UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MUTUAL PHARMACEUTICAL COMPANY; AR SCIENTIFIC, INC.; and AR HOLDING COMPANY, INC.,

Plaintiffs,

v.

IVAX PHARMACEUTICALS, INC.; and ZENITH GOLDLINE PHARMACEUTICALS, INC.

Defendants.

CASE NO. CV-06-4474-SGL (JCx)

ORDER GRANTING IN PART AND DENYING IN PART MOTION FOR PRELIMINARY INJUNCTION

Presently before the Court are plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc.'s (collectively "Mutual") motion for a preliminary injunction, defendants Ivax Pharmaceuticals, Inc. ("Ivax"), Zenith Goldline Pharmaceuticals, Inc. ("Zenith") and intervenor Teva Pharmaceuticals, USA's ("Teva") opposition thereto, and Mutual's reply. For the reasons set forth below, the motion for preliminary injunction is **GRANTED IN PART AND DENIED IN PART**.

Mutual's business "focuses on drug development, marketing and distribution" of "a wide range of products, including quinine sulfate [that is used] for [the] treatment of malaria." (Compl. ¶ 23). Malaria is an ancient disease caused by

parasites in the blood that is most often transmitted to humans through mosquito bites, and whose principle symptoms are "severe fever and headache" that can rapidly progress to "coma, renal failure, pulmonary edema, and ultimately, death." (Decl. Joseph M. Vinetz ¶ 4). Quinine is a white crystalline alkaloid that slows the growth or kills the parasites in the blood that cause malaria. See http://en.wikipedia.org/wiki/Quinine. Quinine was first used by the Quechua Indians of Peru who extracted it from the bark of the native cinchona tree to halt shivering brought on by cold temperatures. Id. Indeed, the name "Quinine" is derived from the original Quechua word for the cinchona tree bark, "Quina" or "Quina-Quina," which roughly means "bark of bark" or "holly bark". Id. Quinine was later introduced to Europe by missionaries who had observed its use in Peru. It was used to treat malaria as early as 1631 in Rome, where the disease was endemic to the swamps and marshes surrounding the city. Id. The large scale use of quinine as a prophylactic for the treatment of malaria started around 1850. Id. In the years that followed, cinchona bark became one of the most valuable commodities shipped from Peru to Europe. Id. To this day cinchona trees remain the most practical source of quinine. Id.

Despite its long-term usage, "the Food and Drug Administration ("FDA") halted the sale and distribution of all marketed over-the-counter quinine sulfate products [in the United States] in 1998," see Drug Products Containing Quinine for the Treatment and/or Prevention of Malaria for Over-the-Counter Human Use, 63 Fed. Reg. 13526-01 (to be codified at 21 C.F.R. pt. 310 subpt. E), leaving a doctor's prescription as the only means of obtaining the drug. (Compl. ¶ 8). The ban on over-the-counter ("OTC") sales of quinine sulfate was precipitated by evidence demonstrating adverse consequences from use of the drug without the supervision and care of a physician. (Id.) "For example, . . . from 1969 through June 1992, the FDA received 157 reports of health problems related to quinine use, including 23 that resulted in death. Other problems included temporary sight and

hearing disturbances, dizziness, fever, nausea, vomiting, and diarrhea," as well as "thrombocytopenia, a destruction of blood platelets that can lead to massive bleeding and sometimes death." (Id.). Such adverse consequences in OTC use of the drug can be traced in some measure to the fact that quinine sulfate "has a narrow therapeutic index" between the level at which its presence in the blood is considered therapeutic and "toxic." (Decl. Joseph M. Vinetz ¶ 7). Such a narrow margin for safety can become problematic for lay users who, without the supervision and care of a physician, do not have or follow "accurate dosage and instructions-for-use" information for using quinine to treat malaria. (Id.)

