UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

WESTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. 2035 INC., a corporation, and ROBERT L. LYTLE, an individual, d/b/a 2035 PMA and QLASERS PMA, Defendants.	CIV. 14-5075-JLV ORDER GRANTING PRELIMINARY INJUNCTION

INTRODUCTION

On October 21, 2014, plaintiff United States of America filed a complaint seeking a permanent injunction against the defendants 2035 Inc., a corporation, and Robert L. Lytle, an individual, d/b/a 2035 PMA and QLASERS PMA, for alleged violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 332 *et seq.* ("FDCA"). (Docket 1). Plaintiff filed a motion for a preliminary injunction to enjoin defendants from violation of the FDCA during the pendency of these proceedings. (Docket 4). On October 23, 2014, the court entered an order setting a hearing on plaintiff's motion for a preliminary injunction and requiring plaintiff to serve a copy of the order and all documents filed in this case on defendants. (Docket 15). On October 29, 2014, the court entered an order requiring the defendants to file a response to plaintiff's motion for preliminary injunction by November 6, 2014. (Docket 23). The order set a hearing on

plaintiff's motion for preliminary injunction on November 17, 2014. Id. at p. 3. Defendant Robert L. Lytle filed his response in resistance to plaintiff's motion.[1] (Docket 28). Mr. Lytle also filed motions for a more definite statement as to plaintiff's claims and for an administrative hearing. (Dockets 31 & 32). Defendant 2035 Inc., did not file a response to the plaintiff's motion for a preliminary injunction.[2]

At the November 17, 2014, preliminary injunction hearing, the plaintiff appeared through its attorney, Ross S. Goldstein. Mr. Lytle appeared *pro* se.[3] The court considered the filings and arguments of the parties. Based on the analysis and findings set out in this order, the court grants the government's motion for a preliminary injunction.

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[1]The court previously notified the defendants that Mr. Lytle could represent himself but not 2035 Inc. (Docket 24).

[2]Records of the South Dakota Secretary of State identify Fredretta L. Eason of 2216 Cedar Drive, Rapid City, South Dakota, as the registered agent of 2035 Inc. Those same public records identify Mr. Lytle as the president, secretary and treasurer of the corporation. Mr. Lytle was personally served with the pleadings on October 23, 2014. (Docket 25 at p. 1). The Clerk of Court e-mailed copies of the court's order setting the hearing to Mr. Lytle on October 30.

[3]Mr. Lytle asks the court to point out any error or omission he may make in his pleadings and then give him an opportunity to correct his mistakes. (Docket 34 at p. 2). The court has no duty to advise Mr. Lytle about his response to the plaintiff's motion or to advise him of the procedure for doing so. The court cannot act as Mr. Lytle's lawyer. See Bennett v. Dr Pepper/Seven Up, Inc., 295 F.3d 805, 808 (8th Cir. 2002) (finding the district court did not have an affirmative duty to advise a *pro se* litigant of the date by which he was to respond to a motion); Beck v. Skon, 253 F.3d 330, 333 (8th Cir. 2001) (finding the district court was not required to instruct a *pro se* litigant on how to properly respond to a motion). Simply put, "the court is not permitted to act as counsel for either party." Burgs v. Sissel, 745 F.2d 526, 528 (8th Cir. 1984).

