(1 of 41)

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Office of the Clerk **United States Court of Appeals for the Ninth Circuit**

Post Office Box 193939 San Francisco, California 94119-3939 415-355-8000

Molly C. Dwyer Clerk of Court

March 08, 2021

No.: 21-70544

Short Title: AIMS, et al v. USDEA, et al

Dear Petitioner/Counsel

Your Petition for Review has been received in the Clerk's office of the United States Court of Appeals for the Ninth Circuit. The U.S. Court of Appeals docket number shown above has been assigned to this case. You must indicate this Court of Appeals docket number whenever you communicate with this court regarding this case.

The due dates for filing the parties' briefs and otherwise perfecting the petition have been set by the enclosed "Time Schedule Order," pursuant to applicable FRAP rules. These dates can be extended only by court order. Failure of the petitioner to comply with the time schedule order will result in automatic dismissal of the petition. 9th Cir. R. 42-1.

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

FILED

MAR 08 2021

MOLLY C. DWYER, CLERK U.S. COURT OF APPEALS

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC; SUNIL AGGARWAL, Doctor, MD, PhD, FAAPMR; ERINN BALDESCHWILER; MICHAL BLOOM,

Petitioners,

V.

ROBERT M. WILKINSON, Acting Attorney General; D. CHRISTOPHER EVANS, in his official capacity as acting Administrator of the U.S. Drug Enforcement Administration; U.S. DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

No. 21-70544

Drug Enforcement Agency

TIME SCHEDULE ORDER

The parties shall meet the following time schedule.

Mon., March 15, 2021 Petitioner's Mediation Questionnaire due. If your

registration for Appellate CM/ECF is confirmed after this date, the Mediation Questionnaire is due within

one day of receiving the email from PACER

confirming your registration.

Thu., May 27, 2021 Agency petitioner brief due

Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-1, Page 3 of 3

Mon., June 28, 2021

Respondents' answering brief and excerpts of record shall be served and filed pursuant to FRAP 31 and 9th Cir. R. 31-2.1.

The optional petitioner's reply brief shall be filed and served within 21 days of service of the respondents' brief, pursuant to FRAP 31 and 9th Cir. R. 31-2.1.

Failure of the petitioner to comply with the Time Schedule Order will result in automatic dismissal of the appeal. See 9th Cir. R. 42-1.

FOR THE COURT:

MOLLY C. DWYER CLERK OF COURT

By: Janne Nicole Millare Rivera Deputy Clerk Ninth Circuit Rule 27-7 Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-2, Page 1 of 2



Clerk of Court

Office of the Clerk United States Court of Appeals for the Ninth Circuit

Post Office Box 193939 San Francisco, California 94119-3939 415-355-8000

ATTENTION ALL PARTIES AND COUNSEL PLEASE REVIEW PARTIES AND COUNSEL LISTING

We have opened this appeal/petition based on the information provided to us by the appellant/petitioner and/or the lower court or agency. EVERY attorney and unrepresented litigant receiving this notice MUST immediately review the caption and service list for this case and notify the Court of any corrections.

Failure to ensure that all parties and counsel are accurately listed on our docket, and that counsel are registered and admitted, may result in your inability to participate in and/or receive notice of filings in this case, and may also result in the waiver of claims or defenses.

PARTY LISTING:

Notify the Clerk immediately if you (as an unrepresented litigant) or your client(s) are not properly and accurately listed or identified as a party to the appeal/petition. To report an inaccurate identification of a party (including company names, substitution of government officials appearing only in their official capacity, or spelling errors), or to request that a party who is listed only by their lower court role (such as plaintiff/defendant/movant) be listed as a party to the appeal/petition as an appellee or respondent so that the party can appear in this Court and submit filings, contact the Help Desk at http://www.ca9.uscourts.gov/cmecf/feedback/ or send a letter to the Clerk. If you or your client were identified as a party to the appeal/petition in the notice of appeal/petition for review or representation statement and you believe this is in error, file a motion to dismiss as to those parties.

COUNSEL LISTING:

In addition to reviewing the caption with respect to your client(s) as discussed above, all counsel receiving this notice must also review the electronic notice of docket activity or the service list for the case to ensure that the correct counsel are

Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-2, Page 2 of 2

listed for your clients. If appellate counsel are not on the service list, they must file a notice of appearance or substitution immediately or contact the Clerk's office.

NOTE that in criminal and habeas corpus appeals, trial counsel WILL remain as counsel of record on appeal until or unless they are relieved or replaced by Court order. *See* Ninth Circuit Rule 4-1.

REGISTRATION AND ADMISSION TO PRACTICE:

Every counsel listed on the docket must be admitted to practice before the Ninth Circuit AND registered for electronic filing in the Ninth Circuit in order to remain or appear on the docket as counsel of record. *See* Ninth Circuit Rules 25-5(a) and 46-1.2. These are two separate and independent requirements and doing one does not satisfy the other. If you are not registered and/or admitted, you MUST, within 7 days from receipt of this notice, register for electronic filing AND apply for admission, or be replaced by substitute counsel or otherwise withdraw from the case.

If you are not registered for electronic filing, you will not receive further notices of filings from the Court in this case, including important scheduling orders and orders requiring a response. Failure to respond to a Court order or otherwise meet an established deadline can result in the dismissal of the appeal/petition for failure to prosecute by the Clerk pursuant to Ninth Circuit Rule 42-1, or other action adverse to your client.

If you will be replaced by substitute counsel, new counsel should file a notice of appearance/substitution (no form or other attachment is required) and should note that they are replacing existing counsel. To withdraw without replacement, you must electronically file a notice or motion to withdraw as counsel from this appeal/petition and include your client's contact information.

To register for electronic filing, and for more information about Ninth Circuit CM/ECF, visit our website at http://www.ca9.uscourts.gov/cmecf/#section-registration.

To apply for admission, see the instructions and form application available on our website at https://www.ca9.uscourts.gov/attorneys/.

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United States Court of Appeals for the Ninth Circuit

P.O. Box 31478 Billings, Montana 59107-1478

CHAMBERS OF SIDNEY R. THOMAS CHIEF JUDGE

TEL: (406) 373-3200 FAX: (406) 373-3250

Dear Counsel:

I write to introduce you to the court's mediation program. The court offers you and your clients professional mediation services, at no cost, to help resolve disputes quickly and efficiently and to explore the development of more satisfactory results than can be achieved from continued litigation. Each year the mediators facilitate the resolution of hundreds of cases, from the most basic contract and tort actions to the most complex cases involving multiple parties, numerous pieces of litigation and important issues of public policy.

