Lytle v. United States Department of Health and Human Services et al Doc. 31

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

DR. LARRY LYTLE, Plaintiff, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, CHIEF TYRA WISECUP, COMPLIANCE DEPARTMENT, INSPECTOR JESSICA L. JOHNSON, CONSUMER SAFETY OFFICER COURTNEY R.A. TIEGS, and John and Jane Does 1-100, Defendants.	)	CIV. 13-5083-JLV ORDER DISMISSING PETITION WITHOUT PREJUDICE

INTRODUCTION

Plaintiff Dr. Larry Lytle filed a verified petition seeking a declaratory judgment determining that the defendants, both as agencies of the United States government and agency employees, violated Dr. Lytle's and others' constitutional rights.[1] (Docket 1 at p. 6). Plaintiff also claims the individually named defendants committed acts in bad faith, with unclean hands, and committed a fraud on the court in applying for administrative inspection warrants. Id. Finally, plaintiff alleges neither the Food and Drug

[1]Dr. Lytle also filed a verified petition for a temporary restraining order (TRO) or temporary injunction. (Docket 2). On Dr. Lytle's oral motion, the court continued the hearing on plaintiff's motion for a TRO. (Docket 15 at p. 4).

Dockets.Justia.com

Administration (FDA) nor the district court have any jurisdiction or authority over private membership associations (PMAs). Id. at p. 7. Defendants filed a motion to dismiss plaintiff's petition for declaratory relief. (Docket 8). For the reasons stated below, plaintiff's petition is dismissed without prejudice.

FACTUAL BACKGROUND[2]

Plaintiff Dr. Larry Lytle, DDS, is a retired dentist living in Rapid City, South Dakota. (Docket 27 at p. 1). Dr. Lytle and his business associations, Business Wizards, Inc., a/k/a QLaser Solutions Private Membership Association, and 2035, Inc., are involved in the manufacture and distribution of low-level laser devices called "QLasers." 13-MC-42 (Docket 2 at p. 2 ¶ 2). "Two QLaser models, the Q1000 and the 660 FlashProbe, received FDA clearance . . . on January 30, 2009, for providing temporary relief of pain associated with osteoarthritis of the hand, which has been diagnosed by a physician or other licensed medical professional." Id. at p. 3 ¶ 5. The FDA's inspections over a number of years revealed QLasers are distributed throughout the United States. Id. at p. 2 ¶ 3.

On its website, Business Wizards, Inc., markets QLasers to reduce pain associated with high blood pressure, broken bones, varicose veins, diabetes, and other diseases and conditions. Id. This website is also used to solicit

[2]The facts before the court are generally undisputed. Most of these facts are gleaned from the affidavit of a FDA investigator in support of administrative inspection warrants, unless otherwise indicated.

membership in a private membership association, through which members can "receive valuable information about how QLaser can assist . . . in restoring electrons at the atomic level of the cells, control pain, reduce aging, control blood sugar, improve memory and learning and in general help . . . maintain . . . health . . . ." Id. at pp. 2-3 ¶ 4.

The FDA attempted to inspect Dr. Lytle's facilities in December 2012. Id. at p. 4 ¶ 8. Dr. Lytle refused to provide the FDA investigators with access to the facilities or documents required to be maintained under federal law. Id. Dr. Lytle's son, Kip Lytle (Mr. Lytle), advised the FDA investigators he was a "Trustee" of the QLaser Solutions Private Membership Association, which had been in operation for about one and one-half years. Id. at pp. 4-5 ¶ 9. Mr. Lytle explained he distributes QLasers to PMA members across the country and provides those members with education and assistance in meeting their health needs. Id. at p. 5 ¶ 9. When asked by the investigators to produce detailed information about the devices, an adverse event log, and documentation of the PMA agreement, Mr. Lytle refused to do so. Id. at pp. 5-6 at ¶¶ 12 & 13. Mr. Lytle declared the FDA had no "Constitutional right" to be at his establishment. Id. at p. 6 ¶ 14.

The FDA investigator's affidavit included the following declaration: "These [activities and] statements render QLasers devices under the [Food, Drug and Comestics] Act because they demonstrate that QLasers are 'intended

for use . . . in the cure, mitigation, treatment, or prevention of disease,' and are 'intended to affect the structure or any function' of the human body." Id. at p. 3 ¶ 4 (referencing 21 U.S.C. § 321(h)).

On September, 10, 2013, Magistrate Judge Veronica L. Duffy signed warrants for administrative inspections of 2035, Inc., and Business Wizards, Inc., a/k/a/ QLaser Solutions Private Membership Association. See 13-MC-41 (Docket 4); 13-MC-42 (Docket 6); see also Docket 1 at p. 3. The warrants issued by the magistrate judge specifically outlined the FDA's inspection authority.

