IN THE UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	§	
	§	
	§	Docket No. 22-15
Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT	§	
	§	
	§	

MINDSTATE AND TACTOGENS' MOTION TO PURSUE INTERLOCUTORY APPEAL UNDER 21 C.F.R. § 1316.62

Mindstate and Tactogen (the "Research Companies") request consent to pursue an interlocutory appeal of the Order denying the Motion for Summary Disposition (the "Order" and "Motion"), which raises two important threshold legal issues of first impression with consequences beyond this case:

1. According to 21 U.S.C. § 811(b), prior to scheduling a substance under 21 U.S.C. § 811(a), DEA must obtain a medical and scientific evaluation and recommendation with respect to the substance from HHS. Here, DEA requested an evaluation from HHS in 2008, received that evaluation in 2012, and initiated rulemaking in 2021 based off the 2012 evaluation. Under the CSA, can DEA initiate rulemaking based on an HHS evaluation and recommendation that is almost decade old? ***No***.

2. Under 21 U.S.C. § 811(b), evaluation and recommendations as to "scientific and medical matters" "shall be binding" on DEA. Here, after receiving the 2012 HHS evaluation for the substances at issue, DEA continued to research the substances at issue, and in DEA's own analysis, made medical and scientific findings based on research studies post-2012 that were not presented to HHS. Can DEA significantly supplement HHS's medical and scientific findings in this manner before instituting rulemaking? ***No***.

The Order correctly concludes that there are no genuine disputes of material fact as to these issues. But it errs in applying law and Agency precedent to these facts.

The Order leans on the Administrator's decision in *Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV*, 76 Fed. Reg. 77330, 77333-36 (2011) (the "*Carisoprodol* decision"). In the *Carisoprodol* decision, the Administrator overruled the ALJ and concluded that an

HHS evaluation is not binding ***throughout*** a rulemaking proceeding. The Order contends that the Research Companies "do not fully address" this decision and that it cuts against the Research Companies' position. Not so.

Neither the *Carisoprodol* decision nor the authorities it cites directly address the issues presented here. The Research Companies do not contend, as was the case in the *Carisoprodol* proceedings, that the 2012 HHS evaluation and recommendation binds the agency ***throughout*** the rulemaking proceeding. Rather, they contend (1) the HHS evaluation and recommendation that DEA relies upon to institute rulemaking must be *current* and (2) the Agency is bound to that HHS evaluation as to medical and scientific matters before and during rulemaking. Both points flow from the same idea: under the dual-agency delegation in the CSA for scheduling substances where Congress withheld authority from DEA on medical and scientific matters, the Agency cannot rely on an HHS evaluation that is almost a decade old and moreover, cannot supplement that stale HHS evaluation before or during the rulemaking with findings based on new medical and scientific research.

Text, history, and precedent all point this way. To conclude otherwise would be to read out the dual-agency delegation and imbue DEA with power Congress specifically withheld:

> The Attorney General does not have the sole delegated authority under the CSA. He must instead share it with, and in some respects defer to, the Secretary, whose functions are likewise delineated and confined by the statute. The CSA allocates decisionmaking powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary. In the scheduling context, for example, the Secretary's recommendations on scientific and medical matters bind the Attorney General. The Attorney General cannot control a substance if the Secretary disagrees. 21 U.S.C. § 811(b). See H.R. Rep. No. 91–1444, pt. 1, p. 33 (1970), U.S. Code Cong. & Admin. News 1970, pp. 4566, 4600 (the section "is not intended to authorize the Attorney General to undertake or support medical and scientific research [for the purpose of scheduling], which is within the competence of the Department of Health, Education, and Welfare").

Gonzales v. Oregon, 546 U.S. 243, 265 (2006).

Interlocutory review of the issues raised is thus warranted to prevent exceptional delay, expense, and prejudice to the parties and witnesses involved in this rulemaking. The Order correctly concludes that there are no disputes of material fact. And the issues here are not only purely legal, but case dispositive. If the Administrator concludes that the Agency has not properly followed the required by statute in this case—and she should—this rulemaking would be terminated or postponed until DEA obtains a proper HHS evaluation, as it can easily do in a few months' time.