The eight circuit mediators, all of whom work exclusively for the court, are highly experienced attorneys from a variety of practices; all have extensive training and experience in negotiation, appellate mediation, and Ninth Circuit practice and procedure. Although the mediators are court employees, the court has adopted strict confidentiality rules and practices to ensure that what goes on in mediation stays in mediation. See Circuit Rule 33-1.

The first step in the mediation process is case selection. To assist the mediators in the case selection process, appellants/petitioners must file a completed Mediation Questionnaire within 7 days of the docketing of the case. See Circuit Rules 3-4, and 15-2. Appellees may also fill out and file a questionnaire. The questionnaire with filing instructions is available here. Once the Mediation Questionnaire is submitted, the parties will receive via NDA a link to a separate form that will allow them to submit **confidential** information directly to the Circuit Mediators. Counsel may also submit confidential information at any time to ca09 mediation@ca9.uscourts.gov.

In most cases, the mediator will schedule a settlement assessment conference, with counsel only, to determine whether the case is suitable for mediation. Be assured that participation in the mediation program will not slow down disposition of your appeal. Mediation discussions are not limited to the issues on appeal. The discussions can involve other cases and may include individuals who are not parties to the litigation, if doing so enables the parties to reach a global settlement.

Further information about the mediation program may be found on the court's website: www.ca9.uscourts.gov/mediation/. Please address questions directly to the Mediation Program at 415-355-7900 or ca09mediation@ca9.uscourts.gov.

Sincerely, Sinhay a Manne

Sidney Thomas

No.		

In the United States Court of Appeals for the Ninth Circuit

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, Dr. Sunil Aggarwal, MD, PhD, Michal Bloom, and Erinn Baldeschwiler,

Petitioners.

ν.

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

Respondents.

PETITION FOR REVIEW

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ATTORNEYS FOR PETITIONERS

Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-4, Page 2 of 15

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the undersigned counsel of record for Petitioner Advanced Integrative Medical Science ("AIMS") Institute hereby certifies that the AIMS Institute is a professional limited liability company and does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

March 8, 2021

/s/ James F. Williams

James F. Williams 1201 Third Avenue, Suite 4900 Seattle, WA 98101-3099

Phone: 206.359.8000 Fax: 206.359.9000

jwilliams@perkinscoie.com

Attorney for Petitioners

PETITION FOR REVIEW

Pursuant to 21 U.S.C. § 877 and 21 Fed. R. App. P. 15, Petitioners, the Advanced Integrative Medical Science ("AIMS") Institute, its Co-Director, Dr. Sunil Aggarwal, MD, PhD, FAAPMR, and two of Dr. Aggarwal's patients, Erinn Baldeschwiler and Michal Bloom, hereby petition for review of the United States Drug Enforcement Administration's final agency action issued on February 12, 2021, attached as **Exhibit 1** (the "Final Agency Decision").

This Petition for Review ("Petition") regards how the agency will abide by the "Right to Try," as codified in both federal and state law. *See* 21 U.S.C.A. § 360bbb, *et seq.*; RCW 69.77, *et seq.* In 2017, the Washington state legislature enacted its Right to Try legislation and correctly noted that patients with terminal illnesses, like Petitioners Baldeschwiler and Bloom, "do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States [F]ood and [D]rug [A]dministration." RCW 69.77.010. The state legislature further found that such 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 the *patient* with a terminal illness in consultation with the *patient's health care provider. Id.* Washington legislators

made their decision clear: "to allow terminally ill patients to use potentially lifesaving investigational drugs[.]" *Id*.

Despite the legislators' intent that terminally ill patients can make informed decisions with their health care providers about eligible investigational drugs, the reality is not so straightforward. The Right to Try, as contemplated by both federal and state law, relates to the ability of a treating physician to provide certain investigational drug therapies to terminally ill patients, for whom time is of the essence. *See* RCW 69.77.020(8) (defining a qualifying condition as one "in which there is reasonable likelihood that death will occur within six months or in which premature death is likely without early treatment").

Even if a qualified treating physician wishes to exercise the Right to Try and administer the eligible investigational drug of psilocybin to a qualified terminally-ill patient, they cannot do so pursuant to the Final Agency Decision. Psilocybin is a controlled substance, and is currently a Schedule I drug, meaning that the prescribing of this drug is governed by Respondent, the U.S. Drug Enforcement Administration ("DEA"), which administers the Controlled Substances Act. With the DEA's Final Agency Decision, the agency declared that it "has no authority to waive" any of the Controlled Substances Act vitiates Act vitiates the Right to Try. In other words, the DEA's enforcement of the Controlled Substances Act vitiates the Right the Try, as codified by state and federal law. Put differently, qualifying terminally-

ill patients cannot gain access to this eligible investigational drug for which they otherwise qualify because of the DEA's Final Agency Decision.

The DEA's Final Agency Decision was issued in response to an inquiry submitted January 15, 2021, requesting the agency's direction regarding how Dr. Aggarawal could obtain psilocybin for therapeutic use in terminally ill patients. The DEA's letter is attached as **Exhibit 2.**

Petitioners seek review of the Final Agency Decision on the grounds that it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; without observance of procedure required by law; and/or otherwise unsupported by substantial evidence. Petitioners respectfully request that this Court hold unlawful, vacate, and enjoin the Final Agency Decision and mandate, pursuant to the Right to Try, as codified in state and federal law, that the DEA expeditiously consider and accomodate valid requests made from qualified health care providers for the therapeutic use of the eligible investigation drug psilocybin.

Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-4, Page 6 of 15

Dated: March 8, 2021

Kathryn L. Tucker EMERGE LAW GROUP 621 SW Morrison Street, Suite 900 Portland, OR 97205 Phone: 206.595.0097 kathryn@emergelawgroup.com

Matthew C. Zorn YETTER COLEMAN LLP 811 Main Street, Suite 4100 Houston, TX 77002 Phone: 713.632.8000 Fax: 713.632.8002

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Respectfully submitted,

/s/ James F. Williams

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ATTORNEYS FOR PETITIONERS

CERTIFICATE OF SERVICE

I certify that this Petition for Review and Corporate Disclosure Statement was filed with the Court via the Court's electronic filing system, on the 8th day of March, 2021, and copy of the Petition was sent via nonelectronic service to the following:

The Honorable Monty Wilkinson Acting Attorney General U.S. Department of Justice 950 Pennsylvania, NW Washington, DC 20530

Chief Counsel
Office of General Counsel
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

The Honorable D. Christopher Evans Acting Administrator Drug Enforcement Administration 7000 Army-Navy Dr. Arlington, VA 22202

Civil Process Clerk Office of the U.S. Attorney for the District of Columbia 555 4th St NW Washington, DC 20530

/s/ James F. Williams
James F. Williams

Exhibit 1



KATHRYN TUCKER Admitted in Washington (206) 595-0097 kathryn@emergelawgroup.com

621 SW Morrison St., Suite 900, Portland, OR 97205

January 15, 2021

VIA E-MAIL (dea.registration.help@usdoj.gov) AND U.S. FIRST CLASS REGISTERED MAIL

Drug Enforcement Administration Attn: Regulatory Section/DRG 8701 Morrissette Drive Springfield, VA 22152

Dear DEA Regulatory Section:

The Advanced Integrative Medical Science Institute (AIMS) is an integrative oncology clinic located in Seattle, WA. I am counsel to the clinic and its co-director, Dr. Sunil Aggarwal. Dr. Aggarwal is a palliative care specialist who treats patients with advanced cancer. He holds a DEA registration to prescribe controlled substances (DEA # FA4274926). Dr. Aggarwal seeks additional registration to obtain psilocybin, a Schedule I drug (code 7437), for the rapeutic use with terminally ill cancer patients suffering anxiety and/or depression. This registration is sought pursuant to the Washington and U.S. Right to Try (RTT) Acts. This letter provides background information about the RTT, and we seek your guidance on how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients.

Brief Background on Psilocybin's Utility in Relief of Anxiety and Depression in Terminally III Patients

Medical research demonstrates the powerful therapeutic uses of psilocybin in the treatment of anxiety and depression associated with terminal illness. Patients with advanced cancer suffering from treatment resistant anxiety and/or depression experience significant reductions in both anxiety and depression, and improvements of mood, following a single guided treatment with psilocybin, with no safety concerns or clinically significant adverse events.2 This is important because people experiencing late stage terminal disease experience

¹ RCW 69.77 et seq; 21 U.S.C.A. § 360bbb-0a.

² Grob et al., Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer, 68 ARCH GEN PSYCHIATRY 71, 71 (2011) (anxiety levels measured at one, three, and six months after treatment "demonstrated a sustained reduction in anxiety"); Griffiths et al., Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients With Life-Threatening Cancer: A Randomized Double-Blind Trial, 30 J. Psychopharmacology 1181, 1195 (2016) (single dose of psilocybin produced large and significant decreases in depression, anxiety or mood disturbance, and increases in measures of quality of life, life meaning, death acceptance, and optimism in patients with a life-threatening cancer diagnosis; effects sustained at 6 months.); Johnson & Griffiths, Potential Therapeutic Effects of Psilocybin, 30 Neurotherapeutics 734, 734 (2017); Ross S., Therapeutic use of classic psychedelics to treat cancer-related psychiatric distress. Int Rev Psychiatry, 2018 Aug;30(4):317-330. doi: 10.1080/09540261.2018.1482261. Epub 2018 Aug 13(review of clinical trials from 1960-2018 researching therapeutic use of psychedelic treatment in patients with serious or terminal illnesses and related psychiatric illness; psychedelic-assisted treatment can produce rapid, robust, and sustained improvements

January 15, 2021

emotional suffering to a greater extent than those in the general population.³ Dying patients frequently suffer depression and anxiety.⁴ For such patients, psychotherapy facilitated with psychedelics may provide much needed relief: "People in the psychedelic trip often experience being at one with the world or even the universe. It's as if they have died, as if they've gone out to another place. They exist beyond their body. That experience can give them a sense of perpetuity, of permanence, of being part of the cycle of life, which of course we all are."⁵ Patients able to access psychedelic therapy express compelling positive experiences: "I felt like I was being shown what happens after [death], like an afterlife. I'm not a religious person and I'd be hard pushed to say I was anything near spiritual either, but I felt like I'd experienced some of that, and experienced the feeling of an afterlife, like a preview almost, and I felt totally calm, totally relaxed, totally at peace. So that when that time comes for me, I will have no fear of it at all."⁶ This is great news as: "Anxiety is one of the most common reasons for psychiatric consultation in terminally ill cancer patients and has been linked to lower levels of quality of life, increased levels of insomnia, decreased trust in physicians, and poor treatment compliance."

The Right to Try

The state and federal "Right to Try" (RTT) acts⁸ are statutes intended to allow terminally ill patients access to drugs still in investigational stages, recognizing that such patients do not have the luxury of time to await the slow process of new drug approval. Psilocybin qualifies as such a drug.⁹

To qualify as an eligible investigational drug ("EID") under the federal RTT, a drug must satisfy four requirements. First, it must have completed an FDA-approved Phase I clinical trial. Decond, the drug must not be approved or licensed for any use through the federal Food, Drug, and Cosmetic Act ("FD&C Act") or the

https://www.usonainstitute.org/wp-content/uploads/2020/08/Usona_Psilocybin_IB_V3.0_08.31.2020_cc.pdf; https://clinicaltrials.gov/ct2/results?cond=&term=psilocybin&cntry=&state=&city=&dist=.

in cancer-related psychological and existential distress.) See also, *Individual Experiences in Four Cancer Patients Following Psilocybin-Assisted Psychotherapy*, Pharmacol., 03 April 2018 (participants with anxiety, depression, and other existential distress achieved relief with psilocybin treatment, and benefits were sustained throughout follow-up). https://www.frontiersin.org/articles/10.3389/fphar.2018.00256/full. See generally, M. Pollan, *How to Change Your Mind* (2018); Lauren Slater, *How Psychedelic Drugs Can Help Patients Face Death*, NEW YORK TIMES MAGAZINE (Apr. 20, 2012), ("[T]he results showed that administering psilocybin to terminally ill subjects could be done safely while reducing the subjects' anxiety and depression about their impending deaths.").