> Pursuant to the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 374, you are authorized to enter the above-described premises at reasonable times during ordinary business hours to access, copy, and verify the records to which FDA is entitled under the Act for all of the firm's devices. Such records include, but are not limited to: (1) Design Controls, Purchasing Controls, Corrective and Preventive Action Records, Device Labeling, Distribution Records, Device Master Records, Device History Records, Complaint Files, and Servicing Records, as described in 21 C.F.R. §§ 820.30, 820.50, 820.100, 820.120, 820.160, 820.181, 820.184, 820.198, and 820.200; and (2) Additional Listing Information, as described in 21 C.F.R. § 807.26.
>
> The inspection authorized by this administrative warrant will begin as soon as practicable after the issuance of this warrant and will be completed with reasonable promptness. A written notice of inspection and the credentials of the FDA Investigator(s) will be presented as prescribed by 21 U.S.C. § 374(a)(1).

See 13-MC-41 (Docket 4); 13-MC-42 (Docket 6); see also Docket 1 at p. 3.

Assisted by Deputy United States Marshals, FDA investigators executed the administrative inspection warrants on September 10 through September

12, 2013. 13-MC-41 (Docket 7-1); 13-MC-42 (Docket 7-1). The FDA collected numerous records including purchase orders, invoices, receipts, a distributor list, promotional material, and labeling. Id. Dr. Lytle filed this action three months later on December 10, 2013. (Docket 1).

DISCUSSION

DR. LYTLE'S CLAIMS

In his verified petition, Dr. Lytle asserts FDA personnel "violated numerous rights of [Dr. Lytle] and others[3] that are secured to [Dr. Lytle] and others by the Constitution of the State of South Dakota and The Constitution for the United States of America, . . . as amended and ratified by The Bill of Rights, . . . ; that FDA personnel acted in bad faith, with unclean hands, and committed a fraud upon the Court in the affidavits supporting the applications for the warrants by implying that this Court . . . controls the activities of 2035 PMA, QLaser Solutions PMA, QLasers PMA [and] Energy for Life PMA . . . when, in fact, the Court does not." Id. at p. 6 (bold omitted). Plaintiff asserts "[t]he purpose of creating 2035 PMA and QLaser Solutions PMA by a contract was to

[3]The court advised Dr. Lytle that he was "entitled to represent himself . . . [but that] private associations may only make an appearance in federal court through a licensed attorney admitted to practice in this court." (Docket 7 at p. 1) (internal citations omitted). The court denied Dr. Lytle's implied request to certify the issue for interlocutory appeal. (Docket 15 at p. 4). Dr. Lytle filed a request for interlocutory appeal with the United States Court of Appeals for the Eighth Circuit. (Docket 16). The Eighth Circuit dismissed the interlocutory appeal for lack of jurisdiction. (Docket 29).

specifically create a non-statutory private membership association which would not be generally subject to public laws and regulations including, but not limited to, public business entity laws of the State of South Dakota, of any other State of [t]he United States of America, or of the United States." Id. at p. 7. Plaintiff alleges the named "FDA personnel knew, or should have known, that [private membership associations] created by [Dr. Lytle] . . . were not generally subject to the jurisdiction of the Public Law creating the FDA, enforcement [r]egulations or internal [r]ules." Id. Dr. Lytle alleges "[n]either the FDA nor this Court has absolute or, generally, even limited jurisdiction over internal functions of private contracts or of internal activity of private membership associations created by a contract authored by people acting in their real or private character and capacity, as a man or woman." Id. at p. 7 (bold omitted).

In his prayer for relief Dr. Lytle seeks the following remedies:

> 1. Enter[] a Declaratory Judgment . . . declaring that 2035 PMA, QLasers Solutions PMA, QLasers PMA, Energy for Life PMA, and any other PMA created by Petitioner are hereby recognized by the United States as private membership associations created by people pursuant to a contract; and, that pursuant to the PMA contracts, the private membership associations are not generally subject to the jurisdiction of the Public Law creating the FDA; that the FDA generally has no authority to attempt to submit the above referenced PMAs to the Regulations implementing or explaining the laws the FDA enforces; or to the FDA's internal Rules unless the FDA brings to this Court, or to any other court of competent jurisdiction and proper venue, conclusive documentary

evidence or competent sworn testimony proving that any PMA created by Petitioner has, by statements uttered or published, acts committed, or omissions made created a "real and identifiable substantive evil" that the Court must address; and,

