Sproule v. United States Food and Drug Administration et al Doc. 27

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 9:17-CV-80709-ROSENBERG/REINHART

JUSTIN SPROULE,

Plaintiff,

v.

UNITED STATES FOOD AND
DRUG ADMINISTRATION *et al.*,

Defendants.
_____/

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

THIS CAUSE is before the Court on Defendants' Motion to Dismiss Plaintiff's Complaint with Incorporated Memorandum of Law in Support Thereof [DE 17]. The Court has carefully considered Defendants' Motion, Plaintiff's Opposition thereto [DE 20], and Defendants' Reply [DE 23], and is otherwise fully advised in the premises. For the reasons set forth below, Defendants' Motion is **GRANTED** and this case is **DISMISSED WITHOUT PREJUDICE**.

I. INTRODUCTION

This is an action pursuant to the Administrative Procedure Act to set aside a Memorandum of Agreement between Santa Fe Natural Tobacco Company, Inc. ("Santa Fe") and the United States Food and Drug Administration ("FDA"). Plaintiff Justin Sproule asserts that, by entering into the Memorandum of Agreement, the FDA has unlawfully permitted Santa Fe to circumvent the statutory procedure for obtaining authorization to sell a modified risk tobacco product. Because the Court concludes that Plaintiff has not sufficiently alleged standing to sue, this action must be dismissed without prejudice for lack of subject matter jurisdiction.

Dockets.Justia.com

II. LEGAL AND FACTUAL BACKGROUND

Pursuant to the Family Smoking Prevention and Tobacco Control Act (the "Act"), the FDA is responsible for regulating the tobacco industry, including modified risk tobacco products. *See* 21 U.S.C. § 387a(a).[1] As defined by the Act, a "modified risk tobacco product" is "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." 21 U.S.C. § 387k(b)(1). This includes "a tobacco product . . . the label, labeling, or advertising of which represents explicitly or implicitly that . . . the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products," 21 U.S.C. § 387k(b)(2)(A)(i)(I), or that "the tobacco product or its smoke does not contain or is free of a substance," *id.* § 387k(b)(2)(A)(i)(III).

"No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product" without first submitting an application to and obtaining authorization from the FDA. *See* 21 U.S.C. § 387k(a). The FDA may not provide authorization without first reviewing the application and making certain findings:

> [T]he [FDA] shall . . . issue an order that a modified risk product may be commercially marketed only if the [FDA] determines that the applicant has demonstrated that such product . . . will—
>
> (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
>
> (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

21 U.S.C. § 387k(g)(1).

[1] The Act provides that "[t]obacco products, including modified risk tobacco products . . . shall be regulated by the Secretary [of Health and Human Services] . . . ." *See* 21 U.S.C. § 387a(a); 21 U.S.C. § 321(d). The Secretary of Health and Human Services has delegated all functions vested in him under the Act to the Commissioner of the FDA. *See* FDA Staff Manual Guide 1410.10(1)(A)(1), https://www.fda.gov/downloads/AboutFDA/ReportsManuals Forms /StaffManualGuides/UCM273771.pdf.

"Any person may file . . . an application for a modified risk tobacco product." 21 U.S.C. § 387k(d). The application must include:

> (1) a description of the proposed product and any proposed advertising and labeling;
>
> (2) the conditions for using the product;
>
> (3) the formulation of the product;
>
> (4) sample product labels and labeling;
>
> (5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;
>
> (6) data and information on how consumers actually use the tobacco product; and
>
> (7) such other information as the [FDA] may require.

21 U.S.C. § 387k(d). With the exception of "matters in the application which are trade secrets or otherwise confidential, commercial information," the FDA must make the application publicly available and request comments by interested persons. 21 U.S.C. § 387k(e).

Santa Fe manufactures and markets Natural American Spirit cigarettes. *See* DE 1, Complaint ¶ 4. These cigarettes are labeled and advertised as "Natural," "Additive Free," "100% Additive Free," and "Organic," terms that suggest the cigarettes carry health benefits and reduced risk. *Id.* ¶¶ 4, 18. Santa Fe has never submitted an application for a modified risk tobacco product. *Id.* ¶ 6.

On August 27, 2015, the FDA issued a Warning Letter to Santa Fe stating that the FDA had determined that Natural American Spirit cigarettes were modified risk tobacco products and were being sold or distributed without FDA authorization. *Id.* ¶ 44. Specifically, the FDA stated that Natural American Spirit cigarettes were modified risk tobacco products because the product labeling, "which uses the descriptors 'Natural' and 'Additive Free[,]' represents explicitly and/or implicitly that the products or their smoke do not contain or are free of a substance and/or that

the products present a lower risk of tobacco-related disease or are less harmful" than other cigarettes. *Id.* ¶ 45.