³See, e.g., H. Chochinov, *Psychiatry and Terminal Illness*, 45 Can. J. Psychiatry 413,146–48 (2000); W. Lichtenthal et al., *Do Rates of Mental Disorders and Existential Distress Among Advanced Stage Cancer Patients Increase as Death Approaches?* 18 Psycho-Oncology 50, 54 (2009); A. Mitchell et al., *Prevalence of Depression, Anxiety, and Adjustment Disorder in Oncological, Haematological, and Palliative-Care Settings: A Meta-Analysis of 94 Interview-Based Studies*, 12 Lancet Oncology 160, 167 tbl.2 (2011).

⁴ Research shows that 18% of terminally ill cancer patients experience moderate anxiety, while 12% suffer severe anxiety. E. Kolva, et al. Anxiety in Terminally Ill Cancer Patients, 42(5) Journal of Pain and Symptom Management, 691 - 701 (2011).

⁵ Id.

⁶ Id.

⁷ E. Kolva, et al., *Anxiety in Terminally Ill Cancer Patients*, 42(5) J. Pain and Sympt. Management, 691 – 701 (2011).

⁸ RCW 69.77 et seg; 21 U.S.C.A. § 360bbb-0a.

⁹ See supra n. 2, citing clinical trial studies with psilocybin. See also, Usona Institute, Investigator's Brochure

¹⁰ 21 U.S.C. § 360bbb-0a(a)(2)(A).

January 15, 2021

Public Health Services Act ("PHSA"). ¹¹ 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. ¹² Fourth, the drug's active development and production must be ongoing, not discontinued by the manufacturer, and not subject to a clinical hold. ¹³ Similarly, under the Washington RTT, a drug is "investigational" when it has successfully completed Phase 1 and is currently in a subsequent phase of an FDA-approved clinical trial assessing its safety. ¹⁴ Psilocybin meets all of these requirements.

The AIMS Institute intends to purchase psilocybin from Organix, a company which holds an IND for this drug and is registered as a Distrubuter of this drug. ¹⁵ It is clearly within the intention of the RTT to allow this, even though psilocybin is a Schedule I drug. This is evident as neither the U.S. RTT nor the Washington State RTT exclude Schedule I substances from their scope. ¹⁶

Issuance of a registration to enable Dr. Aggarwal to obtain psilocybin for the intended purpose is fully consistent with the public interest. None of the public interest factors that might counsel against issuance of a registration are present.¹⁷

The underlying scope of authority by the DEA is limited to effectuating controls against diversion of controlled substances, and not determinations of the practice of medicine. *Gonzales v. Oregon*, 126 S.Ct. 904.

I look forward to your guidance as to how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients. The existing DEA forms do not appear to accommodate the RTT, which may be due to the fact that it was relatively recently enacted; hence it is confusing to use the existing forms for this purpose. Should Dr. Aggarwal seek registration as a "researcher", though his intention is therapeutic use as a palliative care clinician, treating terminally ill patients, not a "researcher" in the traditional sense? If not a researcher registration, how ought we proceed?

In the interest of the terminally ill patients with refractory anxiety and/or depression, we hope DEA can promptly advise on how to proceed.

¹¹ *Id.* § 360bbb-0a(a)(2)(B). Specifically, the drug may not be approved or licensed for any use under Section 355 of the FD&C Act or Section 351 of the PHSA.

¹² *Id.* § 360bbb-0a(a)(2)(C). Specifically, the application in (1) must be under Section 355(b) of the FD&C Act or Section 351(a) of the PHSA. For brevity's sake, "IND application" in this memo means anything meeting these criteria.

 $^{^{13}}$ Id. § 360bbb-0a(a)(2)(D).

¹⁴ RCW 69.77.020(4).

Organix, Inc. 240 Salem Street, Woburn, MA 01801 www.organixinc.com

¹⁶ In contrast, some RTT statutes explicitly exclude Schedule I substances from RTT shelter. For example, Missouri's RTT statute, in defining what qualifies as an "investigational drug", states that an "Investigational drug ...shall not include Schedule I controlled substances.") Revised Statutes of Missouri, Section 191.480(2014) (2)(emphasis added). Compare: 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 safety of the drug....").

¹⁷ The only pertinent factor relates to assuring effective controls against diversion. Effective controls can and will be established at AIMS, which already stores controlled substances.

Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-4, Page 12 of 15 January 15, 2021

Respectfully submitted,

Kathryn Tucker

Kathryn L. Tucker

Counsel to AIMS Institute and Dr. Sunil Aggarwal

Cc via email: Heather Danner-Ryan, Group Supervisor, Diversion Group 1, New England Field Division, Boston Heather.A.Danner-Ryan@usdoj.gov

Edwin Dizon, Diversion Investigator, Seattle Field Division Edwin.S.Dizon@usdoj.gov

Exhibit 2

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Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-4, Page 14 of 15 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.

Case: 21-70544, 03/08/2021, ID: 12028345, DktEntry: 1-4, Page 15 of 15

Kathryn L. Tucker Page 2

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 W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Office of the Clerk

After Opening an Agency Case: An Introduction for Attorneys

You have received this guide because you filed a petition for review of a federal agency decision in the U.S. Court of Appeals for the Ninth Circuit. It provides information you need to know to represent a petitioner before the court.

This guide is not for immigration cases. If you opened an immigration case, please request our immigration packet.

Read this guide carefully. If you don't follow instructions, the court may dismiss your case.

This Guide Is Not Legal Advice

Court employees are legally required to remain neutral; that means they can't give you advice about how to win your case. However, if you have a question about procedure—for example, which forms to send to the court or when a form is due—this packet should provide the answer. If it doesn't, you may contact the clerk's office for more information.

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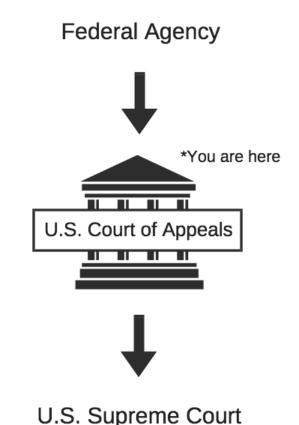
HOW AN AGENCY PETITION WORKS

The chart below shows the path of an agency petition from the agency to the highest court. Review these steps to make sure you understand where you are in the process.