For more than six years following the FDA's action, the market for quinine sulfate was filled by drug makers marketing and selling unapproved prescription quinine sulfate. See 63 Fed. Reg. 13526-01, 13526 (noting that further dispensation of quinine after removal of OTC availability for drug would require "application or abbreviated application approved under section 505 of the [FDCA] and 21 CFR part 314 . . . for marketing[,] [i]n the absence of [which] . . . these products are considered misbranded"). Mutual sought to remedy this void by submitting to the FDA on January 21, 2004, an Investigational New Drug application ("IND") for the treatment of symptoms of imported drug-resistant, uncomplicated malaria by quinine sulfate. (Compl. ¶ 42; Decl. Robert Dettery ¶ 8). Contained with the submission were "literature references" to pharmacokinetic studies on the effects of quinine sulfate between different age (pediatric patients, elderly individuals) and health (those with or without normal renal or liver functions) subgroups of healthy individuals and those with uncomplicated malaria, as well as "21 randomized, active-controlled clinical studies" concerning quinine therapy for the treatment of uncomplicated malaria "identified from over 1300 historical references in the published literature." (Decl. Robert Dettery ¶¶ 8-9). On February 13, 2004, Mutual also submitted a request for orphan drug designation of its 324-mg quinine sulfate capsule. (Decl. Robert Dettery ¶ 11; Compl. ¶ 42). Mutual then

filed a New Drug Application ("NDA") No. 21-799 with the FDA in October, 2004, for its 324-mg quinine sulfate capsules. (Decl. Robert Dettery ¶ 9; Compl. ¶ 42).

In August, 2005, Mutual obtained FDA approval to market its 324-mg quinine sulfate capsule for the treatment of uncomplicated Plasmodium falciparum malaria (hereinafter "uncomplicated malaria") based on the information submitted by Mutual in connection with its IND. (Decl. Robert Dettery ¶ 9; Compl. ¶ 43). To obtain FDA approval, Mutual agreed to sponsor, among other things, a study "in humans to determine the single dose relative bioavailability of Mutual's" 324-mg quinine sulfate capsules "against" those of the 300-mg quinine sulfate tablets "manufactured by the Government Pharmaceutical Organization, Bangkok, Thailand." (Decl. Robert Dettery ¶ 9). Information from this study was "incorporated into the final instructions for use that was approved by [the] FDA for Mutual's quinine sulfate 324-mg capsules." (Id.)

Mutual's quinine sulfate capsule is marketed under the trademark Qualaquin. (Compl. ¶ 4). The FDA, pursuant to the Orphan Drug Act amendments to the Food, Drug, and Cosmetics Act ("FDCA"), see 21 U.S.C. § 360aa-ee,[1] designated

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[1] When the potential market for a drug is small because the target market is relatively small (such as in the case of malaria where only "a few thousand" Americans are stricken with the disease each year, most of them acquiring the disease while traveling abroad (see Decl. Joseph M. Vinetz ¶ 4), it is difficult for a pharmaceutical manufacturer to recover the large research and development costs, and even more difficult to realize a worthwhile return on that investment. The Orphan Drug Act was enacted in 1983 as an effort to provide incentives for market-driven pharmaceutical companies to develop and test drugs for the treatment of "rare diseases or conditions" affecting relatively small number of Americans. See 21 U.S.C. § 360bb(a)(2)(defining a "rare disease or condition" as one "affect[ing] less than 200,000 persons in the United States"); see also David Duffield Rohde, The Orphan Drug Act: An Engine of Innovation? At What Cost?, 55 FOOD & DRUG L.J. 125, 125-127 (2000)(noting that a "drug is considered 'orphaned' when a potentially therapeutic compound is identified, but due to the small potentially-treatable target population associated with the disease, it lacks a sponsor to conduct the clinical trials necessary for FDA approval"; this "limited market" spilled over into "industry concerns over [the orphan] drug['s] profitability" prompting passage of the Orphan Drug Act to provide incentives so pharmaceutical industry could recoup development costs). Designation and approval of a drug as an orphan drug provides certain benefits to

Mutual's 324-mg quinine sulfate capsule as an orphan drug and further granted Mutual a 7-year period (ending in August, 2012) to exclusively market its quinine sulfate capsule for the treatment of uncomplicated malaria. The FDA confirmed this action in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") published by the FDA's Office of Generic Drugs. (Compl. ¶ 5). Relying on this grant, Mutual began distributing and marketing its Qualaquin in July, 2006, through its affiliates, AR Scientific, Inc. and AR Holding