2. Sanction[] all FDA personnel who signed the affidavits supporting the applications for the warrants the Court issued and all FDA personnel who served and executed the warrants; and,

3. Enter[] an Order requiring that the FDA forthwith returns all brochures, books, invoices, serial numbers of products, the personal notes of all investigators involved in the searches complained of herein, any and all other information relevant to the searches and any and all copies thereof relevant to 2035 PMA, QLaser Solutions PMA, QLasers PMA, Laser Wellness PMA, Energy for Life PMA and any other PMA that the FDA received documents concerning or information on and removed same from Petitioner's offices; and,

4. For any and all further relief that the Court finds appropriate or just.

(Docket 1 at p. 10) (bold removed).

DEFENDANTS' RESPONSE

The government's brief in support of the motion to dismiss identifies several grounds for seeking dismissal of plaintiff's petition for declaratory relief. (Docket 9). In summary, those grounds are:

1. Lack of service of process on every defendant—except the United States Attorney's Office—as required by Fed. R. Civ. P. 4(i)(2);

2. Fed. R. Civ. P. 12(b)(1)-lack of subject matter jurisdiction:

   A. no waiver of sovereign immunity by the Unites States or its agencies;

B. Dr. Lytle fails to demonstrate he suffered an injury;

C. Dr. Lytle's claims are not ripe;

D. No 42 U.S.C. § 1983 cause of action exists against federal employees acting under federal law;

3. Fed. R. Civ. P. 12(b)(6)-failure to state a claim upon which relief can be granted:

A. Verified petition for declaratory relief is not pled with sufficient specificity;

B. Verified petition does not state a valid § 1983 claim against the named federal employees;

C. Generalized Bivens[4] claims must fail because:

1. Administrative warrants are not inconsistent with the Fourth Amendment;

2. Administrative warrants were issued by court;

3. FDA employees did not operate outside the scope of the warrants issued by the court.

4. Bivens claims have not been extended to First Amendment rights claims; and

D. Dr. Lytle's formation of private membership associations are subject to federal law.

Id. The court will address only those challenges necessary to resolve defendants' motion to dismiss.

[4]Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics, 403 U.S. 388 (1971).

Federal Rule of Civil Procedure 12 provides in part that "a party may assert the following defenses by motion: . . . lack of subject-matter jurisdiction . . . ." Fed. R. Civ. P. 12(b)(1). The purpose of a Rule 12(b)(1) motion is to allow the court to focus on the issue of jurisdiction "because jurisdiction is a threshold question, judicial economy demands that the issue be decided at the outset rather than deferring it until trial . . . ." Osborn v. United States, 918 F.2d 724, 729 (8th Cir. 1990). "The burden of establishing that a cause of action lies within the limited jurisdiction of the federal courts is on the party asserting jurisdiction . . . . ." Arkansas Blue Cross & Blue Shield v. Little Rock Cardiology Clinic, P.A., 551 F.3d 812, 816 (8th Cir. 2009).

Rule 12 also provides that "a party may assert the following defenses by motion: . . . failure to state a claim upon which relief can be granted . . . ." Fed. R. Civ. P. 12(b)(6). "(A) complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Fusco v. Xerox Corp., 676 F.2d 332, 334 (8th Cir. 1982) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957) (footnote omitted)). "Where the allegations show on the face of the complaint there is some insuperable bar to relief, dismissal under Rule 12(b)(6) is appropriate." Benton v. Merrill Lynch & Co., Inc., 524 F.3d 866, 870 (8th Cir. 2008).

PRIVATE MEMBERSHIP ASSOCIATIONS

Defendants argue "[Dr.] Lytle's challenge to the FDA's jurisdiction is based on the flawed premise that he can evade the law by forming a contractual relationship with members of his PMAs." (Docket 9 at p. 17). Without citation to legal authority, Dr. Lytle claims PMAs are a valid method by which to avoid federal interference. (Docket 27 at pp. 8-9).

Private membership associations may not be used to avoid the FDA's inspection authority or its supervision over adulterated or misbranded devices. See United States v. Allgyer, Civil Action No. 11-02651, 2012 WL 355261 *4 n. 15 (E.D. Pa. Feb. 3, 2012) (a private membership association "is merely a subterfuge" to avoid FDA regulation).

RIPENESS

Defendants' Rule 12(b)(1) motion asserts Dr. Lytle's claims are not ripe for judicial review. (Docket 9 at p. 11). Without specifically addressing defendants' ripeness challenge, Dr. Lytle argues "[a]ny court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such." (Docket 27 at p. 5) (citing 28 U.S.C. § 2201) (bold removed).