Federal Agency. Cases come to the U.S. Court of Appeals from several different federal agencies. For example, a petition may arise from a final decision at the Federal Aviation Administration, National Labor Relations Board, Federal Trade Commission, or another agency. The important thing to understand is that you must have exhausted all of your options for appeal within the agency itself before filing a petition for review with the court of appeals. Many agency decisions must first be challenged in a U.S. District Court before you can come to the court of appeals.

U.S. Court of Appeals. When reviewing the federal agency decision in your case, the court of appeals (usually a panel of three judges) will carefully consider everything that has happened so far. The court will also read all the papers that you and opposing counsel file during your case. The court will look to see whether any agency, officer, or lower court has made a legal or factual mistake. You are not allowed to present new evidence or testimony on appeal.

U.S. Supreme Court. If you do not agree with the decision of the court of appeals, you can ask the United States Supreme Court to review your case. The Supreme Court chooses which cases it wants to hear. It reviews only a small number of cases each year.



Your case may not go through all of the stages shown above. For example, if the U.S. Court of Appeals resolves your case the way that you want, you won't need to file a petition in the U.S. Supreme Court.

PRACTICE RULES AND RESOURCES

This guide highlights rules that you **absolutely must follow** after filing a case. You are also responsible for reviewing and following the Federal Rules of Appellate Procedure (Fed. R. App. P.), the Ninth Circuit Rules (9th Cir. R.), and the general orders. The Federal Rules and the Ninth Circuit Rules are available at www.ca9.uscourts.gov/rules.

Practice Guides

In addition to the rules above, the following guides can support your practice before this court. You can find these and other resources on the court's website under *Legal Guides*:

- Appellate Practice Guide. A thorough manual of appellate practice prepared by the Appellate Lawyer Representatives.
- **Perfecting Your Appeal.** You can view this video for free at www.ca9.uscourts.gov or purchase it from the clerk's office for \$15.00.

Appellate Mentoring Program

The appellate mentoring program provides guidance to attorneys who are new to federal appellate practice or who would benefit from mentoring at the appellate level. Mentors are volunteers who have experience in immigration, habeas corpus, or appellate practice in general. If you are interested, a program coordinator will match you with a mentor, taking into account your needs and the mentor's particular strengths.

To learn more, email the court at mentoring@ca.9.uscourts.gov or go to www.ca9.uscourts.gov. On the website, select the "Attorneys" tab, look for "Appellate Mentoring Program," then choose "Information."

IMPORTANT RULES FOR ALL CASES

The rules in this section apply to all attorneys who file an agency petition in the court of appeals. You must understand and follow each one.

Ninth Circuit Bar Admission

To practice before the court of appeals, you must be admitted to the Bar of the Ninth Circuit. For instructions on how to apply, go to www.ca9.uscourts.gov. Select the "Attorneys" tab, look for "Attorney Admissions," then choose "Instructions."

Register for Electronic Filing

Unless the court gives you an exemption, you must use the Ninth Circuit's electronic filing system, called CM/ECF (Case Management/Electronic Case Files). To learn more and to register, go to www.ca9.uscourts.gov then click "Filing a Document – CM/ECF."

For additional guidance on filing documents and making payments electronically, read the Ninth Circuit Rules, especially Rule 25-5. For a complete list of the available types of filing events, see the <u>CM/ECF User Guide</u>. To find the guide, go to "Filing a Document" as described just above, look for "Documentation & Training," then select "CM/ECF User Guide."

Complete a Mediation Questionnaire

After you file a petition for review of an agency decision, you must complete a mediation questionnaire. (9th Cir. R. 15-2.) The court uses the questionnaire to assess settlement potential.

You must file the questionnaire no later than **seven days** after the clerk's office dockets your petition. To find the form, go to www.ca9.uscourts.gov/forms.

If you want to request a conference with a mediator, call the Mediation Unit at (415) 355-7900, email ca09_mediation@ca9.uscourts.gov, or make a written request to the Chief Circuit Mediator. You may request conferences confidentially. For more information about the court's mediation program, go to www.ca9.uscourts.gov/mediation.

Meet Your Deadlines

Read all documents you get from the court. They will contain important instructions and deadlines for filing your court papers. If you miss a deadline or fail to respond to the court as directed, the court may dismiss your case.

Complete Your Forms Properly

Everything you send to the court must be clear and easy to read. If we can't read your papers, we may send them back to you. To make the clerk's job easier, please:

- ✓ Include your case number on all papers you send to the court or to opposing counsel.
- ✓ Number your pages and put them in order.
- ✓ If you are not filing electronically, use only one paper clip or a single staple to keep your documents organized. The clerk's office must scan your documents and extra binding makes that job difficult.

Deliver Papers the Right Way

When you deliver papers to the court or to opposing counsel, you must take certain steps to show you sent them to the right place on time.

- ✓ **Use the correct address.** Before you put anything in the mail, make sure the address is current and correct.
 - To find current addresses for the court, see "How to Contact the Court," at the end of this guide. You may deliver a document to the court in person, but you must hand it to someone designated to receive documents in the clerk's office.
 - To find the correct address for opposing counsel, see opposing counsel's notice of appearance. Opposing counsel should have sent a copy of this notice to you after you filed your petition for review. The notice states opposing counsel's name and address.
- ✓ **Attach a certificate of service.** You must attach a signed certificate of service to each document you send to the court or to opposing counsel unless all parties will be served via CM/ECF. See 9th Cir. R. 25-5(f).
- ✓ **Send a copy of** *all* **documents to opposing counsel.** When you file a document with the court, you must also send a copy (including any attachments) to opposing counsel unless they will be served via CM/ECF.

Keep Copies of Your Documents

Make copies of all documents you send to the court or to opposing counsel and keep all papers sent to you.

Pay the Filing Fee or Request a Waiver

The filing fee for your case is \$500.00. The fee is due when you file a petition for review. If you don't pay the fee, you will receive a notice informing you that you have **21 days** to either pay the fee or request a waiver because the petitioner can't afford to pay.

• If the petitioner can afford the fee. Submit your payment through the electronic filing system, or send a check or money order to the court. Make the check out to "Clerk, U.S. Courts." Don't forget to include the case number. Please note that after you pay the fee, we cannot refund it, no matter how the case turns out.