Put simply, the threshold issues presented are of first impression and would benefit from full briefing before the Administrator. There is little point in proceeding and wasting resources with a full-blown rulemaking when, as explained below, there is a bona fide disagreement on a novel question of law. That being the case, there is a reasonable chance any rule promulgated by the Agency will be overturned by the Court of Appeals, after which the Agency will have to start at square one and start the entire rulemaking process anew. *E.g.*, *California Wilderness Coal. v. DOE*, 631 F.3d 1072, 1085-99 (9th Cir. 2011) (DOE's failure to consult with "affected states" as required by statute was not harmless error and invalidated rule; consultation required more than notice-and-comment rulemaking). Immediate review is both in the public interest because the legal questions go to the heart of how the scheduling process under the CSA functions and is necessary for "efficient execution of the administrative hearing process" in this case. 84 Fed. Reg. 18,138 at 139 (Apr. 30, 2019).

I. Before DEA Schedules a Substance, it Must Obtain a *Current* Evaluation and Recommendation From HHS.

Before instituting rulemaking, DEA cannot rely on an HHS evaluation that is nearly a decade old. As the Research Companies argued in their briefing, this conclusion flows out of the text, structure, intent, and logic of the CSA. The structure of section 811(b) and (c) requires assessment of *current* evidence. *See* Opposed Obj. and Mot. to Stay at ¶ 10.

The Order concludes otherwise. It states that "the statute nowhere contains the word 'current' when discussing the HHS evaluation and recommendation." Order at 10. This is incorrect. Section

811(b), which contains the evaluation and recommendation requirement, textually incorporates subsection (c). 21 U.S.C. § 811(b) (HHS "shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c).'). Two of these subsection (c) factors contain the word "current." Factor 3 is the "state of *current* scientific knowledge regarding the drug or other substance." And Factor 4 in subsection (c) is the "history and *current* pattern of abuse."

The Order states that subsection (c) sets forth "the eight factors to be considered by the Attorney General." Order at 11. True, and according to subsection (b) and case law, it also sets forward factors that must be considered by HHS. *See, e.g.*, *Nat'l Org. for Reform of Marijuana L. (NORML) v. DEA*, 559 F.2d 735, 738 (D.C. Cir. 1977) ("The evaluation prepared by the Secretary *must* address the scientific and medical factors enumerated in Section 201(c)") (emph. added). These factors evaluated by HHS not only relate to accepted medical uses, but importantly, they also relate to "abuse potential." *See id.*

The Order states that "only Factor Three falls within HHS's bailiwick" and suggests Factor 4 does not involve HHS because it "involves information obtained directly by DEA." Order at 11. To the extent the Order asserts that *evaluating* Factor 4 involves information *exclusively* obtained by DEA and that such evaluation is exclusively within DEA's province, the Order cites no support or authority to support the proposition. And that proposition runs contrary to the text and past practice. Subsection (b) leaves nothing to the imagination: "scientific and medical considerations involved" in assessing the "history and current pattern of abuse" must be evaluated by HHS before rulemaking.

And it frequently does. Sometimes in detail. For example, in the December 16, 2013 evaluation supporting the rescheduling of the opiate Hydrocodone, *Schedules of Controlled Substances: Placement of Hydrocodone Combination Products into Schedule II*, DEA-2014-0005-0001 (https://downloads.regulations.gov/DEA-2014-0005-0001/content.pdf), the HHS evaluation contains a detailed Factor 4 analysis of the "history and current pattern of abuse" evaluating current data obtained directly by DEA, but also from other databases, including a National Survey on Drug Use

and Health. For eleven pages, the HHS documents evaluates of the data from a medical and scientific viewpoint. *See also*, *e.g.*, HHS Analysis supporting *Schedules of Controlled Substances: Tramadol; Schedule IV*, 2013-0010-0001 (https://www.regulations.gov/document/DEA-2013-0010-0005) (surveying and analyzing prescription data and other health databases).

Thus, the notion that "the plain language of § 811 requires only that one factor of the HHS evaluation and recommendation reflect current information, not the entire evaluation and recommendation," Order at 11, rests on erroneous statutory construction and ignoring past practice. At least two of the eight factors must be current—maybe more.[1] And that being the case, though not expressly stated, the text and structure of the CSA evidences a clear Congressional intent to require DEA to obtain an evaluation and recommendation from HHS that examines *current* data. *See, e.g.*, *Nat'l R.R. Passenger Corp. v. Bos. & Maine Corp.*, 503 U.S. 407, 417 (1992) ("In ascertaining whether the agency's interpretation is a permissible construction of the language, a court must look to the structure and language of the statute as a whole."). DEA must consult with its HHS counterpart before acting under § 811(a)—not its counterpart of more than a decade ago. *Cf. California Wilderness*, 631 F.3d 1072, 1087 (9th Cir. 2011) ("[R]equiring DOE to actually confer with the affected States is consistent with the purpose of the EPAct … where, as here, Congress has directed an agency to consult