On January 23, 2017, the FDA and Santa Fe entered into a Memorandum of Agreement providing that the FDA would not initiate an enforcement action as long as Natural American Spirit cigarettes were not advertised as "natural" or "additive free," but Santa Fe could continue to use the term "Natural" in the Natural American Spirit brand name and trademarks. *Id.* ¶¶ 46–47. According to Plaintiff, this effectively "authorizes Santa Fe to sell and distribute [a modified risk tobacco product] without going through *any* of the procedures mandated by the Act—including public notice and comment on an application—and without FDA making *any* of the findings mandated by the Act for an FDA order authorizing [a modified risk tobacco product]." *Id.* ¶ 47. Plaintiff asserts that, because it permits Santa Fe to market a modified risk tobacco product without complying with the statutory procedure for obtaining authorization, the FDA's decision to enter into the Memorandum of Agreement is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *see* 5 U.S.C. § 706(2)(A), and must therefore be set aside pursuant to the Administrative Procedure Act. *Id.* ¶ 49.

III. DISCUSSION

In the Motion presently before the Court, Defendants argue that Plaintiff has failed to establish standing and that this action must therefore be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. In the alternative, Defendants argue that this action must be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. The Court agrees that this action must be dismissed for lack of subject matter jurisdiction. Having reached that conclusion, the Court does not address whether Plaintiff has failed to state a claim upon which relief can be granted.

"Article III of the Constitution limits the jurisdiction of the federal courts to the consideration of 'Cases' and 'Controversies.'" *Stalley ex rel. U.S. v. Orlando Reg'l Healthcare Sys., Inc.*, 524 F.3d 1229, 1232 (11th Cir. 2008) (quoting U.S. Const. art. III, § 2). To satisfy this case-or-controversy requirement and establish standing to sue, Plaintiff must show:

> (1) [he] has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Fla. Wildlife Fed'n, Inc. v. S. Fla. Water Mgmt. Dist., 647 F.3d 1296, 1302 (11th Cir. 2011) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). In the absence of Article III standing, this Court lacks subject matter jurisdiction. *See Stalley*, 524 F.3d at 1232. As the party invoking the Court's jurisdiction, Plaintiff bears the burden of establishing its existence. *See id.* (quoting *Parker v. Scrap Metal Processors, Inc.*, 386 F.3d 993, 1003 (11th Cir. 2004)). To meet this burden at the pleading stage, Plaintiff must clearly allege facts demonstrating each of the three elements of Article III standing. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citing *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). This case must be dismissed[2] if Plaintiff fails to meet this burden. *See Fla. Wildlife Fed'n*, 647 F.3d at 1302 (11th Cir. 2011) (citing *CAMP Legal Def. Fund, Inc. v. City of Atlanta*, 451 F.3d 1257, 1277 (11th Cir. 2006)).

A. Injury in Fact

With respect to the first element of standing, Plaintiff argues that he "has clearly pled sufficient facts to establish standing by alleging an injury in fact in the deprivation of information to which he, an interested member of the public, is entitled under the Tobacco

[2] "A dismissal for lack of subject matter jurisdiction is not a judgment on the merits and is entered without prejudice." *Stalley*, 524 F.3d at 1232 (citing *Crotwell v. Hockman–Lewis Ltd.*, 734 F.2d 767, 769 (11th Cir. 1984)).

Control Act." DE 20 at 6–7. More specifically, Plaintiff argues that no application to sell Natural American Spirit cigarettes was ever submitted despite the FDA's determination that these cigarettes were modified risk tobacco products, and the information required to be submitted in conjunction with the application was never made publicly available, because the FDA entered into a Memorandum of Agreement that allowed Santa Fe to circumvent the statutory requirements. According to Plaintiff, "[i]f the FDA had followed the procedures that Congress designed, Plaintiff would have had access to a whole host of information that Plaintiff now lacks. The FDA's violation of statutory requirements harms Plaintiff by depriving him of information to which he is legally entitled." *Id.* at 7.

The Court need not, and therefore does not, decide whether Plaintiff has sufficiently alleged an injury in fact. Assuming for the sake of argument that Plaintiff has sufficiently alleged an informational injury as described above, Plaintiff has not sufficiently alleged either causation or redressability. Accordingly, Plaintiff lacks standing to sue.

B. Causation and Redressability

The Court begins by noting that Plaintiff's asserted injury arises from the FDA's alleged failure to regulate Santa Fe's modified risk tobacco products as prescribed by law.

> When . . . a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else* . . . causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction—and perhaps on the response of others as well. The existence of one or more of the essential elements of standing depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict, and it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury. Thus, when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily substantially more difficult to establish.

