United States Court of Appeals
For the Eighth Circuit

No. 14-3715

Dr. Larry Lytle

Plaintiff - Appellant

v.

United States Department of Health and Human Services; Food and Drug Administration; Tyra Wisecup, Chief; Compliance Department; Jessica L. Johnson, Inspector; Courtney R.A. Tiegs, Consumer Safety Officer; John and Jane Does, 1-100

Defendants - Appellees

No. 15-1214

United States of America

Plaintiff - Appellee

v.

2035, Inc., a corporation

Defendant

Robert L. Lytle, an individual, doing business as 2035 PMA, doing business as QLasers PMA

Defendant - Appellant

Appeals from United States District Court
for the District of South Dakota - Rapid City

Submitted: June 12, 2015
Filed: August 21, 2015

Before WOLLMAN, LOKEN, and BENTON, Circuit Judges.

PER CURIAM.

South Dakota resident Robert L. Lytle (also known as Larry Lytle) appeals district court orders in two actions related to his marketing of laser devices. In one action, the district court dismissed without prejudice his declaratory-judgment action, in which he challenged the authority of the Food and Drug Administration (FDA) to execute administrative warrants for the inspection of his laser-device businesses. After carefully reviewing the record and the parties' arguments on appeal, Plymouth Cnty., Iowa v. Merscorp, Inc., 774 F.3d 1155, 1158-59 (8th Cir. 2014) (appellate court reviews de novo dismissal for failure to state claim), we affirm the dismissal of this action.

Lytle asserts that the FDA lacks regulatory jurisdiction over his marketing of laser devices because he distributes them in non-commercial transactions through private membership associations (PMAs). In the Federal Food, Drug, and Cosmetic Act (FDCA), Congress has authorized the FDA to regulate the safety and effectiveness of medical devices. See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1203 (8th Cir. 2010) (affirming dismissal of tort claims as preempted). A device can be safe for one use, but unsafe for other uses. Thus, the FDA approves a device on the basis of its intended use, and the FDA-approved use

must be included in the product's labeling. See 21 U.S.C. § 321(h)(2) (defining device to include instrument intended for use in cure, mitigation, treatment, or prevention of disease in humans or animals); 21 C.F.R. § 801.5 (device must include adequate directions for use, including statement of intended use); Martello v. Ciba Vision Corp., 42 F.3d 1167, 1169 (8th Cir. 1994) (FDA approval shows FDA reviewed device's intended use and labeling, among other things, and decided device is safe and effective). The FDA regulations prohibit labeling or advertising a device "in a matter that is inconsistent with any conditions to approval specified in [an] approval order for the device." 21 C.F.R. § 814.80. Violation of FDA labeling restrictions results in a device being "misbranded" or "adulterated," Hot Stuff Foods, LLC v. Houston Cas. Co., 771 F.3d 1071, 1075-76 (8th Cir. 2014) (violation of FDA labeling restrictions results in product being misbranded or adulterated), and bars introduction of the misbranded or adulterated devices into the marketplace. See 21 U.S.C. §§ 331(a) (prohibiting the introduction into interstate commerce of adulterated or misbranded device), 351 (defining adulterated devices), 352 (defining misbranded devices). The government proves a violation of this FDCA provision by establishing that (1) the defendant's products were devices within meaning of the FDCA, (2) the devices were adulterated or misbranded, and (3) the devices moved in interstate commerce. See United States v. Endotec, Inc., 563 F.3d 1187, 1190 (11th Cir. 2009) (elements required to show violation). That a product is sold through a PMA does not exempt it from the application of this provision. See 21 U.S.C. § 321(e) (person subject to FDCA includes association); United States v. Allgyer, No. 11-02651, 2012 WL 355261 (E.D. Pa. Feb. 3, 2012) (unpublished memorandum order) (holding defendant was regulated by FDCA despite defendant's creation of PMA for distribution); cf. United States v. Cole, No. 3:13-cv-01606, 2015 WL 471594 (D. Ore. Feb. 5, 2015) (finding defendant's plan to create PMA to continue providing misbranded and adulterated product showed necessity for injunction to prevent future FDCA violations). We thus conclude that Lytle's argument fails.

Lytle also appeals the district court's entry of a preliminary injunction in the government's separate civil enforcement action to preclude him from continuing to manufacture, process, hold, or distribute laser devices for medical uses not approved by the FDA. Having reviewed the record and the parties' arguments on appeal, see 28 U.S.C. § 1292(a)(1) (appellate court has jurisdiction of interlocutory appeal of order granting preliminary injunction); Planned Parenthood Minn., N.D., S.D. v. Rounds, 530 F.3d 724, 733 (8th Cir. 2008) (en banc) (appellate court reviews for abuse of discretion ruling on preliminary injunction motion), we conclude that, for the reasons stated above, the government was entitled to preliminary injunctive relief. We note that injunctive relief must be narrowly tailored to remedy only the specific harms established by the plaintiff. See St. Louis Effort for AIDS v. Huff, 782 F.3d 1016, 1022-23 (8th Cir. 2015) (affirming preliminary injunction in part, vacating remainder, and remanding); United States v. Blue Ribbon Smoked Fish, Inc., 56 Fed. Appx. 542, 544 (2d Cir. 2003) (unpublished summary order) (noting that while reach of the FDCA is broad, injunction should not enjoin conduct beyond what is necessary to redress or prevent illegal activity; striking portion of injunction and remanding); Allgyer, 2012 WL 355261 at *5 (enjoining defendant from distributing misbranded product, but declining to grant government access to facility); United States v. Organic Pastures Dairy Co., 708 F. Supp.2d 1005, 1016 (E.D. Cal. 2010) (granting injunction, but declining to include FDA right to inspect without notice because evidence did not show that plant conditions affected integrity of product, and injunctive relief should be no broader than necessary to accomplish purpose). Because we are unable to determine from the record whether a more narrowly-tailored injunction might be sufficient, we remand for a reconsideration of the preliminary injunctive order. We note that if a ruling regarding permanent injunctive relief is imminent, such a reconsideration may become moot.

The judgment dismissing the declaratory judgment (Appeal No. 14-3715) is affirmed. The grant of a preliminary injunction (Appeal No. 15-1214) is remanded for further consideration in accordance with this opinion. We deny Lytle's pending motions.
