriminalization measures with overwhelming bipartisan support.

Gonick offered before the court, "The policy and purpose of the State Right-To-Try laws and the Federal Right-To-Try law support the use of of Schedule I controlled substances by patient's suffering from life threatening diseases or conditions. 41 states have passed RTT laws and the Washington [State] legislature passed it by unanimous vote. The Federal RTT was similarly bipartisan. It is entirely consistent with the purpose and language of State and Federal RTT laws to include any controlled substances that have completed Phase I trials including Schedule I controlled substances and that are currently being actively investigated. It is entirely inconsistent with the RTT laws to prevent patient access to these treatments merely because the drugs have not yet been determined to have an accepted medical use [final FDA approval]."

Just this week on October 4, 2021, the Seattle City Council voted unanimously, with a 9-0 vote, in favor of decriminalizing psychedelic drugs. Council Member Andrew Lewis, who introduced the resolution, said in a press release, "These non-addictive natural substances have real potential in clinical and therapeutic settings to make a really significant difference in people's lives. Entheogens, commonly known as psychedelics have been shown to benefit the well-being of individuals suffering from depression, severe anxiety, problematic substance use, post traumatic stress, end-of-life anxiety, grief and intergenerational trauma. These and other physical and mental conditions are plaguing many communities, which have been further demonstrated to be exacerbated by the impact of COVID-19".

As reported by Ben Adlin of *Marijuana Moment*, Attorney Matthew Zorn, who represented the patients and clinic suing the DEA at Thursday's oral arguments, argued to the court that the agency's response effectively gave them no options. "That response was: There is no process." Zorn said. "If they had identified a process, we would have used that process. Because the agency said, "There is nothing for you to use, there is nowhere for us to go."

Thomas Pulham, DEA attorney and DOJ appellate lawyer, was unable to offer the court a means in which the DEA could accommodate RTT laws. When asked by Judge Sandra Segal Ikuta, "What about under Right to Try Law, though? Is there a pathway where they could apply under the Right to Try Act?" Pulham replied no. "As the agency indicated in its letter, there is no procedure available ...because the Right to Try Act does not provide the agency any authority to waive the requirements of the CSA."

Under Section II Part D of their Amicus Brief, the Goldwater and Cato Institutes proposed reasonable tools the DEA has available at their disposal to "easily accommodate RTT patients". According to the brief:

> The DEA has authority to waive its CSA requirements and regulations, [21 U.S.C. §§ 822(d), 871(b)], and has exercised that authority in the past. [Pet'rs' Br. at 20–22.] It can easily accommodate treating physicians who do not hold a Schedule 1 registration, by issuing guidance for Right to Try treatments. This solution would be consistent with the purpose of Right to Try without undermining the DEA's core mission, which is the "field of drug abuse." [Oregon v. Ashcroft, 368 F.3d 1118, 1125, 1128 (9th Cir. 2004)]. [REF: Goldwater and Cato Amicus Brief]

Pulham argued that if the AIMS Institute and its patients were to proceed with psilocybin therapy and face enforcement action by the DEA, they could then raise their right-to-try arguments at that point. To which Judge Ryan D. Nelson replied, "Usually we don't require a party to go and subject themselves to liability in order to appeal. It sounds like there might actually be some legal consequences here. I mean, it is prohibiting them from doing what they want to do, and it's subjecting them to enforcement action if they were to go forward."

In May 2021. Amici briefs were filed in court further arguing:

