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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Nutrition Distribution LLC,

Plaintiff,

v.

Custom Nutraceuticals LLC, et al.,

Defendants.

No. CV-16-00173-PHX-DGC

ORDER

Defendants are nutritional supplement companies that manufacture and market Ostarine, a selective androgen receptor modulator ("SARM") with effects similar to those of anabolic steroids. Doc. 20, ¶¶ 1, 19. Plaintiff, a competing nutritional supplement company, asserts that Defendants have violated the Lanham Act by engaging in false advertising of Ostarine. ¶¶ 25-36. Plaintiff also asserts that Defendants have violated the Racketeer Influenced and Corrupt Organizations Act ("RICO") by engaging in a pattern of criminal activity in connection with their sale of Ostarine and similar products. ¶¶ 37-41. Defendants move to dismiss these claims, or in the alternative, to stay the action pending the Ninth Circuit's resolution of a related case. Doc. 21. The motion has been fully briefed (Docs. 25, 26), and the Court concludes that oral argument will not aid in its decision.[1] For the reasons that follow, the Court will dismiss the RICO claim with leave to amend, and otherwise deny the motion.

[1] Defendants' request for oral argument is therefore denied. *See* Fed. R. Civ. P. 78(b); *Partridge v. Reich*, 141 F.3d 920, 926 (9th Cir. 1998).

I. Lanham Act.

"The Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014); *see* 15 U.S.C. § 1125(a)(1)(B) ("Any person who . . . uses in commerce . . . any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods . . . shall be liable in a civil action"). This cause of action may be invoked by competitors – those entities that stand to suffer "'an injury to a commercial interest in sales or business reputation'" as a proximate result of the defendant's misrepresentations. *Id.* (*quoting Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1395 (2014)).

Plaintiff alleges that Defendants have made false and misleading representations about Ostarine. First, Plaintiff alleges that Defendants have labeled their Ostarine products as "not for human consumption," while simultaneously representing that Ostarine is a body-building drug and an "[e]asy to dose oral SARM." Doc. 20 ¶¶ 1, 26. Second, Plaintiff alleges that Defendants have failed to disclose that the World Anti-Doping Agency and the U.S. Anti-Doping Agency have banned the use of SARMs – information that may be material to the competitive athletes targeted by Defendants' marketing. ¶ 31. Third, Plaintiff alleges that Defendants have represented that Ostarine has few side effects, when medical evidence suggests that it has potentially serious side effects. ¶¶ 27-30. Plaintiff alleges that Defendants' statements have caused it a loss of good will and a diversion of business from its own products. ¶¶ 18, 24, 35.

Defendants do not dispute that Plaintiff has adequately pleaded the elements of a Lanham Act claim. Instead, they argue that the Court should abstain from deciding this claim because it raises issues that should be answered in the first instance by the Food and Drug Administration ("FDA").

In general, "[a] federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging." *Lexmark*, 134 S. Ct. at 1386. The primary

jurisdiction doctrine constitutes a limited exception to this principle. This doctrine allows a federal court to abstain from deciding a case within its subject matter jurisdiction if it determines that the "initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). Such abstention may be appropriate where a claim "implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the regulatory industry." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (citation omitted). Courts should consider "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Id.*

The Court concludes that it should not dismiss this case under the primary jurisdiction doctrine. The Court need not consult the FDA to determine whether it is false and misleading to label a product as "not for human consumption" while touting the benefits of such consumption. This question is not one "that "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.* at 760 (quotation marks and citations omitted); *cf. United States v. Storage Spaces Designated Nos. 8 & 49 Located at 277 E. Douglas, Visalia, Cal.*, 777 F.2d 1363, 1367 (9th Cir. 1985) ("Because the products are labeled as 'incense,' when it appears that they are, in fact, intended for drug use, there is a reasonable basis for believing that the labeling is false and misleading.").

