UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

REV. RYAN "SASHA" GALLAGHER,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION *et al*.,

Defendants.

Civil Action No. 18-2154 (TJK)

MEMORANDUM OPINION

Plaintiff Rev. Ryan "Sasha" Gallagher, proceeding *pro se*, sues the Food and Drug Administration (FDA) and Dr. Stephen D. Hardeman, a senior official at its Center for Drug Evaluation and Research. Before the Court is Defendants' motion to dismiss. Because Gallagher's complaint does not include a short and plain statement showing why he is entitled to relief, the Court will grant the motion and dismiss the case without prejudice for failure to comply with Federal Rule of Civil Procedure 8(a).

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Pleadings prepared by *pro se* litigants are held to less stringent standards than those that apply to pleadings prepared by lawyers. *See Haines v. Kerner*, 404 U.S. 519, 520 (1972). However, *pro se* litigants must follow the Federal Rules of Civil Procedure. *Jarrell v. Tisch*, 656 F. Supp. 237, 239 (D.D.C. 1987). Rule 8(a) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). "The purpose of the rule is to give fair notice of the claim being asserted so as to permit the adverse party the opportunity to file a responsive answer, prepare an adequate defense and determine whether the doctrine of *res judicata* is applicable." *Brown v. Califano*, 75 F.R.D. 497, 498

(D.D.C. 1977). "Where a complaint is insufficiently focused, it places an undue burden on the defendant to answer or move and it invites unnecessary delay and confusion in the proceedings." *Achagzai v. Broad. Bd. of Governors*, 109 F. Supp. 3d 67, 71 (D.D.C. 2015).

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Even liberally construed, Gallagher's complaint and his subsequent pleadings do not contain a short and plain statement explaining why he is entitled to relief.[1] Gallagher's complaint focuses on the substance 4-Hydroxy-N-methyl-N-isopropyltryptamine ("4-OH-MiPT"). According to Gallagher, it is central to his religious beliefs:

> Within the Shaivite Temple, we do believe that Dr. Sasha Shulgin performed Miracles in his life, we do believe Shaivism, created in the Bronze age, is the Religion of the Atomic Age. We believe 4-OH-MiPT to be the Lord God Soma. AN UNSCHEDULED SUBSTANCE. 4-OH-MiPT is a Sacred Food, not a Drug.

ECF No. 1 ("Compl.") at 2. Gallagher alleges that he wrote to the FDA about "a Religious Exemption for 4-OH-MiPT use within the practices of the Shaivite Temple." *Id.* at 1. Hardeman responded. *Id.* at 4. The FDA interpreted Gallagher's letter as a request for an exemption from the requirement to submit an Investigational New Drug Application (IND) to conduct a clinical investigation of 4-OH-MiPT. *Id.*; *see also* 21 C.F.R. § 312.2(b). Hardeman listed the requirements for an exemption, but informed Gallagher that he did not appear to qualify for one. Compl. at 4. Hardeman informed Gallagher that, as a result, he would have to submit an IND if he wished to conduct a clinical investigation of 4-OH-MiPT. *Id.* Gallagher further alleges that Hardeman told him in a later email that the FDA "does not consider Religiousity [sic] when evaluating the safety of proposed clinical experimentation on Humans." *Id.* at 2.

[1] The Court considers a *pro se* plaintiff's pleadings "*in toto*" when determining whether to dismiss. *See Brown v. Whole Foods Mkt. Grp., Inc.*, 789 F.3d 146, 151 (D.C. Cir. 2015).

In his complaint, Gallagher alleges that the FDA's "IND program is in violation of the First Amendment," and cites a case in which the D.C. Circuit held that the Drug Enforcement Administration (DEA) was not required to provide a religious-use exemption from federal laws proscribing marijuana. *Id.* at 2 (citing *Olsen v. Drug Enf't Admin.*, 878 F.2d 1458 (D.C. Cir. 1989). He also asserts that "they are refusing to create processes similar to the DEA's" and cites a case in which the Supreme Court held that the Department of Justice had not shown, under the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb–1 *et seq.*, a compelling interest in barring a religious sect's sacramental use of a substance regulated under Schedule I of the Controlled Substances Act (CSA), 21 U.S.C. § 812(c). *Id.* at 3 (citing *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006)).

The complaint also includes several unexplained references to marijuana. For example, Gallagher references "Federal Marijuana Patients, [sic] and GW Pharma THCv," and says he told Hardeman that "[w]e consider THCv to be the non-Marijuana form of Lord Shiva." *Id.* at 1. And he alleges that "Synthetic THCv is not Scheduled" and cites a case from outside this Circuit holding that "the DEA's relevant rules and regulations may be enforced only insofar as they ban the presence of marijuana or synthetic THC." *Id.* at 7 (quoting *Hemp Indus. Ass'n. v. Drug Enf't Admin.*, 357 F.3d 1012, 1013 (9th Cir. 2004)). But he never explains how marijuana or THC bear on the instant case.[2]

[2] Gallagher briefly revisits marijuana in his "Motion for Rule 5.1 Hearing & Jurisdiction Response," which the Court construes as an opposition to the motion to dismiss. ECF No. 15 at 1 ("I would first like to point out that the Defendant Completely ignored the [Center for Drug Evaluation and Research] and other aspects of this case, involving Marijuana as an Investigative New Drug and the [National Institute on Drug Abuse] contract with the University of Mississippi."). Again, he fails to explain how marijuana is relevant to any claim in this case. To the extent he seeks to relitigate his past marijuana-related claims that have already been adjudicated, *res judicata* bars him from doing so. *See, e.g.*, *Gallagher v. DEA*, No. 3:18-CV-