[1] A "current" requirement is also implied by other subsection (c) factors. For example, the statute requires HHS to evaluate what "risk there is to the public health," if any. A complete assessment of "risk to the public health" necessarily considers risk to the public health today, not the circumstances of ten years ago. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency acts arbitrarily and capriciously when it "entirely failed to consider an important aspect of the problem."); *see also, e.g.*, *See also*, *e.g.*, HHS Analysis supporting *Schedules of Controlled Substances: Tramadol; Schedule IV*, 2013-0010-0001 (https://www.regulations.gov/document/DEA-2013-0010-0005) (reviewing in detail medical implications of current overdose data in reviewing toxicity risks and whether tramadol presented risk to public health). Having this factor re-assessed by HHS in 2022 is particularly important because "[i]f a drug creates no danger to the public health, it would be inappropriate to control the drug under [the CSA]." Vodra, The Controlled Substances Act, Drug Enforcement, Vol. 2, No. 2, at 38 (Spring 1975).

with States before taking action that may curtail traditional State powers, we must require that the agency heed Congress's direction.").

The Order's attempt to distinguish situations like those presented in *NAACP v. USPS*, 496 F. Supp. 3d 1, 7 (D.D.C. 2020) is not persuasive. In *NAACP*, the district court exercised jurisdiction over a non-statutory *ultra vires* claim and enjoined the agency from proceeding where the Postal Service failed to seek an advisory opinion from the Postal Regulatory Commission beforehand as required by statute. According to the Order, cases like *NAACP* differ because "nothing in § 811(a) require the *entire* evaluation and recommendation be 'current'." Order at 10. But even under a view that § 811(a) only requires *some* of the HHS evaluation to be current, DEA acts *ultra vires*. If *some* of the § 811(b) evaluation must be current, and the HHS scheduling recommendation is based on all the § 811(b) factors, then the bottom-line HHS scheduling recommendation based on the § 811(b) factors necessarily also must be *current*; otherwise, HHS would either have to ignore one or more factors or rely on *past* data for that factor. But the word "[c]urrent" in the statute cannot mean "past." *Cf. E. E. by & through Hutchison-Escobedo v. Norris Sch. Dist.*, 4 F.4th 866, 872 (9th Cir. 2021) ("The ALJ lacked the legal authority to effectively reinterpret the word 'current' in the statute to 'future.'").

Even if the Order's observation about Factor 4 were correct (it is not) and the statute left a gap for the agency to fill-in with just one factor requiring an assessment of current scientific data (it would not), the position urged by the Agency—that the statute imposes no temporal requirement on how long DEA can wait to act after receiving a recommendation—is unreasonable. Under the view espoused by the Agency, DEA can initiate a scheduling action based on an HHS evaluation and recommendation that is thirty or even fifty years old. Tomorrow, the Agency could initiate a § 811(a) rulemaking based on a thirty-year old evaluation requested in 1990 and tendered in 1992.

This proves too much. And considering the text, structure of the CSA, case law, and the legislative history, it is a reading unlikely to survive scrutiny as it would render the reticulated dual

agency allocation described in *Gonzales*, numerous other cases, and the legislative history, "a worthless addendum to the statute." *Citizens for Resp. & Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180, 188 (D.C. Cir. 2013) (Kavanaugh, J.). "Such a result strongly suggests that the agency's interpretation is impermissible." *Id.* (citing *Williams v. Taylor*, 529 U.S. 362, 404 (2000) ("It is ... a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute.") (internal quotation marks omitted)). *See also Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837, 844 (1984) (no deference to interpretations that are "manifestly contrary to the statute").

II. The Statute Forbids DEA From Supplementing a Stale HHS Evaluation with Significant Additional Medical and Scientific Research.

To reject another of the Research Companies' position—that DEA cannot supplement the stale evaluation *ad libitum* with additional medical and scientific findings of its own—the Order relies on the Administrator's decision in the *Carisoprodol* case and concludes:

> Because the Interested Parties fail to address, and distinguish, cases that run contrary to their interpretation of § 811, they have not met their burden of proving that summary disposition is the only available outcome here under the statutory framework of 21 U.S.C. § 811.

If anything, the *Carisoprodol* decision supports the Research Companies' position and confirms the impropriety of the agency action in this case.