Nor does the Court require the FDA's expertise to determine whether it is false and misleading to market a product to competitive athletes while neglecting to mention that it has been banned by the World Anti-Doping Agency and the U.S. Anti-Doping Agency. It is not clear that this question even implicates the FDA's regulatory scheme; the Food, Drug, and Cosmetic Act ("FDCA") "'is not focused on the truth or falsity of advertising claims,' but is instead directed to protecting'" public safety. *Mut. Pharm. Co.*

v. Ivax Pharm., Inc., 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) (quoting *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990)). Thus, the FDCA does not prohibit all omissions that might be material to a consumer, but only those that are material "with respect to consequences which may result from the use of the article." 21 U.S.C. § 321(n). Even assuming the FDA *could* require Defendants to disclose that their product has been banned by major sports agencies, the issue is not one that implicates the agency's technical and policy expertise. Indeed, Plaintiff may have a superior understanding of how consumers of body building products would react to this information. *Cf. POM Wonderful*, 134 S. Ct. at 2238 (competitor's "awareness of unfair competition practices may be far more immediate and accurate than that of" the FDA).

Finally, the Court will not abstain from deciding Plaintiff's claim that Defendants made false and misleading statements about Ostarine's side effects. The FDA certainly has primary jurisdiction to regulate statements about the side effects of drugs. *See, e.g.*, 21 U.S.C. § 352(n) (prescription drugs are mislabeled if advertising materials do not contain a true statement of the drug's "side effects, contraindications, and effectiveness"); 21 C.F.R. § 201.66(c)(5)(vi)-(vii) (requiring statement of side effects for over-the-counter medications). But Defendants deny that Ostarine is a drug (Doc. 21 at 16) and apparently have not sought approval to market it as a drug. Having denied the FDA's authority to regulate Ostarine as a drug, Defendants cannot invoke the same authority to avoid a suit under the Lanham Act.[2]

Defendants argue that abstention is appropriate because the complaint raises a variety of issues that Congress has committed to the FDA, including whether Ostarine is a "drug" or "new drug," as opposed to a "dietary supplement," whether Defendants acted illegally in advertising and selling Ostarine, and whether Ostarine is "safe and effective." Doc. 26 at 10. But Plaintiff's theories do not require the Court to determine whether

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[2] Defendants contend that Ostarine is a nutritional supplement, subject to regulation under 21 U.S.C. § 343(s) and 21 C.F.R § 101.36. Doc. 21 at 14-15. Neither of these authorities governs statements about a nutritional supplement's side effects. Thus, regulating these statements cannot be said to fall within the FDA's primary jurisdiction.

Ostarine is a drug or whether Defendants' sale of Ostarine violated the FDCA. Even if Defendants are lawfully marketing Ostarine as a nutritional supplement, their statements about the product may still be false and misleading.

Finally, Defendants argue that only the FDA can decide if Ostarine is safe. But while the FDA is charged with determining whether products like Ostarine are safe enough to be sold in interstate commerce (21 U.S.C. §§ 355(d), 350b(a)(2)), this case presents a different question: whether Ostarine is as safe *as Defendants claimed*. The Court can decide this question without expressing any opinion on the technical and policy questions committed to the FDA. *Cf. ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, No. 14-15180, 2016 WL 1460171, at *1 (9th Cir. Apr. 14, 2016) (deciding whether a nutritional supplement distributor "falsely advertised its products as 'safe' . . . require[s] no interpretation of the FDCA").

As the Ninth Circuit has noted, "[n]ot every case that implicates the expertise of federal agencies warrants invocation of primary jurisdiction." *Astiana*, 783 F.3d at 760. In addition, "courts must also consider whether invoking primary jurisdiction would needlessly delay the resolution of claims." *Id.* (citation omitted). For reasons explained above, the Court concludes that this case is not one of the "limited set" requiring FDA expertise, and that the delay involved in seeking FDA guidance would not be justified in light of the allegations made. *Id.* (citation omitted).

II. RICO.

RICO makes it unlawful for "any person employed by or associated with any enterprise engaged in . . . interstate or foreign commerce, to conduct or participate . . . in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c). "Racketeering activity" includes any of several listed crimes "which is chargeable under State law and punishable by imprisonment for more than one year," as well as any act chargeable under one of several enumerated federal statutes. § 1961(1). A "'pattern of racketeering activity' requires at least two acts of racketeering activity," § 1961(5), which must be "related" and "amount to or pose a threat of continued criminal

activity." *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 239 (1989).