These allegations in the complaint do not constitute "a short and plain statement of the claim" showing that Gallagher "is entitled to relief." Fed. R. Civ. P. 8(a). An IND is the start of the process through which pharmaceutical drug sponsors seek FDA approval to test proposed new pharmaceutical drugs for safety and efficacy, before they are approved for sale and marketing. *See* 21 U.S.C. § 355(i); 21 C.F.R. § 312.1. But Gallagher does not allege that he *seeks* to test, sell, or market a pharmaceutical drug. *See generally* Compl. Nor does he allege that his intended use of 4-OH-MiPT—whatever that may be—would cause that substance to be subject to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* *See* 21 U.S.C. § 321(g)(1) (defining the term "drug").[3] In sum, he does not explain how the "IND program" or any part of the FDCA even applies to him, let alone violates his First Amendment rights or burdens the practice of his religion.[4]

Gallagher's subsequent filings only further muddy the waters, as he appears to shift the basis for his claim away from the allegations in the complaint. In his Opposition, he reiterates

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263-NBB-DAS, 2019 WL 1997481 (N.D. Miss. Apr. 16, 2019), *R. & R. adopted*, 2019 WL 1996675 (N.D. Miss. May 6, 2019); *Gallagher v. Drug Enforcement Administration*, No. 1:18-CV-2439-UNA (D.D.C. Dec. 3, 2018).

[3] As Defendants point out, 4-OH-MiPT does not appear in the official U.S. Pharmacopeia. ECF No. 12 at 3 n.2. Therefore, to be subject to the FDCA, it must fall within one of the statute's conduct-based definitions. *See* 21 U.S.C. § 321(g).

[4] Because the complaint fails to allege how Gallagher was injured by the "IND program," it also warrants dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *See Henthorn v. Dep't of Navy*, 29 F.3d 682, 684 (D.C. Cir. 1994) (noting that, despite the lenient standard applied to *pro se* pleadings, "the district court 'need not accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint'"). And to the extent Gallagher alleges an injury solely based on the government's abstract failure to follow the law, he lacks standing, and the complaint warrants dismissal for lack of subject-matter jurisdiction as well. *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 485 (1982) (finding no standing where a plaintiff did not "identify any personal injury suffered by them *as a consequence* of the alleged constitutional error").

that "our Temple, the Shaivite Temple, believes that 4-OH-MiPT, Miprocin, is a Soma, a Sacred Drink, a Sacred Substance, used by and given to us by the Gods." ECF No. 15 at 1. He requests, with more specificity than in the complaint, that he "be allowed to Manufacture and Transport this NON-SCHEDULED SUBSTANCE" and that he "be able to use it in Ritual and Ceremony." *Id.* And he suggests that he is barred from doing so under the Controlled Substance Analogue Enforcement Act ("Analogue Act"), *see* 21 U.S.C. § 813, because "the FDA and DEA are treating 4-OH-MiPT, Miprocin, when ingested by Humans, as if it is a Schedule I substance." *Id.* But once again, Gallagher does not allege that he seeks to test, sell, or market a pharmaceutical drug such that he would need an IND, the focus of his complaint and the letter he received from Defendants. Moreover, he does not plead facts that suggest that the government is, in fact, treating 4-OH-MiPT as a Schedule I substance. And even assuming it is, this allegation hardly clarifies his claim—because he *also* asserts that the FDA informed him that the Analogue Act "has no bearing on the applicability of" an IND exemption. *See* Compl. at 2. As Defendants point out, "[t]he laws regulating scheduled substances are separate and distinct from the new drug provisions of the FDCA."[5] ECF No. 12 at 4.

Finally, in a subsequent "Motion to Deny Defendant," Gallagher argues—for the first time—that "this is an Administrative Procedure Act (APA) case, regarding the FDA." ECF No.

[5] To the extent that Gallagher's claim is grounded in a concern that the CSA will be enforced against him in the future, he does not plead facts suggesting that such enforcement is imminent or even likely, especially given that he concedes that 4-OH-MiPT is not a controlled substance. Therefore, he lacks standing to assert a claim based on future enforcement, and his complaint warrants dismissal for lack of subject-matter jurisdiction. *See Seegars v. Gonzales*, 396 F.3d 1248, 1255 (D.C. Cir. 2005) (holding that plaintiffs who "allege no prior threats against them or any characteristics indicating an especially high probability of enforcement against them" lacked pre-enforcement standing).

20 at 1. But he does not identify any allegedly unlawful final agency action that caused him harm. *See* 5 U.S.C. § 704.[6]

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As explained above, nowhere in Gallagher's complaint or subsequent pleadings does he provide a short and plain statement of why he is entitled to relief. Therefore, he has failed to comply with Rule 8(a). Accordingly, the Court will grant Defendants' motion and dismiss the case without prejudice. A separate order will issue.

/s/ Timothy J. Kelly
TIMOTHY J. KELLY
United States District Judge

Date: November 25, 2019

[6] To the extent that Gallagher suggests that the letter he received from Hardeman is final agency action, he has pled no facts that suggest that this is so. To the contrary, Hardeman noted that Gallagher's original letter to the FDA had "reference[d] the Religious Freedom Restoration Act (RFRA)" but clarified that the FDA's response was "limited to the issues raised in [his] letter related to the Federal Food, Drug, and Cosmetic Act." Compl. at 4. Therefore, it appears the letter did not reflect agency action *of any kind* concerning Gallagher's request as it related to his religious beliefs. *Cf. Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944 (D.C. Cir. 2012) (holding that a letter from the FDA warning of potential enforcement action in the future did not constitute final agency action under the APA).