UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LARRY W. FAIRCLOTH,

Plaintiff,

v. Civil Action No. 2:16-cv-5267

FOOD AND DRUG ADMINISTRATION,
SCOTT GOTTLIEB, M.D., Commissioner
of Food and Drugs, and
THOMAS PRICE, Secretary
of Health and Human Services

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is defendants' motion to dismiss, filed on October 28, 2016.

I. Introduction

On June 10, 2016, Larry W. Faircloth, a resident of West Virginia, instituted this action against the United States Food and Drug Administration ("FDA"), Dr. Scott Gottlieb in his capacity as Commissioner of Food and Drugs, and Thomas Price in his capacity as Secretary of Health and Human Services.[1]

[1] At the outset of this case, Dr. Robert Califf was the Commissioner of Food and Drugs and Sylvia Mathews Burwell was the Secretary of Health and Human Services. Pursuant to Fed. R. Civ. P. 25(d), their successors are automatically substituted as defendants.

The complaint challenges the legality of the FDA's final rule, "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" ("Rule" or "Deeming Rule"), which regulates "vaping devices," also known as "e-cigarettes," and "e-liquids." See Compl. at 1-2; Mem. in Supp. of Mot. to Dismiss at 4. Mr. Faircloth filed this action in this court, invoking jurisdiction under 28 U.S.C. §§ 1331, 2201-02 and 5 U.S.C. § 701 providing for judicial review of final agency actions.

On May 10, 2016, under the authority conferred upon it by Congress in 21 U.S.C. § 387a(b), the FDA issued the final Rule deeming several new products, including vaping devices, as "tobacco products" subject to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), as amended by the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) ("TCA"). See Deeming Rule 81 FR 28974 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143) (deeming electronic nicotine delivery systems, including "e-cigarettes," "e-liquids," "vape pens," and "advanced refillable personal vaporizers" as included in "tobacco

products" under the TCA). "Tobacco products" include "any product made or derived from tobacco including any component, part or accessory." 21 U.S.C. § 321(rr)(1).

Vaping devices "use a heat source to convert e-liquid into vapor." Compl. at ¶ 2. E-liquids typically contain propylene glycol, glycerol, flavors, and various concentrations of nicotine, though some e-liquids contain zero nicotine. See Compl. at ¶ 3-4. In 2010, the D.C. Circuit ruled that the FDA had properly categorized vaping devices and e-liquids as "tobacco products" because the nicotine contained in e-liquids is derived from tobacco. Sottera, Inc. v. Food & Drug Admin., 627 F.3d 891, 897-99.

In deeming vaping devices to be "tobacco products," the FDA subjects manufacturers, retailers, importers, and distributors of "tobacco products" to manufacturing, sale, and marketing requirements designed to protect public health. See, e.g., 21 U.S.C. §§ 387d(a), 387a-1(a)(2)(G); Mem. in Supp. of Mot. to Dismiss at 6; Compl. at ¶ 26. These requirements include, inter alia: (1) providing accurate information about ingredients and additives to the FDA, 21 U.S.C § d(a)(1)-(2); (2) labeling products with ingredients, id. at 387c; (3) including necessary warnings, 15 U.S.C. § 4402(a)(1); (4) undergoing premarket review of products claiming "modified

risks" when compared with traditional cigarettes, 21 U.S.C. § 387k; (5) registering as manufacturers with the FDA, id. at § 387e(b); (6) adhering to manufacturing requirements set by the FDA, id. at § 387f(e); (7) abiding by regulations limiting the concentration of ingredients, id. at § 387g(a)(3); (8) undergoing premarket review of new "tobacco products" entering the market after February 15, 2007, id. at § 387j; and (9) discontinuing the distribution of products as free samples, 21 C.F.R. § 1140.16(d).