> "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 APP27–28, https://www.fda.gov/patients/learn-about-expanded-access-and-othertreatment-options/right-try (last visited 5/9/21)]. When those strict conditions are met, the Right To Try is permitted, without further government intervention." [REF: EOLW et. al. Amicus Brief]
>
> In enacting the CSA, Congress intended to criminalize diversion, not legitimate medical use prescribed to a patient receiving end-of-life care. The enactment of the Federal RTT Act (and the State RTT Act as well) was intended to create a legal pathway allowing physicians to provide access to investigational drugs that they would otherwise be criminally barred from providing to terminally ill patients. However, the DEA's erroneous understanding of the intersection between the CSA and the Federal RTT Act expressly frustrates this purpose. Physicians have a right to practice medicine as properly regulated under federal and state law, and to do so free from unlawful criminal prosecution. Likewise, eligible patients have a right to seek use of EIDs—which should encompass

approved Schedule I controlled substances—from physicians free from unlawful criminal prosecution. And the DEA has no place in interfering in this doctor-patient relationship and criminalizing its lawful expression. [REF: ACLU of WA Brief]

In their final brief, petitioners argue this case is not about rescheduling psilocybin or obtaining an exemption from the CSA under RTT. RTT allows the DEA, as a regulatory agency, authority to accommodate the discreet therapeutic use of Schedule I substances when those drugs have been proven safe but have not yet completed the FDA approval process as a prescribed medication. Petitioners advocate: diversion control, not prohibition. RTT requires the DEA to regulate and accommodate, not abdicate.

Gonick concluded in asking the court to refer to Gonzales v. Oregon regarding Federalism concerns of this case. The ACLU of WA et. al. amici brief offers further support stating:

> "The "regulation of health and safety matters is primarily, and historically, a matter of local concern." [Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc., 471 U.S. 707, 719 (1985)] In Gonzales v. Oregon, the Court rejected an attempt by an executive officer of the federal government to use the CSA to regulate a state's practice of medicine. [546 U.S. at 275] In the instant case, the DEA is interfering with a state's ability to regulate the practice of medicine, as well as preventing individuals from receiving the medical care their health providers recommend. Far from being the arbiters of proper medical procedures, the DEA's role in this arena is limited to "prohibiting a doctor from acting as a drug pusher instead of a physician." [Gonzales v. Oregon, 546 U.S] Here, like in Gonzales v. Oregon, there is a very limited potential for diversion because the RTT scheme by its terms is carried out only through licensed physicians. Beyond this limited job regarding diversion, the DEA has no role left to play under the circumstances." [REF: ACLU of WA Brief]
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> The DEA as a federal agency of unelected officials serves not only as a figurative arm of a "remote central power," [Bond, 564 U.S. at 22], but it is also less attuned to the desires of a local constituency. As such, it is unable to respond to the needs of that constituency which are expressed through the democratic process. One of the main tenets of the Tenth Amendment is to "promote political accountability," through the ballot box. [Murphy v. Nat'l Collegiate Athletic Ass'n, 138 S. Ct. 1461, 1477 (2018); see also FTC v. Ticor Title Ins. Co., 504 U.S. 621, 636 (1992)] ("Federalism serves to assign political responsibility, not to obscure it.") "Accountability is thus diminished when, due to federal coercion, elected state officials cannot regulate in accordance with the views of the local electorate in matters not pre-empted by federal regulation." Were the Federal Government to take over the regulation of entire areas of traditional state concern, areas having nothing to do with the regulation of commercial activities, the boundaries between the spheres of federal and state authority would blur and political responsibility would become illusory". Moreover, the DEA's actions here are doubly offensive since its interpretation also stands as an obstacle to the realization of rights conferred by legislation enacted by a centralized government. Neither of the RTT Acts dictate any role for the DEA to play, and the self-serving role asserted by the agency inflicts a patently undemocratic result. [REF: ACLU of WA Brief]

The ACLU of WA further highlights the individual liberties at stake:

> Individual liberty is protected not just by courts recognizing substantive rights, but also by structural constraints, diffusion of power, and the political process—i.e., federalism, separation of powers, and democracy. Therefore, when a federal executive agency like the DEA claims that a federal statute supersedes a democratically enacted expression of the police powers of a state, not only are principles of federalism, separation of powers, and democracy at risk, but so are individual liberties. [REF: ACLU of WA Brief]

...

So here I sit. 4 days drafting this letter, 5 weeks after oral arguments, 1 year after seeking investigational treatment under RTT laws, and 18 months into a 24-month-end-of-life-sentence ... a patient continuing to be expected to wait, patiently.