In the *Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV*, 76 Fed. Reg. 77330, 77333-36 (2011) decision, interested party Meda sought to challenge the medical and scientific findings in an HHS report in a § 811(a) rulemaking. The ALJ concluded, however, that the CSA limits the scope of the administrative hearing to those issues outside of medical and scientific fact-findings of the FDA. As a result, the ALJ denied Meda's request, rejecting "Meda's contention that the FDA's findings as to medical and scientific matters are only binding on the Agency's decision as to whether to initiate a scheduling proceeding and that the Secretary's

findings are not binding on either the ALJ or the Administrator in evaluating the record of the hearing." *Id.* at 77,334. "[N]otwithstanding the Secretary's expertise as to the scientific and medical matters," the Administrator concluded, "the Agency is (and the ALJ was) obligated to consider ***Meda's*** contrary evidence even as to the Secretary's medical and scientific findings." *Id.* at 77,336 (emph. added).

The *Carisoprodol* decision thus establishes that an HHS evaluation is not binding on the Administrator ***throughout*** a rulemaking proceeding—start to finish—as the Research Companies explained in their prior briefing.[2] The Administrator is obliged to consider the entire record after the hearing. But contrary to the Order's reasoning, the decision says nothing about the issues presented here: whether the HHS evaluation binds DEA ***before*** the rulemaking or its position during the evidentiary hearing and whether, before or during the hearing, DEA can dramatically supplement a stale HHS evaluation with evidence that HHS never evaluated in the first instance. Whether ***an interested party*** can challenge an HHS evaluation at the merits hearing (issue in *Carisoprodol*) versus and whether ***DEA*** can rely on a stale HHS evaluation and then dramatically supplement such evaluation before the hearing to bolster its position (this case) are very different issues. As clear as the statute is in permitting the former, it is equally clear in forbidding the latter, because permitting DEA to supplement the HHS evaluation and recommendation at will with its own medical and scientific findings reads out a portion of the statute that courts uniformly agree is essential to its functioning. *See, e.g.*, *Oregon*, 546 U.S. at 265 ("The CSA allocates decisionmaking

[2] The Order claims that the Research Companies address the *Carisprodol* decision with "little analysis." Order at 13. In the Revised Supplement, however, the Research Companies explained clearly, albeit succinctly, that while "agency precedent holds that these findings do not bind the agency *throughout* the proceeding, *see id.*, the plain language forbids DEA from *sua sponte* supplementing its Eight Factor analysis with additional medical and scientific evidence." *See* Order at n.13 (emph. added). While the Research Companies respectfully disagree with other ways the Order characterizes the record, most do not relate to the merits and are therefore best saved for another day.

powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary"); *Touby v. United States*, 500 U.S. 160, 162 (1991) ("When adding a substance to a schedule, the Attorney General must follow specified procedures."); *United States v. Kelly*, 874 F.3d 1037, 1042 (9th Cir. 2017) ("The DEA may not schedule the drug if the Secretary recommends against it.").

The Research Companies did not devote more attention to the *Carisprodol* decision for that reason: it stops short of addressing the relevant issues. The issue is not whether they or any other interested party can present additional evidence at the hearing. Nor is it whether the Administrator can evaluate the full record of the hearing—including additional medical and scientific evidence presented by the parties—in deciding on a final rule. According to the *Carisprodol* decision, she clearly can. She must. The issue here is about the Agency's position and conduct *before* the hearing: whether the HHS medical evaluation binds the Agency's position going into the rulemaking before and during the hearing. Put another way, can DEA rely on a 2012 evaluation and then add more recent medical and scientific data to its own 2021 Eight-Factor Analysis?

That the *Carisprodol* decision does not address this question emphasizes the need for interlocutory review. No agency precedent the Research Companies are aware of addresses the question, and how it is decided not only determines the trajectory of these proceedings and what is admissible evidence, but how the Agency must conduct scheduling proceedings going forward. At best, the *Carisprodol* decision does not address these important questions, but some of the authorities it cites do and point away from the conclusion in the Order.

Start with the text. "The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters." 21 U.S.C. § 811(b). If "the Attorney General determines that ***these*** facts and all ***other*** relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that

the drug or other substance should be removed entirely from the schedules." *Id.* So while it is the case that the Attorney General may consider *other* relevant data in deciding to initiate rulemaking, the HHS evaluation binds the Agency going into the rulemaking on the listed factors on medical and scientific matters. An evaluation and recommendation cannot be at once *binding* but also open to liberal supplementation.