Mr. Faircloth is a consumer and user of vaping devices and e-liquids. See Compl. at ¶¶ 6, 9, 29. As a former user of tobacco cigarettes, he smoked approximately two packs per day. Id. at ¶¶ 29-30. He used vaping devices and e-liquids to quit using traditional tobacco cigarettes. Id. at ¶ 29. Mr. Faircloth asserts that if he could no longer use vaping devices and e-liquids, he would likely return to using traditional tobacco cigarettes. See Id. at ¶¶ 29-30.

Mr. Faircloth raises five claims for relief. Count I asserts that the FDA lacks the statutory authority to deem vaping devices as "tobacco products" under the FDA. Compl. at ¶¶ 37-8. Count II claims the Rule is arbitrary and capricious because the premarket approval process required for new "tobacco products" imposes an "extraordinary burden" on manufacturers,

treats vaping devices the same as traditional tobacco cigarettes in the face of "compelling safety data," and imposes a de facto moratorium on the introduction of new vaping devices pending their premarket approval. Id. at ¶¶ 39-41, 43-45. Count III alleges the FDA's cost-benefit analysis "erroneously concludes the Rule's benefits outweigh its costs" and fails to recognize the "severe regulatory burdens" placed on manufacturers. Id. at ¶¶ 49, 51. Count IV asserts that the Rule violates Mr. Faircloth's First Amendment rights by restricting his ability to receive free samples, and "truthful and non-misleading statements" about vaping devices from manufacturers. Id. at ¶¶ 55-56. Finally, Count V alleges that the Rule violates the Tenth Amendment by "co-opting [West Virginia]'s ability to control its Medicaid budget" by compelling the state "to expend money . . . on tobacco related healthcare costs." Id. at 58.

Defendants move to dismiss the entire action for lack of jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1), alleging that Mr. Faircloth lacks standing to challenge the Deeming Rule as a consumer of vaping devices, and that his challenge is unripe.

II. Governing Standard

Federal district courts are courts of limited subject matter jurisdiction, possessing "only the jurisdiction authorized them by the United States Constitution and by federal statute." United States ex. rel. Vuyyuru v. Jadhav, 555 F.3d 337, 347 (4th Cir. 2008). As such, "there is no presumption that the court has jurisdiction." Pinkley, Inc. v. City of Frederick, 191 F.3d 394, 399 (4th Cir. 1999) (citing Lehigh Mining & Mfg. Co. v. Kelly, 160 U.S. 327, 327 (1895)). Indeed, when the existence of subject matter jurisdiction is challenged under Rule 12(b)(1), "[t]he plaintiff has the burden of proving that subject matter jurisdiction exists." Evans v. B.F. Perkins Co., 166 F.3d 642, 647 (4th Cir. 1999); see also Richmond, Fredericksburg, & Potomac R .R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991). If subject matter jurisdiction is lacking, the claim must be dismissed. See Arbaugh v. Y & H Corp., 546 U.S. 500, 506 (2006).

Subject matter jurisdiction may be attacked by a defendant with either a facial or a factual challenge. Kerns v. United States, 585 F.3d 188, 192 (4th Cir. 2009). In a facial challenge, the defendant is asserting that the allegations contained in the complaint fail to sufficiently establish the existence of subject matter jurisdiction. Id. In a facial

attack, the plaintiff is "afforded the same procedural protection as she would receive under a Rule 12(b)(6) consideration," so that "facts alleged in the complaint are taken as true," and the defendant's motion "must be denied if the complaint alleges sufficient facts to invoke subject matter jurisdiction." Id. In a factual challenge, a defendant may argue "that the jurisdictional allegations of the complaint [are] not true." Id. This permits a trial court to consider extrinsic evidence or hold an evidentiary hearing to "determine if there are facts to support the jurisdictional allegations." Id.

III. Standing

Defendants argue that Mr. Faircloth lacks standing to challenge the Deeming Rule for three reasons. First, they contend that all of plaintiff's alleged injuries are indirect and conjectural because, as a consumer, Mr. Faircloth is not regulated under the law, and his hypothetical injuries are the result of downstream economic effects and individual choices to return to traditional cigarettes. Mem. in Supp. of Mot. to Dismiss at 9-12. Second, they assert that his alleged injuries, were they cognizable, cannot be causally traced to the Deeming Rule. Id. at 12-13. Finally, defendants point out that Mr. Faircloth, as an individual, cannot properly bring a claim under the Tenth Amendment for federal commandeering. Id. at 14-15.