ANALYSIS

Jurisdiction

"The district courts of the United States . . . shall have jurisdiction, for cause shown to restrain violations of section 331 of this title . . . ." 21 U.S.C. § 332(a). Where Congress provided for statutory injunctions to protect the public interest, an equity court has powers broader and more flexible than in a case between private litigants. Mitchell v. Robert D. Mario Jewelry, Inc., 361 U.S. 288, 291 (1960). "Where the plaintiff is a sovereign and where the activity may endanger the public health, 'injunctive relief is proper, without resort to balancing.' " Illinois v. Milwaukee, 599 F.2d 151, 166 (7th Cir. 1979), *rev'd on other grounds*, 451 U.S. 304 (1981). In public health legislation, such as the Food, Drug and Cosmetic Act, 21 U.S.C. § 332 *et seq.* ("FDCA"), the emphasis shifts from irreparable injury to concern for the general public interest. "The United States . . . is not bound to conform with the requirements of private litigation when it seeks the aid of the courts to give effect to the policy of Congress as manifested in a statute. It is a familiar doctrine that an injunction is an appropriate means for the enforcement of an act of Congress when it is in the public interest." Shafer v. United States, 229 F.2d 124, 128 (4th Cir. 1956). Thus the criteria of Dataphase Systems, Inc. v. C L Systems, Inc., 640 F.2d 109 (8th Cir. 1981) (*en banc*), are not considered.

Rather, when a federal statute, 21 U.S.C. § 332(a), authorizes the district court to enjoin violations of § 331, the government need only show: (1) the statute

applies to defendants; and (2) there exists some cognizable danger of recurrent violations. See United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953) (district courts are statutorily vested with the jurisdiction to restrain violations of the legislative acts of Congress).

Mr. Lytle moves for dismissal with prejudice pursuant to Fed. R. Civ. P. 12(b)(2) "for want of personal jurisdiction over" him and Rule 12(b)(6) "for Plaintiff's failure to state a claim upon which relief can be granted." (Docket 28 at p. 2). Mr. Lytle also bases his motion for dismissal on "the Court's Oath of Office; requirement of good Behavior; and Good Faith . . . ." Id. (bold omitted). Mr. Lytle argues "[t]he FDCA regulates the commercial distribution of a device that is intended for human use." Id. at p. 4 (bold omitted). He claims private membership associations and he, individually, are beyond the jurisdiction of the FDCA, the Food and Drug Administration ("FDA"), and the court because "[t]he low-power laser devices manufactured and marketed by Defendants are primarily for peoples' (1) private education, (2) private experimentation and research, (3) for veterinary use on their pets, domestic animals and beasts (see [Docket 28-1]); and (4) for whatever other private use a man or woman who elects to obtain one decides to apply it . . . ." Id. (bold omitted). Mr. Lytle argues "[t]here are no facts or section(s) of the FDCA cited in Plaintiffs pleadings proving that this Court can exert any lawful personal jurisdiction over the private noncommercial distribution activity of Defendants LYTLE, 2035 PMA and QLasers PMA." Id. at p. 5 (bold omitted).

The First Amendment provides protection to Mr. Lytle for embracing and advocating alternative medical treatment. "The First Amendment protects expression, be it of the popular variety or not. . . . And the fact that an idea may be embraced and advocated by increasing numbers of people is all the more reason to protect the First Amendment rights of those who wish to voice a different view." Boy Scouts of America v. Dale, 530 U.S. 640, 660 (2000). By placing devices and their operational manuals into the stream of commerce, Mr. Lytle goes beyond protection ensured by the First Amendment. Hiding behind a curtain of private membership associations, 2035 PMA and QLaser PMA, does not shield Mr. Lytle from the authority of the FDCA or the jurisdiction of the court.

The court has jurisdiction over the subject matter of this action and has personal jurisdiction over the parties pursuant to 28 U.S.C. §§ 1331 and 1345 and 21 U.S.C. § 332. Mr. Lytle's motion to dismiss for lack of personal jurisdiction is denied.

Conduct of the Defendants

The record discloses Mr. Lytle,[4] both individually and through his private membership associations 2035 PMA and QLasers PMA, and 2035 Inc., have a long history of interaction with the FDA.

[4]Mr. Lytle is also known as "Dr. Robert Lytle" or "Dr. Larry Lytle." Mr. Lytle was a dentist in Rapid City, South Dakota, until his license to practice dentistry was permanently revoked by the South Dakota Board of Dentistry on February 24, 1998. The court takes judicial notice of the findings of fact, conclusions of law and order, and decision of the South Dakota Board of Dentistry pursuant to Fed. R. Evid. 201(b) (2) and 803(8)(A) & (B).

