No. 21-70544

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, *et al.*,

Petitioners,

v.

MERRICK B. GARLAND, Attorney General, *et al.*,

Respondents.

On Petition for Review of a Non-Final Action of the Drug Enforcement Administration

SUPPLEMENTAL EXERPTS OF RECORD

Volume 1 of 1

BRIAN M. BOYNTON
Acting Assistant Attorney General

MARK B. STERN
THOMAS PULHAM
Attorneys, Appellate Staff
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U.S. Department of Justice
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Washington, DC 20530
(202) 514-4332

INDEX

Page

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Kathryn L. Tucker, Esq.
Emerge Law Group
621 S.W. Morrison Street
Portland, Oregon 97205
kathryn@emergelawgroup.com

Dear Kathryn Tucker:

This letter is in response to your letter dated January 15, 2021, to the Drug Enforcement Administration (DEA). In your letter you state that you are counsel to Advanced Integrative Medical Science Institute and its co-director, Sunil Aggarwal, M.D. You state that Dr. Aggarwal is a palliative care specialist who treats patients with advanced cancer and currently holds a DEA registration as a practitioner. Dr. Aggarwal seeks additional authorization or additional registration (from DEA) to obtain psilocybin, a schedule I controlled substance, for therapeutic use for terminally ill cancer patients suffering anxiety and/or depression. You state that Dr. Aggarwal seeks such authorization pursuant to the "Right to Try Act" (RTT), officially designated as the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. You ask DEA for guidance on how DEA will accommodate the RTT, so that Dr. Aggarwal may obtain psilocybin for therapeutic use with terminally ill patients. DEA appreciates the opportunity to address your request.

DEA understands and appreciates the intent of the RTT, that is, to provide easier access to experimental drugs to patients afflicted with terminal illness. However, absent an explicit statutory exemption to the Controlled Substances Act (CSA), DEA has no authority to waive any of the CSA's requirements pursuant to the RTT. As is made clear in 21 U.S.C. 360bbb-0a(b), excerpted below, the RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations.

> *(b) Exemptions*
>
> *Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 352(f), 353(b)(4), 355(a), and 355(i) of this title, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.*

A potential avenue for Dr. Aggarwal to pursue is to apply for a schedule I researcher registration with DEA to conduct research with psilocybin, a schedule I controlled substance. The procedures for such application are outlined in 21 U.S.C. 823(f), 21 CFR 1301.18, and 21 CFR 1301.32.

Finally, in your email to DEA, sent on February 2, 2021, you inquire as to the possibility of DEA issuing an exemption from prosecution to Dr. Aggarwal. You state in your email that this would be akin to the exemption provided for in 21 CFR 1316.24, titled, "Exemption from prosecution for researchers." The exemption provided in this regulation, however, only applies to individuals already registered with DEA to engage in research in controlled substances. *See* 21 CFR 1316.24(a) ("Upon registration of an individual to engage in research in controlled substances . . . the Administrator . . . may exempt the registrant when acting within the scope of his registration, from prosecution . . ."). It would therefore not be applicable to Dr. Aggarwal at this time. Should Dr. Aggarwal obtain a schedule I researcher registration from DEA, he may then petition the DEA Administrator for a grant of exemption from prosecution following the procedure set forth in 21 CFR 1316.24(b).

I trust this letter adequately addresses your inquiry. For additional information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have additional questions regarding this issue, please contact the Policy Section at (571) 362-3260.

