UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JEFFREY NATHAN SCHIRRIPA, **Plaintiff,** **v.** **JANET WOODCOCK,** **Defendant.**	**Civil Action No. 20-532 (JEB)**

MEMORANDUM OPINION

Like many entrepreneurs in the United States, Plaintiff Jeffrey Nathan Schirripa has jumped on the marijuana trend. But unlike those who sell unregulated body lotions or dog treats laced with the cannabinoids found in the popular plant, Schirripa has developed a dietary supplement that requires approval from the Food and Drug Administration. After failing on his first petition to the agency, Plaintiff asked for reconsideration. Following denial of this reconsideration petition, he filed this *pro se* suit against the then-FDA commissioner, asking this Court to set aside the agency's decision. In now seeking summary judgment, FDA has identified two reasons why the Court should not do so: Schirripa lacks standing and the agency decision conformed to standards of rationality. Although the Court disagrees on standing, it finds ample justification for the agency's decision and will therefore grant its Motion for Summary Judgment.

I. Background

While the Court must at this stage view the facts in the light most favorable to Schirripa, see Talavera v. Shah, 638 F.3d 303, 308 (D.C. Cir. 2011), he has made parsing such facts is no

easy matter. According to Plaintiff, he has "invented the first method of commercializing a new line of dietary supplements" containing marijuana-derived cannabinoids. See ECF No. 1 (Compl.), ¶ 1; see also ECF No. 25 (Def. MSJ) at 1. In September of 2015, Schirripa filed a citizen petition with FDA urging it to "protect and utilize" an older patent "pertain[ing] to methods of using cannabinoids, specifically cannabidiols, as a class of antioxidant drugs with particular application as neuroprotectants," which is held by the Department of Health and Human Services. See Def. MSJ at 5 (citation omitted). The citizen-petition process allows an individual to ask the FDA commissioner "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). The commissioner must then deny, approve, dismiss, or provide a tentative response to any petition within 180 days of receipt. Id. § 10.30(e). After FDA did not respond within 180 days, Plaintiff filed a different suit in May 2017 alleging violations of the Administrative Procedure Act that were premised on such delay — violations that were cured when FDA denied the petition in July of that year. See Schirripa v. Gottlieb, No. 17-1060, 2018 WL 4567163, at *1 (D.D.C. Sept. 24, 2018); Def. MSJ at 5–6.

Following his failure on the first petition, Schirripa filed a petition for reconsideration, see 21 C.F.R. § 10.33, "which included gifted-samples" of his product and a "proposed . . . partnership" with the agency. See Compl., ¶ 4. Defendant denied the reconsideration petition on several grounds. See Def. MSJ at 7. First, FDA found it untimely under the applicable 30-day deadline, see 21 C.F.R. § 10.33(b), and the agency also found "no good cause for extending that deadline." Def. MSJ at 7. Additionally, it applied the four necessary factors for reconsideration outlined in 21 C.F.R. § 10.33(d): 1) "The petition demonstrates that relevant information or views contained in the administrative record were not previously or adequately considered"; 2)

"The petitioner's position is not frivolous and is being pursued in good faith"; 3) "The petitioner has demonstrated sound public policy grounds supporting reconsideration"; and 4) "Reconsideration is not outweighed by public health or other public interests." Id. FDA concluded that "it had carefully reviewed all relevant information" in the initial petition and "that it would neither be in the public interest nor the interest of justice to grant the reconsideration petition." Def. MSJ at 7–8.

Schirripa took issue with the denial, prompting this suit asking the Court to set aside FDA's decision. See Compl. at 1. Plaintiff alleges that "there is substantial evidence that would lead a reasonable person to conclude that there is no rational basis" for FDA's denial. Id., ¶ 12. Specifically, he asserts that Defendant neglected to consider his "gifted-sample." Id., ¶¶ 10–11. After several months of back and forth, the parties have now filed Cross-Motions for Summary Judgment.

II. Legal Standard

Because of the limited role federal courts play in reviewing administrative decisions, the typical Federal Rule 56 summary-judgment standard does not apply to the parties' dueling Motions. Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89–90 (D.D.C. 2006). Instead, "the function of the district court is to determine whether or not . . . the evidence in the administrative record permitted the agency to make the decision it did." Id. at 90 (quoting Occidental Eng'g Co. v. INS, 753 F.2d 766, 769 (9th Cir. 1985)). Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and is otherwise consistent with the APA standard of review. Bloch v. Powell, 227 F. Supp. 2d 25, 31 (D.D.C. 2002).

The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if, for example, the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Under this "narrow" standard of review, an agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" Id. (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)). Put another way, the court's role is only to "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Am. Oceans Campaign v. Daley, 183 F. Supp. 2d 1, 4 (D.D.C. 2000) (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971)).

It is not enough, then, that the court would have come to a different conclusion from the agency. See Oceana, Inc. v. Pritzker, 24 F. Supp. 3d 49, 58 (D.D.C. 2014) (citing Steel Mfrs. Ass'n v. EPA, 27 F.3d 642, 646 (D.C. Cir. 1994)). The reviewing court "does not substitute its own judgment for that of the agency." Id. A reviewing court holds an agency only to "certain minimal standards of rationality." Nat'l Env't Dev. Ass'ns Clean Air Project v. EPA, 686 F.3d 803, 810 (D.C. Cir. 2012) (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36–37 (D.C. Cir. 1976) (*en banc*)).

III. Analysis

Plaintiff maintains that judgment in his favor is appropriate on his APA claims, while FDA counters that Schirripa both lacks standing and cannot succeed on the merits. The Court will begin its analysis with the former issue. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94 (1998) (establishing that courts are "bound to ask and answer" the "first and fundamental question" of jurisdiction) (citation omitted). Because it finds that Schirripa has standing, it will then move to the central question presented — whether FDA made a clear error in denying reconsideration.