Mr. Philips is a FDA Compliance Officer stationed in Minneapolis, Minnesota. (Docket 6 ¶ 1). Mr. Philips provided the following information, under oath, regarding the matters before the court. Id. at p. 11.

Mr. Lytle has been manufacturing and distributing QLaser devices since approximately 1997, and has operated under more than ten different company names. (Docket 6 ¶ 6). He markets the QLaser devices as low level laser therapy devices intended for home use. Id. The QLaser System includes the following devices: the Ql0, QI000, Ql000NG, Ql000NG+, 660 FlashProbe, 660 Enhancer Probe, 660NG Enhancer Probe, 660NG+ Enhancer Probe, 808 FlashProbe, 808 Enhancer Probe, 808NG Enhancer Probe, and 808NG+ Enhancer Probe. Id. ¶ 7. Distributed with QLaser devices is a document captioned "Low Level Laser Application Guide," which Mr. Lytle authored.[5] Id. ¶ 6.

QLasers PMA distributes QLaser devices nationwide. Id. ¶ 8. In addition, QLasers PMA holds QLaser seminars nationwide, solicits individuals to join defendants' "private membership associations," and distributes labeling and other materials associated with QLaser devices. Id.

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[5]The "Low Level Laser Application Guide" is over 200 pages in length. (Dockets 7-1, 7-2, 7-3, 8-1, 8-2, 9-1, 9-2 & 10-1). "This manual is designed to use a Western Medicine index of symptoms, illness or disease. Look up your symptom, disorder or disease in the index and GO TO THAT PAGE for directions on how to use your QLaser System both directly and with acupoint therapy." (Docket 7-1 at p. 16) (capitalization in original).

On August 29, 2002, the FDA sent Mr. Lytle a letter informing him that his products were medical devices and, as such, he was required to obtain marketing clearance before offering them for sale. (Docket 6-2). By an October 28, 2002, letter, Mr. Lytle's attorney advised the FDA that Mr. Lytle's devices were veterinary devices and promised, among other things, to "eliminate" certain statements contained in his product labeling. (Docket 6 ¶ 12).

In May 2007, an FDA investigator called Mr. Lytle to request information about his current activities involving the QLaser System. Id. ¶ 13. In a voicemail left on the FDA investigator's cell phone, Mr. Lytle, apparently believing that the call had terminated, declared to an unknown person that if the FDA investigator questions Mr. Lytle about his businesses or his laser devices, he will tell the FDA investigator that he makes "low level lasers for a veterinary type of thing." Id.

During a May 2010 inspection, the FDA learned 2035 Inc., was responsible for manufacturing QLaser devices and had contracted production of these devices to Tri-Tech Manufacturing, Inc., ("Tri-Tech") of Rapid City, South Dakota. (Docket 6 ¶ 5). The FDA also learned that once Mr. Lytle created the private membership associations 2035 PMA and QLasers PMA in 2010, 2035 Inc.'s, activities were limited to owning a premarket clearance for the QLaser QI000 and QLaser 660 FlashProbe, holding patents to QLaser devices, and licensing those patents to 2035 PMA. Id. The 2035 PMA is responsible for developing the specifications for the devices in the QLaser System. Id. ¶ 7. Mr.

Lytle is the president of 2035 Inc., and the director of 2035 PMA and QLasers PMA. Id. ¶ 6.

During the 2010 inspection, an FDA investigator collected a number of documentary samples, including defendants' labeling materials captioned "QLaser Use Instructions & Product Warranty" and "QLaser Low Level Laser Therapy: Tomorrow's Health Care Today." Id. ¶ 14. This labeling indicated QLaser devices treat "tendonitis, arthritis, burns . . . and any pain or inflammation . . . speed[s] bone repair . . . help(s) repair damaged DNA . . . repolarize[s] damaged cell walls . . . and [is] a multiorgan cell-reenergizer . . . [and is] proven effective and beneficial for healing, and to benefit inflammation or disorders of all internal, and the treatment of any unknown condition." Id.