Sincerely,

THOMAS PREVOZNIK Digitally signed by THOMAS PREVOZNIK Date: 2021.02.12 11:09:30 -05'00'

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

From: Kathryn Tucker <kathryn@emergelawgroup.com>
Sent: Tuesday, February 2, 2021 1:03 PM
To: Purcell, John J. <JPurcell@dea.usdoj.gov>
Cc: Danner-Ryan, Heather A. <HADanner-Ryan@dea.usdoj.gov>; Dizon, Edwin S <ESDizon@dea.usdoj.gov>
Subject: Re: Right to Try psilocybin

Hello John:

I recognize that DEA has not yet addressed how it will accommodate the Right to Try (RTT) law. As DEA works to determine this, it occurred to me that perhaps another way for it to do so would be to issue an **exemption from prosecution** from the CSA to Dr. Aggarwal for treating his patients with psilocybin under Right to Try. Dr. Aggarwal and his patients would be willing to provide affidavits delineating the scope of the RTT use (ie. specifying the quantity of psilocybin, record keeping, and security measures etc).

Under this approach, it would be necessary for DEA to make clear that the exemption would permit the manufacturer/distributor (Organix) to supply its psilocybin to Dr. Aggarwal for RTT purposes.

This approach would be something akin to what is provided for in 21 C.F.R. § 1316.24, **Exemption from prosecution for researchers**, although the use would be therapeutic rather than 'research' in the traditional sense.

As you may be aware, exemptions have been granted on similar facts in Canada by the Canadian Health Ministry. Information about the Canadian exemptions can be found here on the Therapsil website: https://therapsil.ca/about/

Please provide DEA's guidance on whether it would be preferable to proceed with a Petition for Exemption. I remind you that the patients are in advanced stage of cancer and time is of the essence to accommodate their rights under RTT.

Thank you.
KT

Kathryn Tucker | Special Counsel
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621 SW Morrison Street, Suite 900
Portland, OR 97205
O: 503.227.4525 **F:** 503.200.1124 **D:** 206.595.0097
E: kathryn@emergelawgroup.com
emergelawgroup.com

From: Kathryn Tucker <kathryn@emergelawgroup.com>

Date: Sunday, January 24, 2021 at 11:19 AM

To: "john.purcell@usdoj.gov" <john.purcell@usdoj.gov>

Cc: "Heather.A.Danner-Ryan@usdoj.gov" <Heather.A.Danner-Ryan@usdoj.gov>, "Edwin.S.Dizon@usdoj.gov" <Edwin.S.Dizon@usdoj.gov>

Subject: Re: Right to Try psilocybin

Hello John:
Thanks so much for your call on Friday, advising you are in receipt of my letter dated 1/15/21, regarding the AIMS Institute and Dr. Sunil Aggarwal. I am copying you on my email of 1/15/21, the initial transmission of the letter via email, to introduce you to the field officers I have been in touch with about this matter. Because of the urgency of this matter for my clients, we hope you will be able to provide guidance on which form of registration Dr. Aggarwal ought seek in order to obtain psilocybin for therapeutic use with his terminally ill patients pursuant to Right to Try. The dying patients do not have the time for a drawn out proceeding, as I hope you can appreciate.
If it would facilitate faster action on this matter, Dr. Aggarwal is willing to proceed with filing a registration, for example as a researcher, which was suggested by one of the field officers, even though it seems not quite to fit the present situation.
We await your guidance. Thank you for your prompt attention to this matter.
KT

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E: kathryn@emergelawgroup.com
▶▶▶ emergelawgroup.com

From: Kathryn Tucker <kathryn@emergelawgroup.com>

Date: Friday, January 15, 2021 at 3:57 PM

To: "dea.registration.help@usdoj.gov" <dea.registration.help@usdoj.gov>

Cc: "Heather.A.Danner-Ryan@usdoj.gov" <Heather.A.Danner-Ryan@usdoj.gov>, "Edwin.S.Dizon@usdoj.gov" <Edwin.S.Dizon@usdoj.gov>

Subject: Right to Try psilocybin

Dear DEA Officials:
I have had the opportunity to speak with both Ms. Danner-Ryan(Boston Field Office) and Mr. Dizon(Seattle Field Office) about the matter discussed in the attached letter, which is also being sent via Registered Mail. Neither official could clarify which registration status my client should seek in the present situation. We appreciate your prompt attention to, and guidance about, this matter, as the interests of terminally ill patients are at stake and time is of the essence.
Thank you,
KT

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E: kathryn@emergelawgroup.com
emergelawgroup.com

From: Donahue, Brian F. <BFDonahue@dea.usdoj gov>
Sent: Friday, December 18, 2020 5:39 PM
To: Danner-Ryan, Heather A. <HADanner-Ryan@dea.usdoj gov>
Subject: Fwd: psilocybin

Please see below. Not sure who can answer this.