Dr. Lytle cites 28 U.S.C. § 2201, the declaratory judgment section of the United States Code, but he fails to include the most important portion of that section, the preamble: "[i]n a case of actual controversy within its jurisdiction . . . ."

28 U.S.C. § 2201. The phrase "case of actual controversy" incorporates the ripeness requirements of Article III.[5] MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id.

A declaratory action is not ripe for judicial intervention unless there has been final agency action. Lane v. United States Department of Agriculture, 187 F.3d 793, 795-96 (8th Cir. 1999). The court previously ruled that a warning letter sent by the FDA to Dr. Lytle was not "final agency action." Lytle v. Berg, 11-5089-JLV (D.S.D. Sept. 24, 2012) (Docket 20 at p. 12) (citing Holistic Candlers and Consumers Assoc. v. FDA, 664 F.3d 940, 944 (D.C. Cir. 2012)). Similarly, execution of an administrative inspection warrant is not final agency action. "It is well established . . . that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has

[5]U.S. Const. Art. III, § 2. "Article III of the United States Constitution confines the jurisdiction of federal courts to justiciable cases and controversies." Mosby v. Ligon, 418 F.3d 927, 933 (8th Cir. 2005).

been exhausted . . . ." Babcock & Wilcox Co. v. Marshall, 610 F.2d 1128, 1135 (3d Cir. 1979) (internal citation and quotation marks omitted) (court challenge to an administrative inspection warrant).

Dr. Lytle's claims are not ripe for judicial review. Rule 12(b)(1) requires dismissal of plaintiff's claims.

STANDING

Defendants also assert Dr. Lytle lacks standing to assert his claims because he "cannot make the requisite showing of injury in fact." (Docket 9 at p. 10). Dr. Lytle alleges he suffered the following injuries:

> [I] was irreparably injured by three days of searches and seizures executed by FDA personnel and armed U.S. Marshalls [sic] inside the private property and private offices of Plaintiff and the above-referenced PMAs. During the course of the searches, Plaintiff lost significant amounts of his personal time, all his privacy, an incalculable amount of money, was placed under enormous stress which negatively affected his health and wellbeing [sic] and lost his peace of mind and his faith in government. Plaintiff was irreparably injured both directly and as creator of and proper party to the above-referenced PMAs.

(Docket 27 at p. 4). In an earlier verified pleading, Dr. Lytle acknowledged he "fully cooperat[ed] with the FDA by answering the FDA's questions and allowing the FDA access to confidential private books and records of Petitioner and the PMAs and made copies of documents requested by the FDA (on Petitioner's time and at Petitioner's expense) which were taken and removed by the FDA." (Docket 2 at p. 7).

"To show standing under Article III . . . [Dr. Lytle] must demonstrate (1) injury in fact, (2) a causal connection between that injury and the challenged conduct, and (3) the likelihood that a favorable decision by the court will redress the alleged injury." Young America Corp. v. Affiliated Computer Services (ACS), Inc., 424 F.3d 840, 843 (8th Cir. 2005) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)). "The party invoking federal jurisdiction bears the burden of establishing these elements." Id. (citing Lujan, 504 U.S. at 561). "[I]f a plaintiff lacks standing, the district court has no subject matter jurisdiction." Id. (citing Faibisch v. University of Minnesota, 304 F.3d 797, 801 (8th Cir. 2002)).

The first element, injury in fact, must be both "concrete and particularized . . . and . . . actual or imminent, not conjectural or hypothetical." Id. (citing Lujan, 504 U.S. at 560). "If the plaintiff offers no factual allegations, specific or general, demonstrating an injury in fact, the court should dismiss the claim." Id. When seeking "injunctive relief, the 'injury in fact' element . . . requires a showing that the plaintiff faces a threat of ongoing or future harm." Tracie Park v. Forest Service of the United States, 205 F.3d 1034, 1037 (8th Cir. 2000) (internal quotation marks omitted). " '[A]bstract injury is not enough. It must be alleged that the plaintiff has sustained or is immediately in danger of sustaining some direct injury as the result of the challenged . . . official conduct.' " Public Water Supply Dist. No. 10 v. City of Peculiar, 345

F.3d 570, 573 (8th Cir. 2003) (citing O'Shea v. Littleton, 414 U.S. 488, 494 (1974)). "The plaintiff[] need not wait until the threatened injury occurs, but the injury must be 'certainly impending.' " Id. (internal citation omitted).