On March 3, 2011, the FDA issued a warning letter to Mr. Lytle and 2035 Inc. (Docket 6-3). Based on the FDA investigation, including the on-site inspection and examination of defendants' websites, the warning letter advised Mr. Lytle that the QLaser devices were devices within the meaning of the FDCA, 21 U.S.C. § 321(h), because they were "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or are intended to affect the structure or any function of the body." Id. at p. 1. The warning letter also advised Mr. Lytle "the Q10 Laser and the 808 Enhancer Probe are adulterated under section 501(f)(1)(B) of the [FDCA] because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, . . . or an approved application for investigational device exemption (IDE) under section 520(g) of the Act . . . ." Id.

The Q10 Laser and the 808 Enhancer Probe "are also misbranded under section 502(o) . . . because you did not notify the [FDA] of your intent to introduce the devices into commercial distribution as required by section 510(k) . . . ." Id. at pp. 1-2.

Concerning the Q1000 Laser and the 660 Enhancer Probe, the warning letter noted the FDA had "cleared a premarket notification (510(k)) for [these devices] with an intended use 'for providing temporary relief of pain associated with osteoarthritis of the hand, which had been diagnosed by a physician or other licensed medical professional.' " Id. at p. 2. Despite this limited 510(k) clearance, Mr. Lytle's websites were promoting these devices:

- to re-energize muscle, ligament, and tendon cells for healing wounds and injuries or for reducing pain and inflammation . . . [also] benefits tendonitis, arthritis, burns, sprains, cuts, bruises, muscle pulls, sore throat, and any pain or inflammation;
- to re-energize the brain and heart cells and to normalize brain neuropeptides and heart cell energy;
- as a multi-organ cell re-energizer that cycles through 29 different frequencies proven effective and beneficial for healing, and to benefit inflammation or disorders of all internal, and for the treatment of any unknown condition;
- for acute or chronic pain and inflammatory conditions; and
- [to] help[] Balance the Autonomic Nervous System.

Id. at pp. 2-3. Mr. Lytle's promotional materials also claimed the QLaser System would benefit macular degeneration of the eyes.

> To sum it up, if electrical micro current or biocurrent [sic] is effective, low level lasers should be equally or more effective for Age Related Macular Degeneration, especially if the laser is used early-on as a preventive procedure.

Id. at p. 3.

The FDA requested Mr. Lytle and his corporation "immediately cease marketing the Q1000 and 660 Enhancer Probe for unapproved uses . . . ." Id. Mr. Lytle was directed to submit a plan for discontinuation of the promotional materials contrary to the 510(k) clearance authorization. Id. In response, Mr. Lytle submitted "a series of letters challenging [the FDA's] jurisdiction over his distribution of the QLaser system through his 'private membership associations.' " (Docket 6 ¶ 16). Mr. Lytle's June 15, 2010, letter indicated "all manufacturing and sale of our products to the public is hereby terminated." (Docket 6-3 at p. 4). As of January 12, 2011, the FDA confirmed Mr. Lytle's websites "were still operating and contain claims other than those cleared in the 510(k) premarket notification." Id.

The FDA investigators attempted a follow-up inspection of Mr. Lytle's businesses between December 4 and December 6, 2012. (Docket 6 ¶ 18). At that time, Mr. Lytle refused to disclose any information concerning the activities being conducted as "he could not comment on the activities of his private membership association because the investigators were not members and . . . the activities of his private membership associations are outside the jurisdiction of the FDA." Id.