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the sponsor of the drug. Id. at 128 (listing as "at the heart of the Act" the provision of marketplace grounded incentives "to encourage research, development, and marketing of orphan drugs"). For example, such a designation permits the FDA to assist the sponsor in studying the drug, see 21 U.S.C. § 360ee, and allows the sponsor to claim the benefit of a tax credits for clinical testing costs. See 26 U.S.C. § 44(H). More importantly for purposes of this case, orphan drug designation and approval confers the drug's sponsor the exclusive right to market the orphan drug for seven years for use in treating the particular disease or condition. See 21 U.S.C. § 360cc(a). As the House Report submitted in connection with the passage of the Orphan Drug Act explained, the purpose of this seven-year market exclusivity period was to allow the orphan drug's sponsor "to recoup the cost of development by capturing all revenues from the sale of the drug for the rare disease." H.R. REP. NO. 99-153, reprinted in 1985 U.S.C.C.A.N. 301, 303.

In 1992, the FDA promulgated its final orphan drug regulations on how to implement the orphan drug exclusivity right. In these regulations, the FDA made it clear that it would enforce this market exclusivity by refusing to approve any application for the "same drug" used for the same therapeutic purpose as the first-approved drug until the seven-year period of exclusivity expires. 21 C.F.R. § 316.3(b)(12). The regulation further provided a definition for determining when two drugs are the "same drug" and thus the second drug may not be approved for market exclusivity. See 21 C.F.R. § 316.3(b)(13)(i). In essence, that regulation provides that two drugs will be considered the same drug if they contain the same active moiety, unless the second drug is deemed to be "clinically superior." 21 C.F.R. § 316.3(b)(13)(i). As one commentator noted, "[t]he Orphan Drug Act market protection is narrow because only the use of that particular drug for treating the designated rare disease is protected. . . . A second pharmaceutical manufacturer may seek FDA approval of a different drug for the same disease (or the same orphan drug for different orphan diseases or non-orphan diseases) but the sponsor of a subsequent drug for the same disease bears the burden of proof to demonstrate that its drug is different." Robert A. Bohrer and John T. Prince, A Tale of Two Proteins: The FDA's Uncertain Interpretation of the Orphan Drug Act, 12 HARV. J.L. & TECH. 365, 371-72 (1999). Its only when "the drug is not approved for any other medical indication" that "the Orphan Drug exclusivity is essentially as effective as patent protection." Id. at 372.

Company, Inc.

Despite this grant of market exclusivity, defendants Ivax, Zenith, and, through them, their parent company Teva continue to market and distribute quinine sulfate (of varying milligram dosages per capsules or tablets) to the public for the treatment of both complicated and uncomplicated malaria. Defendants' quinine sulfate has "never been approved for sale by the FDA for the treatment of malaria or any other disease or condition." (Compl. ¶ 7). It is alleged that in marketing and distributing their quinine sulfate product defendants have made representations to the public "that their quinine sulfate products are safe, effective and approved by the FDA for the treatment and/or prevention of malaria, when in fact, they are not." (Compl. ¶ 14). It is on account of this promotional and distribution activity in the sale of their products that Mutual alleges defendants have violated the Lanham Act and related state law claims for making false or misleading advertising.

Mutual alleges in its complaint that the descriptions and representations in defendants' advertising are false or misleading in various respects:

- Defendants marketing their drug product by placing it on privately integrated drug dispensing databases and pricing systems ("clinical/price lists"), such as Medispan and First Databank ("the nation's two principal vendors of integratable drug information databases"), that "represent a major drug-marketing communications-channel to pharmacists and chain store buyers." (Decl. Martin Buncher ¶ 11; Compl. ¶¶ 59-67). Such clinical/price lists are used by pharmacists to decide which drug brand to dispense to fill a prescription.[2] (Decl. Martin Buncher ¶ 11; Decl. Robert Graul ¶ 5).
- The information contained on defendants' drug products labels is incomplete or incorrect as it does not list all the drug-to-drug interactions that

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[2] Defendants also market their quinine sulfate through other commercial channels, "including national drugstore chains, wholesale generic buyers, [and] independent pharmacies, in addition to clinical/price lists." (Decl. Rich Foster ¶ 3). Mutual does not challenge this distribution activity.

could occur with the use of quinine sulfate, "recommends incorrect (and potentially dangerous) dosage" schedule, fails to list all the possible adverse consequences from using the drug, and provides inaccurate instructions for use of the drug from that required by the FDA, as evidenced by what the FDA required Mutual to place on its labels for Qualaquin. (Compl. ¶¶ 15, 17, 76-84, 86-90; Decl. Joseph M. Vinetz ¶ 10).