> **Thank you,**
> **Brian Donahue**
> *Diversion Investigator*
>
> DEA Boston Field Division
> JFK Federal Building
> 15 New Sudbury St. Room E-400 | Boston, MA 02203
> p. 571-362-9041 | f. 617-557-2126 | e. Brian.F.Donahue@usdoj.gov

Begin forwarded message:

> **From:** Howard Sard <sard@organixinc.com>
> **Date:** December 18, 2020 at 5:13:50 PM EST
> **To:** "Donahue, Brian F." <BFDonahue@dea.usdoj.gov>, Paul Blundell <blundell@organixinc.com>
> **Subject: Fwd: psilocybin**
> **Reply-To:** sard@organixinc.com
>
> Hi Brian,
>
> We have been approached by a medical group in Portland Oregon seeking to obtain psilocybin (Schedule I) from us for use in a palliative care setting, however, they do not have a DEA Schedule I license. In summary, they would like to receive the psilocybin under the 'Right to Try' act. I have told them that unless we hear otherwise from DEA, we can only provide psilocybin to an entity with a DEA Schedule I license. They have asked me to inquire with DEA and so I have forwarded the entire email trail below. Could you please pass this on to the appropriate department in Headquarters if appropriate? Thanks!
>
> Regards,
>
> Howard

-------- Forwarded Message --------
Subject: Re: psilocybin
Date: Fri, 18 Dec 2020 19:32:01 +0000
From: Kathryn Tucker
To:sard@organixinc.com , Paul Blundell
CC: Sunil Aggarwal

Great, thanks so much.

As noted, I anticipate that this will be the first time DEA has been alerted to the application of RTT to psilocybin. I would imagine a fair bit of ramp up will be required. My team, which includes a leading law firm with specialized expertise in FDA and DEA matters, is available to assist with that and would be pleased to do so.

Should the DEA take the erroneous position that RTT does not allow access to psilocybin, it would be a matter well worth taking up for judicial review. The courts, of course, are the final arbiter about the reach and application of a statute. Because psilocybin can be so tremendously effective as a therapy to relieve anxiety and depression suffered by terminally ill patients, we are eager to clarify that it is an EID under RTT.

Should consideration of judicial review become appropriate, my team is in position to take a lead role in any such action. We consider this a public interest matter and would not look to Organix to cover the costs, though we would be pleased to work collaboratively with your chosen counsel to make the strongest case possible.

Best,
KT

Kathryn Tucker | Special Counsel
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E: kathryn@emergelawgroup com
}}} emergelawgroup.com

From: Howard Sard
Organization: Organix, Inc.
Reply-To: "sard@organixinc.com"
Date: Friday, December 18, 2020 at 11:23 AM
To: Kathryn Tucker , Paul Blundell
Cc: Sunil Aggarwal
Subject: Re: psilocybin

Hi Kathryn,

I will inquire with DEA, referencing your email to us of Dec-15-2020, and provide your contact information to DEA if they request.

Regards,

Howard

Howard Sard, Ph.D
Vice President,
Organix, Inc.
240 Salem Street,
Woburn, MA 01801
781-932-4142
sard@organixinc.com
www.organixinc.com

On 12/16/2020 3:49 PM, Kathryn Tucker wrote:

Hi Friends:

As to your suggestion that you would inquire with your DEA contact about the

propriety of Organix supplying psilocybin to Dr. Aggarwal for his use with his terminally ill patients at the AIMS clinic, pursuant to Right to Try. We agree that this would be appropriate. As mentioned, it is likely the DEA will not be familiar with such a request, and will need to come to speed on the RTT and its application in context of this particular investigational drug. I hope you can share my message of 12/15 with the DEA when you make inquiry. I would be pleased to provide additional information about this to the DEA official as they consider the matter.