Footnote 8 of the *Carisprodol* decision cites the *Reckitt & Coleman* opinion, where the court concluded that while § 811(b) was ambiguous on this question, it could be read so that "DEA must follow HHS's recommendations on the specified matters in deciding whether to initiate scheduling." *Reckitt & Colman, Ltd. v. Adm'r, Drug Enf't Admin.*, 788 F.2d 22, 27 (D.C. Cir. 1986). That is, of course, what the Research Companies argue here. The Administrator noted in the *Carisprodol* decision, that "[w]hile the DC Circuit's discussion is not binding, it is dictum which the Agency ignores at its peril." So too here.[3]

The Order also claims that the Interested Parties do not address *Grinspoon v. DEA*, 828 F.2d 881, 897 (1st Cir. 1987), which the *Carisoprodol* decision cites. But *Grinspoon* is also unhelpful and addresses a different issue. There, the First Circuit rejected the petitioners' challenge to "procedural shortcomings" in the HHS evaluation. *See* Order at 14. But here, the Research Companies do not challenge procedures followed by HHS in rendering an evaluation. Rather, they challenge the procedure followed by ***DEA***, namely: *first*, DEA's failure to seek a *current* evaluation from HHS prior to initiating rulemaking; and *second*, DEA's improper supplementation of the HHS analysis with copious medical and scientific findings of its own.

"As *Grinspoon* makes clear, while the Secretary *is the expert as to the scientific and medical matters at issue* in the scheduling decision, the Attorney General is obligated to conduct

[3] The Agency has not claimed deference under *Chevron* or *Brand X*.

a hearing and to consider *contrary* evidence even as to these issues." *Carisoprodol* decision at 77,335 (emph. added). In discussing *Grinspoon*, the *Carisoprodol* decision thus embraces the Research Companies' position. The Administrator is obliged to consider contrary evidence presented *by the parties*. *See also id.* at 77,336 (noting that Administrator was "obligated to consider *Meda's* contrary evidence").

Grinspoon does highlight two salient points. *First*, HHS has broad discretion in how it produces its evaluation and recommendation to DEA. The recommendation can be brief. [4] But before initiating rulemaking, DEA must seek out a current evaluation from HHS, however brief. The statute forbids DEA from going at the process alone or rehabilitating a deficient or sparing HHS evaluation from years ago. To do so would be to deprive the process of "the expert as to the scientific and medical matters." *Second*, the statute requires the Administrator to conduct a hearing to consider *contrary* evidence, i.e., presented by parties other than the Agency. At the hearing, the Agency is bound by the HHS evaluation and recommendation on medical and scientific matters and cannot present medical and scientific evidence of its own. But at the conclusion of the hearing, the Administrator can (indeed must) consider the entire record "to ensure that the final rule rests on permissible legal standards and substantial evidence." Packing the record before and during the hearing with DEA's own evaluations of the medical and scientific research to supplement a stale evaluation is a far cry from compliance with the elaborate "referral machinery contemplated by Congress" reflected in the statute. *NORML*, 559 F.2d at 749.[5]

[4] The Research Companies do not concede, however, that any pro forma evaluation would suffice. *See NORML*, 559 F.2d at 749 ("The one-page letter makes conclusory statements without providing a basis for or explanation of its findings").

[5] The Order opines that "this is not a case in which DEA conducted its 'own research [because it] was dissatisfied with [the] scientific and medical evaluation.'" But that is exactly what it did. In numerous areas—particularly areas tied to scientific and medical evaluation—the DEA

(continued on the next page)

For the same reasons, *United States v. Sullivan*, 967 F.2d 370, 373–74 (10th Cir. 1992), *United States v. Lafoon*, 978 F.2d 1183, 1184 (10th Cir. 1992), and *United States v. Casey*, 788 F. Supp. 725, 728 (S.D.N.Y. 1991) are of no moment. The Research Companies challenge neither the substance of the HHS evaluation nor the procedure followed by HHS in putting together that evaluation. Rather, they challenge DEA's reliance on an HHS determination and recommendation that everybody acknowledges is not current and DEA's dramatic supplementation of the stale piece.[6]

The Order contends that "the Interested Parties fail to address why, if cursory and essentially pro forma HHS evaluations and recommendations are permissible, ten-year old HHS evaluations and recommendations fall short of the statutory requirement." Order at 15. But history and precedent answer that question as well. The reticulated dual agency process in the CSA is about more than the substance of the HHS evaluation and recommendation. Congress was concerned with unilaterally delegating authority to a law enforcement agency to schedule controlled substances and stifle medical and scientific research.[7] *See NORML*, 559 F.2d at 749. The 1970 Act Congress carefully crafted allocates authority over medical and scientific matters to

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pharmacologist responsible for putting together DEA's 2021 Eight Factor analysis supplemented HHS's findings with more recent research, including ***her own research*** from before her employment with the agency. Presumably, this was done because the analysis in the HHS evaluations was deficient.