• If the petitioner can't afford to pay. You may ask the court to waive the fee by filing a motion to proceed in forma pauperis. See "Stage One: Opening Your Case," below.

If you do not pay the fee or submit a waiver request by the deadline, the court will dismiss your case. (9th Cir. R. 42-1).

If You Move, Tell the Court

If your mailing address changes, you must immediately notify the court in writing. (9th Cir. R. 46-3.)

- **CM/ECF.** If you are registered for CM/ECF, update your information online at https://pacer.psc.uscourts.gov/pscof/login.jsf.
- **Paper filing.** If you are exempt from CM/ECF, file a change of address form with the court. You can find the form on the court's website at www.ca9.uscourts.gov/forms.

If you don't promptly change your address, including your email address, you could miss important court notices and deadlines. As noted above, missing a deadline may cause the court to dismiss your case.

HANDLING AN AGENCY CASE: THREE STAGES

This section will help you understand and manage the different parts of your case. We describe the basic documents you must file with the court and the timing of each step.

To begin, review the chart below. It introduces the three stages of a case.



- You file a petition for review.
- The court sends you a case schedule.
- · You pay filing fees or get a waiver.
- You start compiling excerpts of record.
- You and opposing counsel may file motions.
- You respond to any court orders or motions from opposing counsel.



- You submit an opening brief and excerpts of record.
- Opposing counsel submits an answering brief.
- You may submit a reply to opposing counsel's brief.



- The court decides your case.
- If you don't like the result, you decide whether to take further action.

Stage One: Opening a Case

By the time you receive this guide, you have already opened a case by filing a petition for review. In response, the clerk's office created the case record and gave you a case number and a briefing schedule.

If you haven't already paid the filing fee, you must do so now. See "Pay the Filing Fee or Request a Waiver," above.



The court may dismiss your case at any time. Even if you pay the fees and get a briefing schedule, the court may decide not to keep your case for a variety of legal reasons. If the court dismisses your case and you think the court was wrong, see "If You Don't Agree with a Court Decision," below.

Now is also the time to start compiling excerpts of record and to file any opening motions with the court. This section discusses each step in turn.

Preparing Excerpts of Record

The Ninth Circuit Court of Appeals does not require an appendix of record. Instead, you must file excerpts of record with your opening brief. (*See* 9th Cir. R. 17-1.) Your excerpts of record should be clear and well-organized. They should include all the documents that the court will need to understand and decide the issues in your petition.

Start putting together your excerpts of record now, before you write your opening brief. Then, as you write the brief, you can mark each record page that you reference so you can easily add the marked pages to your excerpts.

To learn the rules that govern what your excerpts should and should not include, and how to format them, read 9th Cir. R. 17-1 and 30-1. We also recommend that you read Chapter X of Appellate Practice Guide; see "Practice Guides," above.

Filing Opening Motions

Here are two common motions that you might make at the beginning of your case.

Motion to Proceed in Forma Pauperis

File this motion to ask the court to waive the petitioner's filing fee. To file your motion, you must complete and include Form 4: Motion and Affidavit for Permission to Appeal in Forma Pauperis. The form is available on the court's website at www.ca9.uscourts.gov/forms. In addition, please follow the instructions in "How to Write and File Motions," below.

Motion for Injunction Pending Appeal

You can also file a motion for injunction pending appeal, sometimes called a motion for injunctive relief. This type of motion asks the court to order someone to do something or to stop doing something while your case is in progress. Be specific about what type of relief you are asking for, why the court should grant the relief, and the date by which you want the court to respond. In addition, be sure to follow the instructions in "How to Write and File Motions," below.

Stage Two: Preparing and Filing Briefs

During the second stage of your case, you and opposing counsel will prepare and file written briefs. The required components of a brief are set out in Fed. R. App. P. 28 and 32, and 9th Cir. R. 28-2, 32-1, and 32-2. You should familiarize yourself with those rules and follow them carefully. In this section, we cover some key points of briefing practice.

Opening Brief

You will write and file the first brief in your case. In the opening brief, you must:

- state the facts of the case
- describe the relief you are seeking for the petitioner
- provide legal arguments to support your petition, and
- include citations to the excerpts of record.

Deadline for filing. You must file your opening brief and excerpts of record by the deadline stated in the briefing schedule.

If you do not file your brief on time or request an extension, the court will dismiss your case.

Tips for Writing Your Briefs

Keep these points in mind to write a better brief:

Avoid unnecessary words. Don't use 20 words to say something you can say in ten.

Think things through. Make logical arguments and back them up with legal rules.

Be respectful. You can disagree without being disagreeable. Focus on the strengths of your case, not the character of others.

Tell the truth. Don't misstate or exaggerate the facts or the law.

Proofread. Before you file, carefully check for misspellings, grammatical mistakes, and other errors.

Answering Brief

In response to your opening brief, opposing counsel may file an answering brief. If opposing counsel files an answer, they must send a copy to you.

The time scheduling order sets the deadline for the answering brief. Please note that the opening and answering brief due dates are not subject to the rules for additional time described in Fed. R. App. P. 26(c). In particular, if you file your opening brief early, it does not advance the due date for your opponent's answering brief. (*See* 9th Cir. R. 31-2.1.)

Reply Brief

You are invited to reply to opposing counsel's answering brief, but you are not required to do so. If you write a reply brief, do not simply restate the arguments in your opening brief. Use the reply brief to directly address the arguments in opposing counsel's answering brief.

You must file your reply brief within **21 days** of the date the government serves you with its answering brief.

How to File a Brief

Rules for filing briefs depend on whether or not you are required to file electronically.

CM/ECF. After we review your electronic submission, we will request paper copies of the brief that are identical to the electronic version. Do not submit paper copies until we direct you to do so. (*See* 9th Cir. R. 31-1.) You must also send **two copies** of the brief to any exempt or unregistered opposing counsel.

Exempt Filers Only. Please follow these steps:

- ✓ Send the original document and **six copies** of your brief to the court.
- ✓ Send **two copies** to opposing counsel.
- ✓ Attach a signed certificate of service to the original and to each copy for opposing counsel.
- ✓ Keep a copy for your records.

How to File Excerpts of Record

Submit your excerpts in PDF format using CM/ECF on the same day that you submit your brief. You must serve a paper copy of your excerpts on any unregistered party.