To state a RICO civil claim, a plaintiff must allege "(1) the conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 997 (9th Cir. 2014) (citation omitted). "In addition, the conduct must be (5) the proximate cause of harm to the victim." *Id.* (citation omitted). Pleading a pattern of racketeering activity requires the plaintiff to allege that the defendant participated in at least two acts that were chargeable under the enumerated federal statutes. The plaintiff must adequately plead the elements of each predicate act, satisfying the pleading standard that would apply if the predicate act were a stand-alone claim. *See Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392 (9th Cir. 1988) (complaint failed to state a RICO claim because it failed to adequately plead the elements of the predicate act; where predicate act is mail or wire fraud, complaint must plead the elements of this offense with the level of particularity required by Federal Rule of Civil Procedure 9(b)).

Plaintiff alleges that Defendants have (1) engaged in "a comprehensive scheme to obtain money and property by false or fraudulent pretenses, representations and promises, including the illicit sale of SARMs and other pharmaceuticals"; (2) knowingly sold these drugs over the internet and had them delivered through commercial interstate carriers; (3) received income from this activity; and (4) conspired among themselves to engage in this activity. Doc. 20, ¶¶ 38-40. Plaintiff alleges that it has been injured in its business or property as the result. ¶ 41.

Plaintiff has not adequately alleged a pattern of racketeering activity. Although Plaintiff asserts that Defendants have engaged in the illegal sale and distribution of pharmaceuticals, it fails to identify any particular instance in which Defendants engaged in such activity. Nor does Plaintiff explain which of the provisions listed in § 1961(1) it believes Defendant violated. It is not enough to allege that Defendants have violated *some* federal law, since not all violations of federal law are RICO predicates. *See Smith v. Jackson*, 84 F.3d 1213, 1217 (9th Cir. 1996) ("Because appellants' RICO counts do no

more than allege copyright infringement . . . and copyright infringement is not a predicate act under RICO . . . appellants failed to state a claim."). Because Plaintiff has failed to identify two or more instances in which Defendants violated a statute listed in § 1961(1), it has not adequately alleged a pattern of racketeering activity.[3]

Defendants argue that Plaintiff's attempt to plead damages is also deficient. The Court does not agree. Plaintiff alleges that (1) it sells natural nutritional supplements designed to boost testosterone, which compete directly with Defendants' products, and (2) some of its business has been diverted to Defendants' site. Doc. 20, ¶¶ 18, 41. These allegations are sufficient to state a plausible claim for financial injury resulting from Defendants' conduct.

Plaintiff requests leave to amend in the event any of its claims are dismissed. "Leave to amend should be granted if it appears at all possible that the plaintiff can correct the defect." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000). The Court concludes that Plaintiff may be able to allege a pattern of racketeering activity. The Court will therefore dismiss Plaintiff's RICO claim with leave to amend.

III. Stay.

As an alternative to dismissal, Defendants ask the Court to stay this case pending the Ninth Circuit's resolution of *Nutrition Distribution LLC v. Ironmag Labs, LLC*, No. 16-55632 (9th Cir., Apr. 29, 2016). In that case (brought by Plaintiff here), the district court dismissed Lanham Act and RICO claims against another marketer of Ostarine. Doc. 14-1 at 227-30. Plaintiff appealed.

The Court will not stay this matter. Plaintiff's theories in this case differ from those asserted in *Ironmag*. For example, there was no allegation that the defendant in *Ironmag* labeled its Ostarine product as "not for human consumption." *See id.* at 146-68. Although it was alleged that the defendant in *Ironmag* failed to disclose that Ostarine had

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[3] Plaintiff asks the Court to take judicial notice of several cases in which individuals were prosecuted under federal law for marketing misbranded body building drugs. *See* Doc. 25-2. This evidence cannot substitute for the pleadings of the complaint, which must themselves state a RICO claim.

been banned by major sports agencies (*id.* at 156, ¶ 43), the district court did not address this theory of Lanham Act liability (*see id.* at 227-30). Thus, the Ninth Circuit's decision may not answer several important issues raised by this case, and the Court will not delay this case while waiting for what likely will be a years-long appeal process.

IT IS ORDERED:

1. Defendants' motion to dismiss Plaintiff's RICO claim (Doc. 21) is **granted**, with leave to amend. Plaintiff may file an amended complaint by **July 27, 2016**. Defendants' motion is otherwise **denied**.

2. Defendant's motion to dismiss (Doc. 13) is **found to be moot**.

Dated this 8th day of July, 2016.

David G. Campbell
United States District Judge