As these are facial and not factual challenges to Mr. Faircloth's standing, the court will accept all allegations in the amended complaint as true and determine whether plaintiff has sufficiently established a basis for subject matter jurisdiction. See Kerns, 585 F.3d at 192.

A. Applicable Law.

Standing is generally addressed at the motion to dismiss stage under Fed. R. Civ. P. 12(b)(1) because "Article III gives federal courts jurisdiction only over cases and controversies and standing is an integral component of the case or controversy requirement." CGM, LLC v. BellSouth Telecommunications, Inc., 664 F.3d 46, 52 (4th Cir. 2011) (internal citations and quotations omitted). "To satisfy the constitutional standing requirement, a plaintiff must provide evidence to support the conclusion that: (1) 'the plaintiff ... suffered an injury in fact — an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical'; (2) 'there [is] a causal connection between the injury and the conduct complained of'; and (3) 'it [is] likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" White Tail Park, Inc. v. Stroube, 413 F.3d 451, 458 (4th Cir. 2005) (quoting Lujan v. Defenders of Wildlife, 504

U.S. 555, 560-62 (1992).

At the motion to dismiss stage, "general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim." Lujan, 504 U.S. at 561. The court may accept as true allegations that are supported by adequate "'factual matter' to render them 'plausible on [their] face.'" Beck v. McDonald, 848 F.3d 262, 270 (4th Cir. 2017) (citing Ashcroft, 556 U.S. 662, 678 (2009). "The same presumption of truth" does not apply to "conclusory statements and legal conclusions" contained in the complaint. Id.

B. Counts I-III

i. Injury in Fact

Mr. Faircloth asserts that the Deeming Rule injures him as a consumer of vaping products. The implementation of the Deeming Rule on August 8, 2016 subjects manufacturers of vaping devices and e-liquids to "overly burdensome regulations" that "will cause a severe reduction of the availability of the products used by plaintiff." Compl. at ¶¶ 26-27. Faced by the economic burden of complying with the requirements of the TCA, these manufacturers will "discontinue existing product lines"

and fail to introduce new products leading to an increase in price for vaping products remaining in the market. Id. at ¶ 28. This increase in price and reduced availability will "likely" cause Mr. Faircloth to "return to the unhealthy habit of using [cigarettes]," resulting in an estimated increase to his healthcare costs of $766,500 over the next thirty years. Id. at 29-30. Plaintiff asserts that these harms are "inevitable." Pl.'s Reply to Mot. to Dismiss at 3-4.

"[P]laintiffs have standing to sue to prevent anticipated future conduct if they demonstrate a realistic danger of sustaining direct injury as a result." Richmond Tenants Org., Inc. v. Kemp, 956 F.2d 1300, 1305 (4th Cir. 1992) (internal citations and quotations omitted). However, "when, as here, the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control," the Supreme Court has "insisted that the injury proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all." Lujan, 504 U.S. at 564 n.2. Furthermore, when consumers are "paying the end-line cost of an economic regulation" they are not injured unless they are (1) "directly regulated by the law being challenged," or (2) "prevented outright from obtaining" the regulated product. Compare Lane v. Holder, 703 F. 3d 668 (4th

Cir. 2012), with Carey v. Pop. Servs. Int'l, 431 U.S. 678, 682-83 (1977), Freeman v. Corzine, 629 F.3d 146, 154 (3d Cir. 2010), and Bridenbaugh v. Freeman-Wilson, 227 F.3d 848, 849-50 (7th Cir. 2000).