Lujan v. Defs. of Wildlife, 504 U.S. 555, 562 (1992) (internal quotation marks and citations omitted).

To establish causation, "plaintiffs bear the burden of pleading . . . concrete facts showing that the defendant's actual action has caused the substantial risk of harm. Plaintiffs cannot rely on speculation about the unfettered choices made by independent actors not before the court." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013) (internal quotations marks and citation omitted). In the instant case, therefore, Plaintiff bears the burden of pleading concrete facts showing that the FDA's decision to enter into the Memorandum of Agreement with Santa Fe caused Santa Fe not to submit a modified risk tobacco product application, as a result of which Plaintiff was denied access to the information Santa Fe would have submitted in conjunction with its application.

"The Supreme Court has described redressability as 'a *substantial likelihood* that the relief requested will redress the injury claimed.'" *I.L. v. Alabama*, 739 F.3d 1273, 1279 (11th Cir. 2014) (quoting *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 75 n.20 (U.S. 1978)) (emphasis added). Therefore, Plaintiff must also allege facts showing that, if the Memorandum of Agreement is set aside, there is a substantial likelihood that Santa Fe will submit a modified risk tobacco product application.

To establish both causation and redressability,[3] Plaintiff relies on his allegations that the FDA issued a Warning Letter to Santa Fe and that Santa Fe entered into a Memorandum of Agreement with the FDA. Plaintiff asserts that,

> [a]s a matter of common sense, it is substantially likely that a regulated entity that has received a warning from the federal agency with appropriate jurisdiction that the entity's conduct is unlawful, that has been warned of the possibility of fines,

[3] In his Opposition to Defendants' Motion, Plaintiff specifically addresses redressability but not causation. *See* DE 20 at 5–12. The Court nevertheless interprets Plaintiff's arguments as applying both to causation and redressability.

> prosecution, and seizure of its products, and that has taken some steps to come into compliance with the law (although not the ones Congress devised), will in fact attempt to come into compliance with the law.

DE 20 at 12. According to Plaintiff, the Warning Letter listed a number of penalties—aside from an enforcement action—that Santa Fe might face as a result of its violation of federal law, and by entering into the Memorandum of Agreement, Santa Fe has indicated that it will take steps to avoid such penalties. *Id.* at 11–12.

Plaintiff's allegations fail to establish causation. Rather than presenting concrete facts showing that the FDA's decision to enter into the Memorandum of Agreement with Santa Fe caused Santa Fe not to submit a modified risk tobacco product application, Plaintiff relies on speculation about what Santa Fe would have done in response to the Warning Letter if it had not entered into the Memorandum of Agreement. "[A]n FDA warning letter compels action by neither the recipient nor the agency." *Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944 (D.C. Cir. 2012). Had Santa Fe and the FDA not entered into a Memorandum of Agreement, Santa Fe might have made any number of choices in response to the Warning Letter. While Santa Fe may have submitted an application for a modified risk tobacco product, Santa Fe might instead have changed its labeling and advertising to avoid the application process and to avoid penalties. Santa Fe might even have taken no action at all, in response to which the FDA may or may not have initiated an enforcement action or pursued other penalties. Had the FDA initiated an enforcement action, Santa Fe may have chosen to contest such action rather than submit an application or change its labeling and advertising. In other words, Plaintiff is "rely[ing] on speculation about the unfettered choices made by [an] independent actor[] not before the court." *Clapper*, 568 U.S. at 414 n.5. This is insufficient to establish causation. *See id.*

Plaintiff's allegations likewise fail to establish redressability. If this Court were to set aside the Memorandum of Agreement as requested, Santa Fe might submit an application for a modified risk tobacco product, change its labeling and advertising, or take no action at all. Should the FDA initiate an enforcement action or pursue other penalties, Santa Fe might contest such action rather than submit an application or change its labeling and advertising. For these reasons, Plaintiff's allegations fall short of showing a "substantial likelihood" that, if the Memorandum of Agreement is set aside, Santa Fe will submit a modified risk tobacco product application.

IV. CONCLUSION

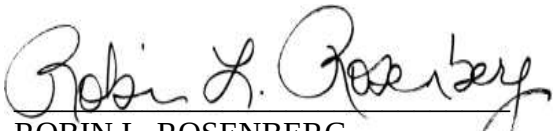
For the foregoing reasons, it is **ORDERED AND ADJUDGED** as follows:

1. Defendants' Motion to Dismiss Plaintiff's Complaint [DE 17] is **GRANTED**.

2. This case is **DISMISSED WITHOUT PREJUDICE**.

3. This case remains **CLOSED**.

DONE AND ORDERED in Chambers, West Palm Beach, Florida, this 13th day of April, 2018.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of record