We are proceeding in a manner consistent with both the federal RTT and the Washington State RTT, since Dr. Aggarwal, his clinic and patients, are located in Washington. The Washington RTT can be found at RCW 69.77 et seq.

Thank you for your interest in ensuring that those entitled to legally access psilocybin are able to obtain this investigational drug.

KT

Kathryn Tucker | Special Counsel
EMERGE LAW GROUP
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O: 503 227.4525 **F:** 503.200.1124 **D:** 206.595 0097
E: kathryn@emergelawgroup.com
▸▸▸ emergelawgroup com

From: Kathryn Tucker
Date: Tuesday, December 15, 2020 at 4:12 PM
To: "sard@organixinc.com" , Paul Blundell
Cc: Sunil Aggarwal
Subject: Re: psilocybin

Hello Friends at Organix:

We believe there is a clear exception to your statement that you can "only ship a DEA Schedule I compound such as psilocybin upon receipt of a copy of the requesting organization's current DEA Schedule I license and a properly filled out DEA 222 form."

Some drugs, which are otherwise prohibited, are intended to be accessible in certain situations under the "Right to Try" (RTT) act, adopted by the federal government in 2018. 21 U.S.C. § 360bbb-0a (2018). See generally, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try.

The purpose of RTT is to allow terminally ill patients access to drugs still in investigational stages because such patients do not have the luxury of time to await the slow process of new drug approval. Psilocybin meets the requirements to qualify as such a drug.

To qualify as an eligible investigational drug ("EID") under the RTT, a drug must satisfy four requirements. First, it must have completed an FDA-approved Phase I clinical trial. Second, the drug must not be approved or licensed for any use through the federal Food, Drug, and Cosmetic Act ("FD&C Act") or the Public Health Services Act ("PHSA") Third, the drug must either: (a) have an application filed under the FD&C Act or PHSA, or (b) be under investigation in a clinical trial that is "intended to form the primary basis of a claim of effectiveness in support of approval" and be the subject of an active IND application under the FD&C Act or PHSA. Fourth, the drug's active development and production must be ongoing, not discontinued by the manufacturer, and not subject to a clinical hold. 21 U.S.C. § 360bbb-0a(a)(2)(A)-(D).

Under the RTT, an EID must be the subject of an IND application. 21 U.S.C. § 360bbb-0a(a)(2)(C). So long as a drug meets the applicable investigational drug criteria, the drug's source is irrelevant.

The exemptions under the federal RTT are broadly worded to apply to a variety of different parties that might handle the EID including: "[…] the sponsor of such eligible investigational drug *or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug.*" 21 U.S.C. § 360bbb-0a(b). The RTT exempts the qualifying EID from the federal prohibition against placing a "new drug" into interstate commerce without approval from the FDA. *Id.*; *see also* 21 U.S.C. § 355(a). The exemptions are connected to the qualifying EID itself.

The goal of the RTT is to increase access for terminally ill patients to investigational new drugs; a patient may obtain an eligible investigational drug from any manufacturer willing to provide it.

The Right to Try is the law of the nation. It protects access to eligible investigational drugs for terminally ill patients. Psilocybin meets the requirements to be deemed an eligible investigational drug. We hope you will consider this additional information as you consider this request.

If you prefer to have me discuss these particulars with your counsel, I would welcome

the opportunity to do so.

Thanks for your consideration of this request. We appreciate it may be the first time you have been asked to supply this investigational drug pursuant to the RTT.