Mr. Faircloth is not directly regulated as a consumer of vaping devices and e-liquids. Similarly, he has not been prohibited or otherwise outright prevented from obtaining his vaping products. Furthermore, his future harms are not sufficiently imminent to have standing to bring Counts I-III against defendants. Mr. Faircloth theorizes that the costs imposed upon the vaping industry will reduce product diversity and increase prices to such an extent that he will inevitably return to using tobacco cigarettes, resulting in increased healthcare costs for the remainder of his life. This injury is squarely the type of "conjectural or hypothetical" future injury that fails to give plaintiff standing as to Counts I-III of his claims.

ii. Causation

Plaintiff must establish that his injury is "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." Lujan 504 U.S. at 560 (quoting Simon v. Eastern Ky. Welfare Rights Organization, 426 U.S. 26, 41-42 (1976)). This is "substantially more difficult" to show when "plaintiff is not the direct subject of government action, but rather the asserted injury arises from the government's allegedly unlawful regulation . . . of someone else." Frank Krasner Enters., Ltd. V. Montgomery County, 401 F.3d 230, 234-35 (4th Cir. 2005) (quoting Lujan, 504 U.S. at 562) (internal quotations omitted). Where a plaintiff claims an injury based on end-line costs and "[n]othing in the challenged . . . regulations directs [regulated parties] to impose such charges," the regulated parties' independent decision to do so "breaks the causal chain." Lane 703 F.3d at 674.

Mr. Faircloth's alleged future injuries cannot be properly traced to the Deeming Rule. His injuries are premised on the choice of manufacturers, retailers, importers, and distributors of vaping products to leave the market, increase prices, cease product innovation, and otherwise reduce the availability of vaping devices in response to regulation. Mr.

Faircloth asserts these decisions will then cause him to resume smoking tobacco cigarettes because his vaping products will no longer be "cost effective and readily availab[le]," and this will result in increased healthcare costs over the remainder of his life. Compl. at ¶¶ 29-30. If these alleged injuries ever come to bear, the chain of causation is broken by the independent actions and decisions of the manufacturers, retailers, importers, and distributers to be traceable to the Deeming Rule.

Mr. Faircloth does not have standing to challenge the Deeming Rule as to Counts I-III of his complaint based on the conjectural and attenuated injuries asserted in his complaint.

C. Count V

"An individual has a direct interest in objecting to laws that upset the constitutional balance between the National Government and the States when the enforcement of those laws causes injury that is concrete, particular, and redressable." Bond v. U.S., 564 U.S. 211, 222 (2011). To assert a suit under the Tenth Amendment, plaintiff must still meet the three requirements for Article III. See Lujan 504 U.S. at 560-62.

Mr. Faircloth seemingly asserts that he is injured as an individual taxpayer on behalf of West Virginia under the Tenth Amendment because the Deeming Rule "usurp[s] the power of . . . West Virginia to shift residents from more dangerous tobacco products to the healthier alternative" of vaping products, "effectively forcing [the state] to expend state tax dollars through Medicaid to pay the healthcare costs associated with use of tobacco." Compl. at ¶¶ 31, 33. Again, plaintiff believes that the Rule's impact on the vaping market will cause vaping products to become less available and more expensive. Id. at ¶ 28. This will not only cause plaintiff to return to using cigarettes, but also prevent other users of traditional "tobacco products" from switching to vaping devices. Id. at ¶¶ 29-31. Because "67% of West Virginia's Medicaid population uses tobacco products," preventing users from switching to vaping devices "effectively forc[es]" West Virginia to spend more tax dollars on the healthcare costs associated with use of traditional "tobacco products," like cigarettes. Id. at 33.

As with the personal injuries Mr. Faircloth alleges, the hypothetical injuries to West Virginia and its taxpayers is too speculative and attenuated to be properly traced to the Deeming Rule. Furthermore, there is no indication that these conjectural injuries would personally harm plaintiff. Any harm that came to pass would impact him only as a taxpayer, and

"state taxpayers have no standing under Article III to challenge state tax or spending decisions simply by virtue of their status as taxpayers." DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 346 (2006).

For the foregoing reasons, Mr. Faircloth does not have standing to challenge the Deeming Rule under the Tenth Amendment.