The FDA obtained warrants for administrative inspection from a United States Magistrate Judge in September 2013. Id. ¶ 19. During this inspection the FDA found QLaser PMA was still distributing QLaser devices nationwide and Mr. Lytle was still operating the QLasers' website. Id.; see also (Docket 10-2).

During this inspection the FDA recovered Mr. Lytle's manual "Low Level Laser Application Guide." (Docket 6 ¶ 20). This manual claims to "treat 'over 200 different diseases and disorders,' including cancer, cardiac arrest, HIV/AIDS, diseases and disorders of the eye and ear, venereal disease, and diabetes, and provides instructions on how to use the devices to treat specific diseases." Id.; see also Docket 7-1.

The FDA inspection of Mr. Lytle's websites in August and September 2014 discovered Mr. Lytle was still claiming "the QLaser devices cure, mitigate, treat, or prevent numerous diseases, including cancer, heart disease, diseases and disorders of the eye and ear, Parkinson's, and diabetes." (Docket 6 ¶ 21). Information packets received from QLasers PMA during the same time period make similar claims. Id. ¶ 22. Over the course of the past few years, the FDA received numerous complaints from physicians and "patients" of Mr. Lytle. Id. ¶¶ 23-25.

Mr. Lytle asserts "[m]embership in QLasers PMA includes things that are not available to the public — FOB [free on board] 235 PMA's office — such as . . . education in the use of the PMA's proprietary products . . . healthcare equipment and products which present alternatives to conventional medical procedures . . . including . . . [a] human body with light . . . low-power lasers . . . ." (Docket 28 at pp. 12-13) (bold omitted).

FDA Conclusions

Ilko Ilev, Ph.D., holds degrees in quantum and laser physics and a doctoral degree in laser physics. (Docket 12 ¶ 1). As a member of the FDA's Senior Biomedical Research Service, Dr. Ilev concludes "the 808, 660, and Q1000 lines of QLaser devices expose users to potentially hazardous levels of laser radiation and raise serious safety concerns." Id. ¶ 9. Efficacy concerns also are identified by Dr. Ilev. "To my knowledge there are no published clinical studies demonstrating the efficacy of the QLaser devices for any of the more than 200 indications listed in, among other places, the *Low Level Laser Application Guide*." Id. ¶ 15. "Although clinical studies using low-level lasers other than the QLaser devices for specific indications have been conducted and published, such studies do not support the efficacy of the QLaser devices, because the efficacy of low-level laser therapy depends upon numerous, multivariable critical parameters, including laser radiation dose, laser wavelength, and laser beam characteristics." Id. ¶ 17. In Dr. Ilev's opinion "the 808 and Q1000 lines of QLaser devices could be dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in their labeling." Id. ¶ 20. Dr. Ilev is concerned because "[a]pplying any of these devices directly over the open eye [as Mr. Lytle's manual instructs] could lead to temporary or permanent damage to the eye." Id.

The FDA has determined "the Q10, Ql000NG, Q1000NG+, 660 Enhancer Probe, 660NG Enhancer Probe, 660NG+ Enhancer Probe, 808 FlashProbe, 808

Enhancer Probe, 808NG Enhancer Probe, and 808NG+ Enhancer Probe . . . are class III devices for which there are no cleared 510(k) notifications or approved applications for premarket approval in effect." (Docket 11 ¶ 5). The FDA also has determined that the Q1000 and 660 FlashProbe are "class III devices because Dr. Lytle has made a major change or modification in the devices' cleared intended use [2009 510(k) approvals], but, to date, FDA has not received a 510(k) notification or application for premarket approval for such change." Id. Because of these conclusions, "all of the QLaser devices are uncleared and unapproved devices." Id.