If the excerpts contain sealed materials, you must submit the sealed documents separately, along with a motion to file under seal. (9th Cir. R. 27-13(e).) You must serve sealed filings on all parties by mail or by email if they are registered for electronic filing, or if mutually agreed, rather than through CM/ECF.

After approving your electronic submission, the clerk will direct you to file individually bound paper copies of the excerpts of record with white covers.

To review the rules for filing excerpts, see 9th Cir. R. 30-1.

If You Need More Time to File

Usually, you may ask for one streamlined extension of up to 30 days from the brief's existing due date. (*See* 9th Cir. R. 31-2.2(a) for conditions.)

- CM/ECF. Electronic filers do not need to use a written motion; you may submit your request using the "File Streamlined Request to Extend Time to File Brief" event on CM/ECF on or before your brief's existing due date.
- **Paper filing.** Make your request by filing Form 13 on or before your brief's existing due date. You can find Form 13 on the court's website at www.ca9.uscourts.gov/forms.

If you need more than 30 days, or if the court has already given you a streamlined extension, you

must submit a written motion asking for more time. Your motion must show both diligence and substantial need. You must file your request at least **seven days** before your brief is due. The motion must meet the requirements of 9th Cir. R. 31-2.2(b). You may use Form 14 or write your own motion.

Usually, in response to an initial motion for more time, the court will adjust the schedule. (*See* Circuit Advisory Committee Note to Ninth Circuit Rule 31-2.2.) If you followed the correct procedures to ask for more time but the court doesn't respond by the date your brief is due, act as though the court has granted your request and take the time you asked for.

What Happens After You File

After you and opposing counsel have filed your briefs, a panel of three judges will evaluate the case. Sometimes the court decides a case before briefing is complete (9th Cir. R. 3-6); if that happens, we will let you know.

Judges conduct oral hearings in all cases unless all members of the panel agree that oral argument would not significantly aid the decision-making process. (Fed. R. App. P. 34(a)(2).)

Notification of oral hearings. We will notify you of the potential dates and location of an oral hearing approximately 14 weeks in advance. After you receive notice, you have **three calendar days** to inform the court of any conflicts. We distribute calendars about ten weeks before the hearing date.

Changes to oral hearing dates or location. The court will change the date or location of an oral hearing only if you show good cause for the change. If you wish to submit a request to continue a hearing, you must do so within 14 days of the hearing. Note, however, that the court grants such requests only if you can show exceptional circumstances. (9th Cir. R. 34-2.)

Oral arguments are live streamed to YouTube. Viewers can access them through the court's website. Go to www.ca9.uscourts.gov and choose "Live Video Streaming of Oral Arguments and Events."

Stage Three: The Court's Final Decision

After the judges decide your case, you will receive a memorandum disposition, opinion, or court order stating the result. If you are happy with the outcome, congratulations.

If you or opposing counsel didn't get the final results you want, either of you may take the case further. We explain your options in the section "After Your Case," below.

HOW TO WRITE AND FILE MOTIONS

This section provides general guidelines for writing and filing motions, including motions discussed elsewhere in this guide. The motion you want to make may have special rules—for example, a different page limit or deadline—so be sure that you also read its description, as noted below.

How to Write a Motion

If you want to file a motion with the court, follow these guidelines:

- ✓ Clearly state **what** you want the court to do.
- ✓ Give the legal reasons **why** the court should do what you are asking.
- ✓ Tell the court **when** you would like it done.
- ✓ Tell the court what the opposing party's position is. (Circuit Advisory Committee Note to Ninth Circuit Rule 27-1(5); 9th Cir. R. 31-2.2(b)(6).)
- ✓ If you are filing a response requesting affirmative relief, include your request in the caption. (Fed. R. App. P. 27(a)(3)(B)) and use the correct filing type.
- ✓ Don't write a motion that is more than 20 pages long unless you get permission from the court.

If you like, you may support your motion with an affidavit or declaration. (28 U.S.C. § 1746.)

Cases Scheduled for Argument or Submitted to a Panel

If your case has been (1) scheduled for oral argument, (2) argued, or (3) submitted to or decided by a panel, then the first page or cover of your motion must include the date of argument, submission, or decision and, if known, the names of the judges on the panel. (9th Cir. R. 25-4.)

How to File a Motion

To file your motion, you must follow the rules described in "Deliver Papers the Right Way," at the beginning of this guide. Keep the following points in mind.

- **CM/ECF.** For electronic filing, follow instructions on CM/ECF. If there are any non-registered parties, you must send a hard copy to that party.
- Paper filing. Send the original document to the court and send a copy to opposing counsel. Remember to attach a signed certificate of service to the original and to any copies. Always keep a copy for your own records.

Note that you should not include a notice of motion or a proposed order with your motion. (Fed. R. App. P. 27(a)(2)(C)(ii) and (iii).)

What Happens After You File

The path of a motion depends on the details of your case. Certain motions—for example, a motion to dismiss the case—may automatically stay the briefing schedule. (*See* 9th Cir. R. 27-11.) The following steps are common after filing a motion.

Opposing counsel may respond. After you file a motion, opposing counsel has ten days to file a response. (*See* Fed. R. App. P. 27(a)(3)(A); Fed. R. App. P. 26(c).) In the response, opposing counsel will tell the court why it disagrees with the arguments in your motion.

You may reply to opposing counsel's response. If opposing counsel responds, you may tell the court why you think opposing counsel's view is incorrect. If you file a reply, don't just repeat the arguments in your original motion. Instead, directly address the arguments in opposing counsel's response. You usually have **seven days** to file a reply with the court, starting on the day you are served with their response. (*See* Fed. R. App. P. 27(a)(3)(B).) Normally, a reply may not be longer than ten pages.

The court decides your motion. After you and opposing counsel file all papers related to the motion, a panel of two or three judges will decide the issue.

How to Respond to a Motion from Opposing Counsel

Your opponent may also submit motions to the court. For example, opposing counsel may file a motion to dismiss the case or to ask the court to review the case more quickly than usual. If opposing counsel files a motion, you are allowed to respond with your arguments against it. Your response may not be longer than 20 pages.

Usually, you must file your response with the court no more than **ten days** from the day opposing counsel serves its motion on you.

Read More About These Motions

If you are making one of the following motions, read the section noted here:

Motion to proceed in forma pauperis in "Filing Opening Motions," above.

