UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ROBERT GORDON, et al.,

Plaintiffs,

v.

CHURCH & DWIGHT CO.,

Defendant.
_____/

No. C 09-5585 PJH

ORDER GRANTING MOTION TO DISMISS

Defendant's motion to dismiss the complaint for lack of subject matter jurisdiction and failure to state a claim came on for hearing before this court on March 24, 2010. Plaintiffs appeared by their counsel Thomas Clarke, and defendant appeared by its counsel Lawrence Weinstein and Baldassare Vinti. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, and good cause appearing, the court hereby GRANTS the motion as follows.

Plaintiffs Robert Gordon and Mele Lau-Smith filed this unfair business practices case as a proposed class action on October 29, 2009. Plaintiffs allege that defendant Church and Dwight Co. ("C&D") manufactures, advertises, and endorses a product (TROJAN-ENZ Brand Latex Condoms – "the product") that contains a spermicidal lubricant known as Nonoxynol-9 ("N-9"). Plaintiffs assert further that C&D has claimed that these

latex condoms help reduce the spread of sexually-transmitted diseases (including AIDS). Plaintiffs assert that in reality, although latex condoms may help to reduce the spread of HIV/AIDS, exposure to N-9 can increase the risk of HIV transmission.

Plaintiffs allege three causes of action – (1) a claim of false and misleading advertising, in violation of Cal. Bus. & Prof. Code § 17500; (2) a claim of fraudulent and deceptive marketing, in violation of Cal. Bus. & Prof Code § 17200; and (3) a claim under the Consumer Legal Remedies Act, Cal. Civ. Code § 1770(5) and (7). Plaintiffs assert under all three claims that C&D makes false and misleading statements on the label of the product.

The court finds that the action must be dismissed because the scope and content of condom labels are within the primary jurisdiction of the U.S. Food and Drug Administration ("FDA"). The "primary jurisdiction" doctrine does not implicate subject-matter jurisdiction as such, but it is a "prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decision-making responsibility should be performed by the relevant agency rather than the courts." Syntek Semiconductor Co., Ltd. v. Microchip Technology, Inc., 307 F.3d 775, 780 (9th Cir. 2002). The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency. Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9th Cir. 2008).

The doctrine is applied at the court's discretion, and courts typically consider whether adjudication of the issue requires the administrative body's expertise and whether there is a need for uniformity within the area of regulation. Syntek, 307 F.3d at 781; see also United States v. Western Pac. R.R. Co., 352 U.S. 59, 63-64 (1956). Courts generally consider four factors when applying the doctrine: "(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." Syntek, 307 F.3d at 781.

The FDA has actively regulated N9 condoms for thirty years, under the authority granted by the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301, et seq. ("FDCA"), as amended by the Medical Device Amendments of 1976, 21 U.S.C. § 360c-360dd. The FDA has carried out this duty by, among other things, promulgating regulations governing the labeling of N9 condoms, and mandating the specific substance of warnings, instructions, and statements of use. The FDA continues to be actively involved in monitoring and evaluating the labeling of N9 condoms. See, e.g., 73 Fed. Reg. 66,522 (Nov. 10, 2008).

In general, cases raising issues of fact that do not fall within the traditional expertise of judges or cases requiring the expertise of administrative authority should be relinquished to the agency established by Congress to regulate the subject matter. See Far East Conference v. United States, 342 U.S. 570, 574 (1952); see Western Radio Servs. Co. v. Qwest Corp., 530 F.3d 1186, 1200 (9th Cir. 2008).

The issue of medical device labeling requires expertise as well as uniformity in administration. The plaintiffs' claims involve a technical area over which the FDA has more expertise than the courts; and, while the claims are based on state law, their effect is to challenge the wording in the warnings that are required to be included in the latex condom packaging pursuant to federal law.

The court notes in particular that the FDA has stated that it is still considering public comments and other data in connection with warnings similar to those that plaintiffs seek to have the court impose on C&D. See 73 Fed. Reg. 66,526. Thus, this issue remains under review. It would be inappropriate for this court to assume the FDA's regulatory role, and to interpret scientific studies or other evidence to determine whether the labeling of N9 latex condoms should be changed to include an additional warning that N9 condoms should not be used when one of the sexual partners has HIV/AIDS or engages in behavior that is risky for transmission of HIV/AIDS, particularly given the important role that condoms play in the fight against the transmission of HIV/AIDS, which continues to be a significant threat to public health.

In accordance with the foregoing, the court finds that C&D's motion must be GRANTED, and that the action must be DISMISSED under the primary jurisdiction doctrine.[1] The dismissal is WITHOUT PREJUDICE.

IT IS SO ORDERED.

Dated: April 2, 2010

PHYLLIS J. HAMILTON
United States District Judge

[1] The court finds it unnecessary to address the other arguments made by C&D in its motion.