Mr. Lytle acknowledges, under oath, that "[f]or over 17 years, under several different business names and types of organizational structures, [he] has publically sold low-power laser devices for education, research, veterinary and private use in The United States of America and other countries." (Docket 28 ¶ 23) (bold omitted). Mr. Lytle admits the private membership association "2035 PMA only manufacturers' [sic] low-power laser devices for education, research, veterinary and private use and on a wholesale basis provides them only to its members — not to the public — [free on board (FOB)] 2035 PMA's office." Id. ¶ 29. He likewise admits:

> Membership in QLasers PMA includes things that are not available to the public — FOB 2035 PMA's office — such as educational materials, presentations and training in everything from ancient but effective treatments, products and procedures through the most modern advanced devices, methods, technologies and products; education in the use of the PMA's proprietary products and how they complement most alternative, conventional, holistic or natural and

> comprehensive healthcare services and modalities; healthcare equipment and products which present alternatives to conventional medical procedures and pharmaceuticals including, but not limited to, devises stimulating an animal or human body with cold, color, electricity, light (low-power lasers), heat, magnetic energy, radiation, sound and inaudible (radio) frequencies; air and water purifiers and treatment equipment, ozone generators, vitamins, minerals, herbs, enzymes, phytonutrients and raw foods etc. All FOB QLasers PMA's office.

Id. ¶ 30 (bold omitted). Distribution of Mr. Lytle's "devices," "products," and "healthcare equipment" to the members of the private membership associations occurs through the United States Postal Service and United Parcel Service. Id. ¶ 31. Mr. Lytle declares that "[m]embers of 2035 PMA and QLasers PMA are people who no longer consent to accept or receive any protection offered by the FDA or any other federal or state administrative agency or court." Id. ¶ 32 (bold omitted). In Mr. Lytle's view, "[m]embers have joined the PMAs preciously [sic] so that the FDA does not either attempt to or actually impair, impede, obstruct, defeat, censor, regulate or interfere with, in any manner whatsoever, their obtaining all available data and information on low-power laser devices and obtaining such devices for their own education, research or private use should they so choose to use one on their pets, domestic animals or beasts." Id. (bold removed).

Justification for issuance of a Preliminary Injunction

Based on a careful review of the extensive and well developed record, the court finds defendants Lytle, 2035 PMA, QLaser PMA, and 2035 Inc., are violating 21 U.S.C. § 331(a). Defendants have shown no intent to discontinue their activities and voluntarily comply with the FDCA.

The court concludes as a matter of law that a preliminary injunction should issue as there is a substantial likelihood the government will succeed on the merits of its claims that the defendants, jointly and severally, violate 21 U.S.C. § 331(a) by:

1. Introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(f)(l)(B);

2. Introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. § 352(o);

3. Introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C.§ 352(a).

4. Introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. § 352(j).

5. Causing articles of device to become adulterated within the meaning of 21 U.S.C. § 351(f)(l)(B) and misbranded within the meaning of 21 U.S.C. §§ 352(a), (j), and (o), while such devices are held for sale after shipment in interstate commerce.

Accordingly, for good cause shown, it is hereby

ORDERED that plaintiff's motion for a preliminary injunction (Docket 4) is granted. A preliminary injunction will be entered as a separate order.

IT IS FURTHER ORDERED that Mr. Lytle's motion for a more definite statement (Docket 31) is denied.

IT IS FURTHER ORDERED that Mr. Lytle's motion for administrative hearing (Docket 32) is denied.

IT IS FURTHER ORDERED that Mr. Lytle's motion for reconsideration and correction of errors (Docket 34) is denied.

IT IS FURTHER ORDERED that Mr. Lytle's motion to dismiss for lack of subject matter jurisdiction (Docket 37) is denied.

IT IS FURTHER ORDERED that Mr. Lytle's motion to strike all of plaintiff's pleadings (Docket 38) is denied.

IT IS FURTHER ORDERED that Mr. Lytle's motion to dismiss (Docket 40) is denied.

Dated January 14, 2015.

BY THE COURT:

/s/ *Jeffrey L. Viken*
JEFFREY L. VIKEN
CHIEF JUDGE