IV. Count IV

A. Standing

A plaintiff may challenge an agency action when that action runs contrary to the plaintiff's constitutional right. See 5 U.S.C. § 706(2)(B). Mr. Faircloth asserts that the Deeming Rule violates the First Amendment by prohibiting him "as a consumer . . . from receiving truthful and non-misleading statements regarding vaping devices, e-liquids, and related products from manufacturers," and "from receiving other forms of protected expression, including free samples of vaping devices or e-liquids from manufacturers." Compl. ¶¶ 55-56.

It is well established that where a willing speaker exists, "the protection afforded is to the communication, to its source and to its recipients both." Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 756

(1976). In Va. State Bd. of Pharmacy the Court found that where the First Amendment protection attached to the flow of prescription drug price information, those rights were enjoyed by both the advertisers seeking to distribute the information and to the plaintiffs, who were recipients of this advertising. "If there is a right to advertise, there is a reciprocal right to receive the advertising." Id. at 757. "Both the speaker and the listener have the right to assert First Amendment rights." N.A.A.C.P., Los Angeles Branch v. Jones, 131 F.3d 1317, 1322 (9th Cir. 1997), see also Minarci v. Strongsville City School Dist., 541 F.2d 577, 583 (6th Cir. 1976), Health Sys. Agency of Northern Va. V. Va. State Bd. of Med., 424 F. Supp 267, 272 (E.D.V.A. 1976).

Mr. Faircloth asserts that he is a consumer of vaping devices and a recipient of information from manufacturers, retailers, and distributers regarding vaping products. He has proper standing to assert his First Amendment claim.

B. Ripeness

As Mr. Faircloth only has standing to assert Count IV of his complaint, defendants' arguments regarding ripeness need only be addressed as to this issue.

Defendants argue that Mr. Faircloth's claims are unripe for largely the same reasons they challenge his standing: he is not directly regulated by the Deeming Rule, he does not identify a particular vaping device or e-liquid that the Rule does regulate, and his alleged injuries are speculative and "dependent on future uncertainties." Doe v. Va. Dep't of State Police, 713 F.3d 745, 758 (4th Cir. 2013).

The ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also [protects] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Pac. Gas and Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n, 461 U.S. 190, 200–01 (1983) (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 148–49, (1967)). "Determining whether administrative action is ripe for judicial review requires [a court] to evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court

consideration." Nat'l Park Hospitality Ass'n v. Dep't of Interior, 538 U.S. 803, 808 (2003) (citing Abbott Laboratories, 387 U.S. at 149). While a "regulation is not ordinarily considered the type of agency action ripe for judicial review under the [Administrative Procedure Act] . . . . a substantive rule, which . . . requires the plaintiff to adjust his conduct immediately . . . . is ripe for review at once." Lujan 497 U.S. at 891 (citing Abbott Laboratories, 387 U.S. at 152-54).

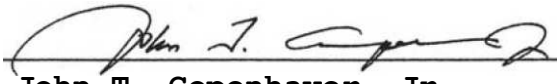
The Deeming Rule is a final rule issued by the FDA on May 10, 2016 after undergoing notice and comment rulemaking pursuant to 5 U.S.C. § 553. The Rule went into effect as of August 8, 2016. "Upon the effective date of this final rule . . . the newly deemed products will be subject to the [same provisions and regulatory requirements] to which cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are subject." Deeming Rule 81 FR 28974, 28976. At the time that the Rule went into effect, Mr. Faircloth's First Amendment rights were potentially abrogated to the extent asserted in Count IV of his complaint. Accordingly, this claim is ripe for review.

V. Conclusion

Based upon the foregoing discussion, it is ORDERED that the defendants' motion to dismiss be, and hereby is, granted as to Counts I-III and V of the complaint. It is further ORDERED that the defendants' motion to dismiss be, and hereby is, denied as to Count IV of the complaint.

The Clerk is directed to transmit copies of this order to counsel of record and any unrepresented parties.

DATED: September 28, 2017



John T. Copenhaver, Jr.
United States District Judge