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VIA CM/ECF

Ms. Molly C. Dwyer
Clerk
U.S. Court of Appeals for the Ninth Circuit
95 Seventh St.
San Francisco, CA 94103-1526

Re: *Advanced Integrative Science Institute, et al. v. U.S. Drug Enforcement Agency, et al.*, No. 21-70544 (9th Cir.)

Dear Ms. Dwyer:

In response to the government's Notice of Supplemental Authority ("Notice") (Dkt. 63), Petitioners make two points.

First, DEA incorrectly characterizes its letter as "simply inform[ing] the [P]etitioners of pre-existing law" and that consequences flow from the law itself, not the letter. DEA's final determination in the letter has concrete legal consequences because it announces the agency's legal conclusion on an issue of first impression related to its own jurisdiction—whether it has the power to accommodate use of Schedule I drugs for therapeutic purposes under the Right to Try by way of a waiver, exemption, or exception to the Controlled Substances Act's (CSA's) control provisions—and its determination forecloses the possibility of any such exemption, exception, or waiver.

The cases the government cites are therefore distinguishable. In *SCAP*, the EPA's nonbinding guidance merely used a specific method in evaluating permit requests, creating a new testing option for the agency. Here, in contrast, DEA's legal determination forecloses all options for Petitioners. Thus, unlike the case in *SCAP* and *Whitewater Draw*, DEA's

determination here diminishes its obligations to consider requests for waivers, exceptions, or exemptions—to Petitioners' detriment.

Second, this case involves "agency action made reviewable by statute." 5 U.S.C. §704. Under § 877 of the CSA, "[a]ll final determinations, findings, and conclusions" are "final and conclusive decisions of the matters involved" and subject to judicial review.

Neither authority cited by the government involves a special judicial review provision, but as Petitioners explained in their Reply, *Whitewater Draw* acknowledges the significance of one. Reply Br. at 16-17 (citing Op. at 18 (explaining that *Bennett*'s second prong addresses itself to "final agency *action*")). *See also Safer Chemicals, Healthy Fams. v. U.S. Env't Prot. Agency*, 943 F.3d 397, 408, 411 (9th Cir. 2019) ("Where (as here) there is a judicial review provision in a statute, any prudential ripeness considerations are satisfied for cases brought under that provision."). Because DEA's letter constitutes a final agency determination or conclusion, it is "made reviewable by statute" and subject to judicial review under § 704, regardless of *Bennett*'s second prong.

Respectfully,

/s/ Thomas J. Tobin
Thomas J. Tobin

CC: Counsel of Record (Via CM/ECF)