That patience is wearing dangerously thin Senator.

I have presented to you overwhelming evidence supporting the purpose, essence, intent and letter of Right-To-Try laws. Yet, access is still denied, a pathway forward blocked, and patient pain and suffering continues to be exacerbated by the DOJ's and DEA's zero-tolerance stance and exhausting stall tactics.

As a US citizen, when the intent and letter of the laws of the land are stalled, blocked, and obstructed by the very government agencies serving to - in theory - protect, uphold, and honor said laws, it greatly erodes my trust in the democratic process and compromises the integrity of the fundamental principles upon which our democracy was founded. As authored by Dr. David R. Hawkins in his book *Power v. Force*, "democracy recognizes the divine right and will of the ruled, rather than the ruler".

> The liberty interests that are at stake here are those of dying patients who seek nothing more than to relieve themselves of unimaginable pain and suffering. [Seeley v. State, 132 Wash. 2d 776, 831 (1997)] Because the DEA "seeks to injure the very class [Washington] seeks to protect," its erroneous interpretation cannot stand. [Windsor, 570 U.S. at 769] [REF: ACLU of WA Amici Brief]

Where is the justice? Who is holding these agencies to account? What consequences do the agencies and/or staff face if they continue to obstruct and ignore the law of the land? How will the DEA, its officers etc. be held to account if it fails to accommodate access under RTT laws? What, if any, time limits are there for the court to rule on this case? What justice exists for patients and practitioners if the agency(s) chartered with enforcing the laws of the land choose to act above the law and are not held to account? If the court rules in favor of the petitioners, how quickly must the agency comply with these laws so patients in need can receive access they require? Can the DEA continue to waste time by "dragging its feet" in implementing a pathway to accommodate RTT laws?

These queries are posed in earnest.

IN CONCLUSION

At the end of the day, this case is about death and ensuring patients do not needlessly suffer emotional, mental, spiritual and/or physical pain at the end of their lives. Humans are indeed mortal, death is an inescapable fact of life, and dying is 100% guaranteed. To make this last chapter anything less than sacred would be an unjust dishonor. [a dishonorable discharge from life itself] For me, this is not a matter of "black or white", "right or wrong", "left or right", 'blue or red", "compliance or dissent", "us or them". Rather it is really an inner battle "between [hu]man's higher and lower natures". This is a matter of *we* the people (by we I mean humans).

So ...

How will we choose to move forward? Will we follow the guidance of our higher nature? Will we walk consciously and conscientiously toward Life, Unity and Equality for Eternity? Will we choose to help heal humanity's deeply-seated-plaguing-core-wounded-conditions of pain and suffering (physical, emotional, mental, and spiritual)? Will we choose to practice resolve, far-sightedness, acceptance, insightfulness (mindfulness), understanding, inquiry, graciousness, compassion, empathy, and integrity, in order that our species will at minimum survive and at best thrive?

Or ...

Will we continue to blindly-acquiesce to our lower nature and the proliferation of humanity's pain and suffering? Will we continue to be controlled, manipulated and governed by fear and force? Will humanity remain destabilized and dominated by authoritative institutional frameworks (developed and directed by humans) that rigidly support and defend debilitating patterns of suppression, oppression, shame, guilt, rejection, denial, indifference, exhaustion, doubt, chaos, intolerance, and constriction that are driving our species directly towards eradication and extinction? Will we follow in the forlorn footsteps of history and sit idly by as the "US Empire" stumbles and fumbles, fails and falls as the many empires before it?

Will we choose ...

Our higher over lower natures? Love over indifference? Compassion over oppression? Forgiveness over intolerance? Which is it *you* choose?

There is always a choice.

Choose wisely.

The survival of our species hinges upon heeding our highest nature. It is with wisdom and compassion, love and acceptance, and protecting the Divine Will of the ruled that humanity shall thrive. In this truth my faith resides.

Honorably,

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