Best,
KT

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From: Howard Sard
Organization: Organix, Inc.
Reply-To: "sard@organixinc.com"
Date: Tuesday, December 15, 2020 at 2:14 PM
To: Sunil Aggarwal , Kathryn Tucker
Cc: Paul Blundell
Subject: Re: psilocybin

Hi Dr. Aggarwal,

Thank you for your inquiry. I do believe that psychedelics can play a valuable role in many areas of medicine, and Organix is committed to assisting researchers whenever possible with these important programs. However, our business operates under DEA regulations, and we can only ship a DEA Schedule I compound such as psilocybin upon receipt of a copy of the requesting organization's current DEA Schedule I license and a properly filled out DEA 222 form.

Regards,

Howard

Howard Sard, Ph.D
Vice President,
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240 Salem Street,
Woburn, MA 01801
781-932-4142
sard@organixinc.com
www.organixinc.com

On 12/10/2020 12:11 AM, Sunil Aggarwal wrote:

> Hi Howard, I wanted to introduce myself. I'm Sunil Aggarwal, a practicing hospice and palliative medicine physician who is making the right to try request on behalf of two of my patients who have terminal illnesses. I have attached here two witnessed signed consent forms for these requests as required under the Washington state law.
>
> We are set up at our clinic for psilocybin-assisted psychotherapy sessions, as we have been practicing with ketamine-assisted psychotherapy for over two years. I have also received MDMA assisted therapy training through MAPS. I believe I have seen your psilocybin crystals when I was training at NYU and was getting a tour by Dr. Stephen Ross. I would be grateful if you would be willing to supply your psilocybin product for my patients under the state and federal right to try laws, or explore how we might achieve this.
>
> Thank you,
> Sunil Aggarwal

Sunil K. Aggarwal, MD, PhD, FAAPMR
Co-Director, AIMS Institute

Advanced Integrative Medical Science Institute
Cutting edge integrative medical care, research, and education in oncology, psychiatry, neurology, rehabilitation, pain and palliative care

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Board-certified, Hospice and Palliative Medicine (HPM) & Physical Medicine and Rehabilitation (PM&R)
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Affiliat
e Assistant Professor of Medicine and Geography
, University of Washington
Affiliate Clinical Faculty Bastyr University School of Naturopathic Medicine
Clinical Faculty, HealthPoint/The Wright Center Family Medicine Residency and Bastyr-affiliated AIMS Institute Residency
Immediate Past Chair, Integrative Medicine Special Interest Group, AAHPM
cannabinologist.org

| *facebook.com/humansunil* | *twitter.com/humansunil* | *Google Scholar*

Unchecked climate change, global nuclear weapons modernizations...outsized nuclear weapons arsenals...endanger every person on Earth.

--
Bulletin of the Atomic Scientists
We must concentrate not merely on the negative expulsion of war, but the positive affirmation of peace. - *Martin Luther King*

On Thu, Dec 3, 2020 at 12:06 PM Kathryn Tucker <kathryn@emergelawgroup.com> wrote:

> Hi Howard: Let us have a moment to think about this Your suggestion is interesting DEA will not be familiar w/a request under RTT, so a considerable amount of education would be required to help it recognize the safe harbor provided by the statute One interesting route to consider would be to seek a Declaratory Judgement from a court, establishing with clarity the application of RTT to psilocybin Would Organix be interested in discussing this possibility?
> KT
>
> Kathryn Tucker | Special Counsel
> **EMERGE LAW GROUP**
> 621 SW Morrison Street, Suite 900
> Portland, OR 97205
> **O:** 503.227.4525 **F:** 503.200.1124 **D:** 206.595.0097
> **E:** kathryn@emergelawgroup.com
> ▶▶▶ emergelawgroup.com
>
> This communication and any attachments may contain privileged or confidential information intended for a specific individual and purpose, and is protected by law If you are not the intended recipient, you should delete this communication and any attachments, and are notified that any disclosure, copying or distribution of this communication and any attachments, or the taking of any action based on it, is strictly prohibited
>
> ---
>
> **From:** Howard Sard <sard@organixinc.com>
> **Organization:** Organix, Inc.
> **Reply-To:** "sard@organixinc.com" <sard@organixinc.com>

Date: Thursday, December 3, 2020 at 12:00 PM
To: Kathryn Tucker <kathryn@emergelawgroup.com>
Cc: Paul Blundell <blundell@organixinc.com>, Sunil Aggarwal <saggarwal@aimsinstitute.net>
Subject: Re: psilocybin

Hi KT,

I can forward your email, with your permission, to our local DEA office, and find out their view on this.

