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

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