Complying with a court issued inspection warrant, without more, does not create an actual injury. Otherwise, every individual subject to the execution of a search warrant would have an injury and a claim for damages. Dr. Lytle's claims amount to a "case [of] imagined injury," which does not satisfy the test for standing. Lytle, 11-5089-JLV (D.S.D. Sept. 24, 2012) (Docket 20 at p. 14) (citing Holistic Candlers and Consumers Association, 770 F. Supp. 2d at 160).

Because Dr. Lytle cannot demonstrate a causal connection between actions taken by the FDA employee defendants and any actual and substantial harm Dr. Lytle may have suffered personally, he lacks standing to bring these claims. Rule 12(b)(1) requires dismissal of Dr. Lytle's claims.

SOVEREIGN IMMUNITY

Defendants argue there has been no waiver of sovereign immunity which would permit Dr. Lytle to sue the United States Department of Health and Human Services or the FDA. (Docket 8 at p. 9). The United States and its agencies are generally immune from suit. FDIC v. Meyer, 510 U.S. 471, 475 (1994) ("Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit."); Brown v. United States, 151 F.3d 800, 803-04 (8th Cir. 1998); Russell v. Dupree, 844 F. Supp. 2d 46, 50 (D.D.C. 2012)

("plaintiff . . . bear[s] the burden of establishing that sovereign immunity has been abrogated in order to overcome the [government's] motion to dismiss"). "Sovereign immunity is a jurisdictional issue . . . ." Rupp v. Omaha Indian Tribe, 45 F.3d 1241, 1244 (8th Cir. 1995). If the government "possess[es] sovereign immunity, then the district court [has] no jurisdiction to hear [plaintiff's claims]." Id.

Dr. Lytle has not met his burden as there is no evidence of waiver of sovereign immunity. Rule 12(b)(1) requires dismissal of plaintiff's claims.

1983 CLAIMS

As the court ruled in Lytle, claims brought pursuant to 42 U.S.C. § 1983 require that an individual be acting under color of state law. Lytle, 11-5089-JLV (D.S.D. Sept. 24, 2012) (Docket 20 at pp. 10-11) (citing Jones v. United States, 16 F.3d 979, 981 (8th Cir. 1994)). A claim under § 1983 is not available when a federal employee acts under federal law. Id.

Rule 12(b)(1) requires dismissal of Dr. Lytle's § 1983 claims.

BIVENS CLAIMS

Defendants challenge Dr. Lytle's petition for failing to state a cause of action against the individually named defendants. (Docket 9 at p. 15). To the extent Dr. Lytle asserts Bivens claims against the named individual defendants for First and Fourth Amendment violations, those claims fail.

First, "inspections authorized by [21 U.S.C. § 374] are reasonable and therefore not inconsistent with the Fourth Amendment." United States v.

Jamieson-McKames Pharmacies, Inc., 651 F.2d 532, 538 (8th Cir. 1981) (internal quotation marks omitted). "Legislatures generally have confined their efforts to authorizing administrative searches of specific categories of businesses that require regulation, and the resulting statutes usually have been held to be constitutional." Illinois v. Krull, 480 U.S. 340, 351 (1987).

Second, unlike Bivens, where federal agents conducted a warrantless search, in this case the FDA investigators inspected the facilities pursuant to administrative warrants issued by Magistrate Judge Duffy. The warrants issued by the magistrate judge specifically outlined the FDA's inspection authority. See 13-MC-41 (Docket 4); 13-MC-42 (Docket 6).

Third, there is no allegation by Dr. Lytle the FDA investigators acted outside the scope of the warrants issued by the magistrate judge. See Dockets 1 and 27.

Finally, the law is clear that Bivens claims may not be asserted for alleged violations of a petitioner's First Amendment rights. Bush v. Lucas, 462 U.S. 367, 390 (1983); Lytle, 11-5089-JLV (D.S.D. Sept. 24, 2012) (Docket 20 at p. 15) (the United States Supreme Court "decline[s] to extend Bivens to a claim sounding in the First Amendment.").

Rule 12(b)(6) requires dismissal of Dr. Lytle's Bivens claims.

ORDER

Based the above discussion, it is hereby

ORDERED that defendants' motion to dismiss (Docket 8) is granted.

IT IS FURTHER ORDERED that plaintiff's petition for declaratory relief (Docket 1) is dismissed without prejudice.

IT IS FURTHER ORDERED that plaintiff's petition for a temporary restraining order or temporary injunction (Docket 2) is denied without prejudice as moot.

Dated September 30, 2014.

BY THE COURT:

/s/ *Jeffrey L. Viken*

JEFFREY L. VIKEN
CHIEF JUDGE