Motion for injunctive relief pending appeal in "Filing Opening Motions," above.

Motion for extension of time to file a brief in "If You Need More Time to File," above.

Motion for reconsideration in "If You Don't Agree With a Court Decision," below.



Emergency Motions

An emergency motion asks the court to act within 21 days to avoid irreparable harm. Your emergency motion must meet the requirements of 9th Cir. R. 27-3.

If you need emergency relief, you must notify the Emergency Motions department in San Francisco before you file the motion. Call them at 415-355-8020 or e-mail emergency@ca9.uscourts.gov. Please note that a request for more time to file a document with the court or any other type of procedural relief does *not* qualify as an emergency motion. (*See* Circuit Court Advisory Committee Note to 27-3(3).)

Finally, if you absolutely must notify the court of an emergency outside of standard office hours, call 415-355-8000. This line is for true emergencies that cannot wait until the next business day—for example, imminent removal from the United States.

IF YOU DON'T AGREE WITH A COURT DECISION

If you think the court of appeals made an incorrect decision about important issues in your case, you can ask the court to take a second look. You may do this during your case—for example, if you disagree with the court's ruling on a motion. Or you may ask the court to review its final decision at the end of your case.

During Your Case: Motion for Reconsideration

If you disagree with a court order or ruling during your case, you may file a motion for reconsideration stating the reasons why you think the court's ruling was wrong. Your motion may not be longer than 15 pages.

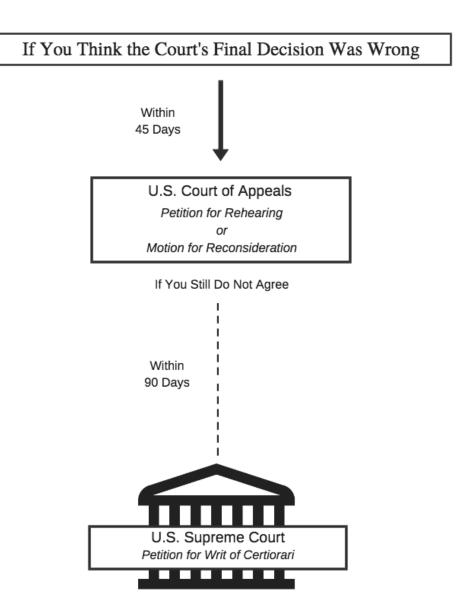
A motion for reconsideration of an order that does not end the case—that is, a non-dispositive order—is due **within 14 days** of the date stamped on the court order. (9th Cir. R. 27-10(a).) In addition to these rules, please follow the general guidelines in "How to Write and File Motions," above.

After Your Case: Motions and Petitions

If you think the court's final decision in your case was wrong and you want to take further action, you have two options:

- File a motion for reconsideration or petition for rehearing in this court.
 - ➤ If the court decided your case in an order, then you would file a motion for reconsideration, as discussed just above. You have **45 days** (instead of 14 days) to file a motion for reconsideration of a court order that ends your case. (9th Cir. R. 27-10(a).)
 - ➤ If the court decided your case in a memorandum disposition or opinion, then you would file a petition for rehearing, discussed below.
- File a petition for writ of certiorari with the U.S. Supreme Court.

It is most common to do these things one after the other—that is, to file a petition for rehearing or motion for reconsideration in this court and then, if that doesn't succeed, petition the Supreme Court. It is technically possible to file both petitions at the same time but that is not the typical approach. Our discussion focuses on the common path.



Court of Appeals: Petition for Rehearing

To ask the court of appeals to review its final decision in your case, you must file a petition for rehearing. Before starting a petition, remember that you must have a legal reason for believing that this court's decision was incorrect; it is not enough to simply dislike the outcome. You will not be allowed to present any new facts or legal arguments in your petition for rehearing. Your document should focus on how you think the court overlooked existing arguments or misunderstood the facts of your case.

A petition for rehearing may not be longer than 15 pages. Your petition is due **within 45 days** of the date stamped on the court's opinion or memorandum disposition. To learn more about petitions for rehearing, see Fed. R. App. P. 40 and 40-1.

Most petitions for rehearing go to the same three judges who heard your original petition. It is also possible to file a petition for rehearing en banc. This type of petition asks 11 judges to review your case instead of three. The court grants petitions for rehearing en banc only in rare, exceptional cases. To learn more about petitions for rehearing en banc, see Fed. R. App. P. 35.

U.S. Supreme Court: Petition for Writ of Certiorari

If the court of appeals denies your petition for rehearing—or if it rehears your case and issues a new judgment you don't agree with—you have 90 days from the denial order or the new decision to petition the U.S. Supreme Court to hear your case. You do this by asking the Supreme Court to grant a writ of certiorari. You must file the petition with the Supreme Court directly. A writ of certiorari directs the appellate court to send the record of your case to the Supreme Court for review.

The Supreme Court is under no obligation to hear your case. It usually reviews only cases that have clear legal or national significance—a tiny fraction of the cases people ask it to hear each year. Learn the <u>Supreme Court's Rules</u> before starting a petition for writ of certiorari. (You can find the rules and more information about the Supreme Court at <u>www.supremecourt.gov.</u>)

HOW TO CONTACT THE COURT

Court Addresses: San Francisco Headquarters

Mailing Address for U.S. Postal Service	Mailing Address for Overnight Delivery (FedEx, UPS, etc.)	Street Address
Office of the Clerk James R. Browning Courthouse U.S. Court of Appeals P.O. Box 193939 San Francisco, CA 94119-3939	Office of the Clerk James R. Browning Courthouse U.S. Court of Appeals 95 Seventh Street San Francisco, CA 94103-1526	95 Seventh Street San Francisco, CA 94103

Court Addresses: Divisional Courthouses

Pasadena	Portland	Seattle
Richard H. Chambers Courthouse 125 South Grand Avenue Pasadena, CA 91105	/	William K. Nakamura Courthouse 1010 Fifth Avenue Seattle, WA 98104

Court Website

www.ca9.uscourts.gov

The court's website contains the court's rules, forms, and general orders, public phone directory, information about electronic filing, answers to frequently asked questions, directions to the courthouses, bar admission forms, opinions and memoranda, live streaming of oral arguments, links to practice manuals, an invitation to join our pro bono program, and more.