A. Standing

Contrary to what laypersons might believe, not every aggrieved person gets to have her day in court. To properly invoke the jurisdiction of federal courts, a plaintiff must demonstrate that she has a "case" or "controversy" within the parameters of Article III, a doctrine known as standing. See U.S. Const. art. III, § 2, cl. 1. Standing requires, at a minimum, that a plaintiff show by a "substantial probability," Sierra Club v. EPA, 292 F.3d 895, 899 (D.C. Cir. 2002) (citation omitted), that she "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016). The "injury in fact" must be both "(a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 180 (2000). An injury is "particularized" when it "affect[s] the plaintiff in a personal and individual way," and it is "concrete" when it is "real, and not abstract," Spokeo, 136 S. Ct. at 1548 (citations and internal quotation marks omitted), although "intangible injuries can nevertheless be concrete." Id. at 1549. The Court "assume[s] for purposes of standing that [Plaintiff] will

ultimately receive the relief sought." Fla. Audubon Soc'y v. Bentsen, 94 F.3d 658, 665 (D.C. Cir. 1996) (*en banc*).

Although Plaintiff does not address standing directly, it is clear from his filings that his injury stems from FDA's denial of his reconsideration petition, foreclosing the marketing of his product. See Compl., ¶¶ 14–16; ECF No. 33 (Pl. Reply) at 1–2. While Defendant contends that this alleged injury is "highly speculative, if not impossible," Def. MSJ at 11, the Court is not persuaded. Schirripa has identified an agency decision that "affect[s him] in a personal and individual way," Spokeo, 136 S. Ct. at 1548: FDA has denied, in a final action, Plaintiff's request for reconsideration, leaving him with no recourse but to challenge the denial in court. The agency counters, without entirely explaining the point, that Schirripa has not suffered any injury because his ability to use the older patent is outside the agency's control, as such patent is assigned to HHS and expired regardless. See Def. MSJ at 6, 11–12. For purposes of standing, however, the Court must assume that Schirripa will succeed on his reconsideration petition and obtain the ability to market his product. See Fla. Audubon Soc., 94 F.3d at 665.

The final two standing elements of causation and redressability can be quickly addressed together. Here, it is not hard to see that FDA directly caused the injury Schirripa has alleged: the agency itself denied the reconsideration petition that is the crux of Plaintiff's case. In that same vein, a decision by this Court setting aside FDA's denial would directly redress the injury by requiring reconsideration of that petition. And, again, although the agency casts significant doubt on the upshot of such reconsideration, see Def. MSJ at 12–13, that does not factor into the standing analysis. See Fla. Audubon Soc., 94 F.3d at 665.

Because the Court finds that Schirripa has satisfied all three standing requirements, it proceeds to consideration of the merits.

B. Merits

In seeking summary judgment, FDA first points out that it correctly denied Schirripa's reconsideration petition as untimely. See Def. MSJ at 7. By regulation, requests for reconsideration "must be submitted . . . no later than 30 days after the date of the decision involved." 21 C.F.R. § 10.33(b). Here, the relevant date of decision is July 27, 2017, when FDA denied Plaintiff's citizen petition. See Def. MSJ at 6. Schirripa did not file for reconsideration until September 1, 2017, id. at 7, five days past his deadline. Denial was thus appropriate. It is true that FDA "may, for good cause, permit a petition to be filed after 30 days," 21 C.F.R. § 10.33(b), but Schirripa has shown no such cause. He claims only that "the parties had a pending case" presenting "issues to be resolved" such that the "the deadlines for filing could not reasonably be met." Pl. Reply at 2. He is referring to his initial suit alleging that FDA failed to respond to his citizen petition within the 180 days required by the APA. See Schirripa, 2018 WL 4567163. Yet Schirripa obtained all the relief he sought there when FDA addressed his petition on July 27. He has thus not explained what further "issues" remained that would have impeded his ability to file for reconsideration. FDA's denial of his petition as untimely was thus plainly reasonable.

Even if this Court found that Schirripa's petition somehow did meet the statutory filing deadline, FDA also denied reconsideration based on the four factors laid out in 21 C.F.R. § 10.33(d), which were described earlier. See *supra* Section I. The Court evaluates FDA's findings "narrow[ly]," giving significant deference to the agency's conclusions. Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43. Section 10.33(d) essentially asks whether the petitioner has pointed to non-frivolous, overlooked information justifying reconsideration. See 21 C.F.R. § 10.33(d). Here, FDA found that "it had carefully considered all relevant information," and that the new

information Plaintiff points to — namely, the "gifted-samples" — was "not previously submitted" and was thus "outside the purview of reconsideration." Def. MSJ at 15–16. Section 10.33(d) makes clear that new information must be "in the administrative record," and the gifted samples (whose value remains opaque) were not. The agency further found no "public policy grounds to support reconsideration" and no "interest[s] of justice" in favor of otherwise granting the petition. See Def. MSJ at 15–16. Again, given the deference owed to FDA, the Court finds that its determinations contain no "clear error[s] of judgment." Am. Oceans Campaign, 183 F. Supp. 2d at 4 (quoting Overton Park, 401 U.S. at 416). The Court, accordingly, would uphold the agency's reasoning even had the petition been timely submitted.

IV. Conclusion

For the foregoing reasons, the Court will issue a contemporaneous Order granting Defendant's Motion for Summary Judgement and denying Plaintiff's.

/s/ *James E. Boasberg*
JAMES E. BOASBERG
United States District Judge

Date: May 24, 2021