- Defendants selling their products through third party internet retailers, such as buygenericdrugs.com, who make representations on their web sites that all the products sold on the site (which includes defendants' quinine sulfate capsules and tablets) are FDA approved. (Compl. ¶¶ 94-95).
- Representations made on defendants' own web sites that strongly imply their drug is FDA approved. (Compl. ¶ 85; Decl. Robert Graul ¶ 13 & Ex. 2; Decl. Brendan Hughes ¶¶ 2-4 & Exs. 1&2; Decl. Robert Dettery ¶ 10 & Ex. 1).

Mutual raised complaints to the FDA (and others) concerning defendants' distribution of their quinine sulfate product. In May, 2006, Mutual's President wrote a letter to the FDA complaining about the FDA's failure to enforce the grant of market exclusivity for Mutual's Qualaquin, labeling the FDA's inaction as a "disturbing laissez-faire approach to the issue of the safety of unapproved quinine sulfate." (Supp. Decl. Rich Foster, Ex. 1). Mutual later requested that the FDA instruct Customs officials to "refuse entry of all quinine sulfate API [Active Pharmaceutical Ingredient] that is not destined for Mutual's use." (Decl. David Marshall, Exs. 9 & 10). Defendants parried Mutual's pleas for action from the FDA by submitting a letter explaining to the FDA that quinine sulfate is not a "new drug" (in general because of its long usage in the treatment of malaria) and therefore does not require FDA approval to be sold legally in the United States as a prescription medication, challenging the FDA's decision to grant Mutual orphan drug exclusivity, and finally requesting that any enforcement action be stayed so as

to give defendants a grace period to pull their product off the market. (Decl. Laura A. Wytsma, Ex. C). As a result of Mutual's efforts, the FDA recently announced that it is considering, but has not yet decided on, an enforcement action against defendants. (Decl. Laura A. Wytsma, Exs. A & B).

The FDA's announcement did not mollify Mutual from going forward with filing the present complaint and seeking to preliminarily enjoin defendants from: "[S]elling, marketing, and distributing non-FDA-approved quinine sulfate for the treatment of uncomplicated malaria or any other condition, and recall such products from the market; remove information regarding their quinine sulfate products from any 'Price List' drug dispensing system in the United States; and refrain from making or disseminating further unlawful statements concerning their quinine sulfate products, including in advertisements, promotional and marketing materials and instructions for use, which falsely suggest their products are safe and effective for the treatment of malaria, have been FDA approved, are generic or therapeutic equivalents to Mutual's Qualaquin or any other drug, and/or can be interchanged with or substituted for prescriptions of Qualaquin or other drugs." (Mot. Prelim. Inj. at 4). It is to that request that the Court now turns.

The Ninth Circuit has provided varying descriptions, "some simple and some ornate," for what is required to obtain a preliminary injunction. Regents of University of California v. American Broadcasting Co., Inc., 747 F.2d 511, 515 (9th Cir. 1984). Regardless of their different formulations, these standards "are not separate tests but the outer reaches of a single continuum" keyed to guiding a "district court's essential task of balancing the equities in the exercise of [its] equitable discretion." Id. For purposes of this case the court will employ the more condensed standard requiring "[t]he moving party [to] show either (1) a combination of probable success on the merits and the possibility of irreparable injury, or (2) that serious questions are raised and the balance of hardships tips sharply in favor of the moving party" for the issuance of a preliminary injunction. Stuhlbarg Int'l Sales

Co., Inc. v. John D. Brush and Co., Inc., 240 F.3d 832, 839-40 (9th Cir. 2001).