Without explicit permission from DEA, we cannot ship a Schedule I compound except to a Schedule I license holder.

Regards,

Howard

Howard Sard, Ph.D
Vice President,
Organix, Inc.
240 Salem Street,
Woburn, MA 01801
781-932-4142
sard@organixinc.com
www.organixinc.com

On 12/3/2020 12:58 PM, Kathryn Tucker wrote:

> Hello Howard: Thanks for your prompt response A colleague at U Wisc, Professor Hutson, alerted me to your company My client, Dr Sunil Aggarwal of the AIMS clinic in Seattle(whom I cc on this message), a respected palliative care physician who treats patients with advanced cancer, seeks psilocybin with which to treat his patients He of course holds a DEA license to prescribe and administer controlled substances on Schedule II and beyond He does not hold a Schedule I license b/c in the 'normal course' substances on that Schedule cannot be prescribed or administered However, Right to Try(RTT) is now the law of the land, and it does not exclude Schedule I substances from its ambit(some of the state versions do so, but not the Federal nor the WA state, where he practices) Hence, it is pursuant to RTT that he seeks access to this 'eligible investigational drug', which psilocybin clearly is, pursuant to statute
> Can we discuss this possibility?
> If you have an attorney within the company, or outside counsel, with whom I could speak, I would be pleased to do so, to discuss the safe harbor provided by RTT in greater depth
>
> Best,
> KT
>
> Kathryn Tucker | Special Counsel
> **EMERGE LAW GROUP**
> 621 SW Morrison Street, Suite 900
> Portland, OR 97205
> **O:** 503.227.4525 **F:** 503.200.1124 **D:** 206 595.0097
> **E:** kathryn@emergelawgroup com
> ▶▶▶emergelawgroup.com
>
>

From: Howard Sard
Organization: Organix, Inc.
Reply-To: "sard@organixinc.com"
Date: Thursday, December 3, 2020 at 8:58 AM

To: Kathryn Tucker
Cc: Paul Blundell
Subject: Re: psilocybin

Hi Kathryn,

Thank you for your inquiry. May I ask how you heard of us?

Under current DEA guidelines, we can ship psilocybin only to a company or university within the US that holds a DEA Schedule I license. Once we receive a copy of the DEA license from such an institution, we can provide further details regarding the purchase of psilocybin.

Regards,

Howard

Howard Sard, Ph.D
Vice President,
Organix, Inc.
240 Salem Street,
Woburn, MA 01801
781-932-4142
sard@organixinc.com
www.organixinc.com

On 12/2/2020 6:59 PM, Kathryn Tucker wrote:

> Hello Friends at Organix:
> I am interested in understanding how one obtains psilocybin from your company I ask because I am working with an integrative oncology clinic in Seattle, whose clinicians seek to access psilocybin for their seriously ill cancer patients We have not been able to access psilocybin through Usona, but wonder if you are able to provide it?
> Our work to obtain psilocybin for use in this clinic with these patients was recently profiled in a Seattle Times article: https://www seattletimes com/seattle-news/health/new-legal-push-in-washington-state-aims-to-speed-magic-mushrooms-to-dying-patients/
>
> If you can supply psilocybin to this clinic we would avoid need to seek manufacturer registration. Pls advise.
> Best,
> KT
>
> Kathryn Tucker | Special Counsel
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> 621 SW Morrison Street, Suite 900
> Portland, OR 97205
> **O:** 503 227.4525 **F:** 503.200.1124 **D:** 206.595 0097
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