[6] These cases are thin reeds. *Sullivan* is a 1992 criminal appeal collaterally challenging the scheduling of amphetamine two decades earlier in 1971. *Casey* is similar, where the defendant sought resentencing in 1991 on grounds that amphetamine was never properly rescheduled to Schedule II in 1971. Notably, while these authorities have limited application to the issues here, they undermine the Order's conclusion that Factor 4 does not require evaluation by HHS. In both cases, the courts noted that in 1971—one year after enactment of the CSA—HHS confirmed that it evaluated scientific and medical considerations with Factor 4 in rescheduling amphetamine.

[7] Interfering with research is precisely the issue in this case and the reason for this rulemaking. DEA proposes interfering with research by scheduling five tryptamine compounds currently being used to develop new groundbreaking medicines, even though over the past two decades there is scant evidence of abuse. Nutmeg, sold in grocery stores, poses a greater public health risk and has a far more significant history and current pattern of abuse. *See, e.g.*, https://www.medpagetoday.com/primarycare/dietnutrition/86335 (discussing popular nutmeg TikTok challenge that can result in hospitalization).

HHS and makes HHS a partner in the delegation to schedule substances. Among other restraints, DEA "may not schedule a substance under the CSA without first obtaining the recommendation of the FDA." *Grinspoon*, 828 F.2d at 890.

In this case, there is every reason to believe that, amidst a resurgence in interest in producing psychedelic medicines, a 2022 HHS might have a drastically different take on these issues than it did in 2012—and perhaps a different recommendation, especially as to the substances at issue in this rulemaking where there is almost no evidence of abuse. The difference between a current *pro forma* HHS evaluation and a ten-year old evaluation, is that in the former case, DEA must still get sign-off from a current HHS that is accountable to the public and respect the statutory design; in the latter case, DEA relies on an evaluation and recommendation from an unaccountable already gone HHS of over a decade ago.

Importantly, the injury here is procedural and informational. Even if the Agency in the exercise of lawful discretion could arrive at the same conclusions after receiving an updated evaluation, moving forward on this evaluation is unlawful. *See, e.g.*, *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 25 (1998); see also C*tr. for Biological Diversity v. EPA*, 861 F.3d 174, 185 (D.C. Cir. 2017) (petitioner satisfied redressability prong by showing that the agency "could reach a different conclusion" with the necessary data).

III. The Research Companies Do Not Bear the Burden of Showing Compliance With the Statute; The Agency Does.

The Order also erroneously states that, "[a]s the moving party, the Interested Parties bear the burden of justifying the relief they seek—summary dismissal." 21 C.F.R. § 1316.56."). Order at 10; *see also* Order at 15. Section 1316.56 does not support this conclusion. The rule states precisely the opposite: "At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof." *Id. See also* 5 U.S.C. § 556(d) (similar).

Here DEA is the proponent of the rule. Therefore, by regulation and statute, DEA has the burden of proving all elements required to sustain a final rule, including showing that it has complied with procedural items. The burden of persuasion should not shift to the Research Companies on a motion for summary disposition or at any point in the proceedings, just as the burden of persuasion does not shift in civil litigation on a motion for summary judgment.

CONCLUSION

Allowing the agency to rely on a 2012 HHS Report and supplement that report with significant additional medical and scientific findings rewrites the CSA and is without precedent. Interlocutory review to the Administrator is warranted so she can review this important unprecedented question and prevent exceptional delay, expense, and prejudice to the parties and witnesses involved in this rulemaking.

Date: May 16, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

On May 16, 2022, I served a copy of this motion on via email to the DEA Judicial Mailbox (ECF-DEA@dea.gov) and the Government Mailbox at (dea.registration.litigation@dea.gov) and: (1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; (2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net; (3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com; (4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com; (5) Dillian DiNardo, Kykeon Biotechnologies Inc., via email at dillan@mindstate.design; (6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com; and (7) Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at mzorn@yettercoleman.com.

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