A. PROBABILITY OF SUCCESS

Section 43(a)(1)(B) of the Lanham Act makes actionable the placement into interstate commerce of a "false or misleading description of fact, or false or misleading representation of fact" concerning "the nature, characteristics, qualities, or geographic origin of" one's own "or another person's goods." The central focus of the statute is to combat false representations in promoting a product in the marketplace. The falsity of the statement can be established either by showing that, in context, the statement "was literally false, either on its face or by necessary implication," or by showing that although the statement was "literally true" it was nonetheless "likely to mislead or confuse consumers" as evidenced by consumer surveys. Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139-40 (9th Cir. 1997). As one court explained:

> After initial uncertainty as to the statute's reach, with some believing it to be little more than a codification of the common law action for deceitful advertising, it is now settled that it creates a new statutory tort of broader scope, which requires neither proof of literal or obvious falsehood, nor of intent to deceive. As we stated in Vidal Sassoon, "§ 43(a) of the Lanham Act encompasses more than blatant falsehoods. It embraces 'innuendo, indirect intimations, and ambiguous suggestions' evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement."

Procter & Gamble Co. v. Chesebrough-Pond's, Inc., 747 F.2d 114, 118-19 (2d Cir.1984) (quoting Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 277 (2d Cir.1981)); see also Cook, Perkiss & Liehe v. Northern California Collection Serv. Inc., 911 F.2d 242, 245 (9th Cir. 1990)("a false advertising cause of action under the Act is not limited to literal falsehoods; it extends to false representations made by implication or innuendo").

These two different forms of falsehoods subject to an action under the Lanham Act have correspondingly different evidentiary requirements: "Where the advertisement is literally false, a violation may be established without evidence of consumer deception." Scotts Co. v. United Indus. Corp., 315 F.3d 264, 273 (4th

Cir. 2002). "If the advertising claim is literally false, the court may enjoin the use of the claim without reference to the advertisement's impact on the buying public." C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P., 131 F.3d 430, 434 (4th Cir. 1997). If, however, "a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers." Scotts Co., 315 F.3d at 273. The reason for this difference in proof is that, while "a court may find on its own that a statement is literally false," whether a representation is impliedly misleading is not something that is readily susceptible to being evaluated absent "evidence [showing] actual consumer deception." Abbott Labs. v. Mead Johnson & Co., 971 F.2d 6, 14 (7th Cir. 1992).

At its core, defendants contest the source of proof Mutual consults to demonstrate the alleged falsity of their representations. They press the point that, in order to prove that their representations are false (as defined above), Mutual must make reference to the Food, Drug and Cosmetics Act ("FDCA") and its implementing regulations, which they argue is an impermissible source upon which to predicate a Lanham Act claim. To understand the legal permutations created through the interaction of these statutes, some context is in order.

The Lanham Act and the FDCA both regulate the marketing of prescription drugs, but each serves different, although somewhat overlapping, purposes. The Lanham Act is "primarily intended to protect commercial interests" from being harmed by the unfair competition created by a competitor peddling his wares using false or misleading advertising. Sandoz Pharmaceuticals v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (3rd Cir. 1990). The Lanham Act vests the power to regulate against such false or deceptive advertising in the marketplace in the hands of private parties. Id. The FDCA, on the other hand, "is not focused on the truth or falsity of advertising claims," but is instead directed to protecting the public by ensuring that drugs sold in the marketplace are "safe, effective and not

misbranded," a task vested in the FDA to implement and enforce. Id. As one court explained, "[t]he FDA's authority in this field derives from the requirement that no drug may be sold in the United States unless it has FDA approval, and then only within the standards set by the FDA." Id. at 226. That the statutes may regulate the same market should not be seen as necessarily requiring that application of one be at the sufferance of the other. Neither statute contains any provision for it to preempt (or act to the exclusion of other statutes) the field in which it operates. Where the statutes overlap they perform different, but complementary roles to regulate what products can make it to market (FDCA), and how those products are then promoted in the market (the Lanham Act and to a certain extent the FDCA through its misbranding standards).

A wrinkle complicating the natural interplay between the two statutes is the fact that, unlike the Lanham Act, the FDCA and its implementing regulations may not be privately enforced. See 21 U.S.C. § 337(a)(providing that "all such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States"). Instead, "the right to enforce the provisions of the FDCA lies exclusively within the federal government's domain, by way of either the FDA or the Department of Justice." Summit Technology v. High-Line Medical Instruments, 922 F.Supp. 299 (C.D.Cal. 1996)("Summit I"). This special consideration has led courts to tread carefully when applying the Lanham Act to the advertising of goods, like quinine sulfate, that are also subject to regulation by the FDCA lest it be used as a vehicle to accomplish indirectly something a party could not accomplish directly. See Sandoz, 902 F.2d at 231 ("what the FDCA . . . do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of these Acts or their accompanying regulations"). Such trepidation, however, should not be seen as an invitation to leave the field completely occupied by the FDCA; the Lanham Act has its place even with respect to goods otherwise subject to regulation by the FDCA. Cf. Cottrell, Ltd. v. Biotrol

Int'l, Inc., 191 F.3d 1248, 1256 (10th Cir. 1999)(refusing to dismiss Lanham Act claim whose subject "touches on issues covered by" another federal statute because "nowhere" did that other federal statute "explicitly preclude Lanham Act coverage"). Courts have instead struck a balance between the two, allowing breathing space for the Lanham Act, but at the same time not letting it be misused as a naked attempt to enforce the FDCA and its implementing regulations.

Thus courts have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and then apply FDCA statutory or regulatory provisions. Application of this rule invariably occurs when the FDA has failed to take a position on the particular issue that is the subject of the alleged false representation comprising the Lanham Act claim. See Sandoz, 902 F.2d at 231; Summit Technology v. High-Line Medical Instruments Co., 933 F.Supp. 918, 933 (C.D. Cal. 1996)("Summit II")(refusing to allow a Lanham Act claim to proceed when "the claim would force the Court to rule directly 'on the legality of Defendants' conduct before the FDA has had a chance to do so'"). In those instances, courts have viewed introduction of the Lanham Act as nothing less than an effort to seek to have "a federal court to 'determine preemptively how a federal agency will interpret and enforce its own regulations,'" and not as an independent, stand-alone claim.

On the other hand, once the FDA has taken a position on a particular matter, courts have consistently allowed the Lanham Act claim to proceed even if in determining the falsity of the alleged representation the court must make reference to the FDA action. See Summit II, 933 F.Supp. at 933 ("[F]alse statements are actionable under the Lanham Act even if their truth may be generally within the purview of the FDA"); Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc., 720 F.Supp. 714, 716 (N.D.Ill. 1989)("The fact that Grove Fresh refers to or relies on an FDA regulation defining orange juice to support its Lanham Act claim is not

grounds for dismissal. . . . Grove Fresh relies on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet. Nothing prohibits Grove Fresh from using the FDCA or its accompanying regulations in that fashion"); cf. Cottrell, 191 F.3d at 1256 (noting that it would preclude a Lanham Act claim "which would require EPA expertise to determine whether claims made for a product were approved by the EPA"). So long as courts are not required to perform "authoritative interpretation and direct application of FDA regulations," then the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act. Summit II, 933 F.Supp. at 933. Thus, for instance, courts have allowed Lanham Act claims to proceed when the alleged false statement was that the product has "FDA approval" because "a court can test the truth of the statement . . . without any need to interpret FDA regulations[;] the question will simply be whether the FDA official conferred 'approval' or not." Id. at 933 & n.7.

It is in this context that many courts have refused to allow a Lanham Act claim to proceed, as the alleged "falsity" is not something that "is verifiable without . . . interpretation and application of FDA regulations." Id. at 936. As explained in Summit I:

> [T]he FDA has not yet determined whether or not the re-imported . . . devices need further approval at all. . . . [T]he FDA is continuing to investigate whether defendants have actually violated FDA regulations by marketing the use of the re-imported machines. . . . Plaintiff's Lanham Act cause of action would thus 'usurp the FDA's discretionary role in the application and interpretation of its regulations.' It would force this Court to rule on the legality of Defendants' conduct before the FDA has had a chance to do so. . . . A Lanham Act cause of action cannot stand if it alleges that a defendant has failed to disclose the fact of FDA non-approval, when the FDA has not yet determined whether or not the product in question has been approved. Simply put, the Lanham Act does not allow a federal court to 'determine preemptively how a federal agency will interpret and enforce its own regulations.'

922 F.Supp. at 306; see also Sandoz, 902 F.2d at 231(refusing to adjudge falsity of a cough syrups label when "the FDA has not found conclusively that [the product is

mislabeled]"). Taking these precedents, the following legal principle emerges: If the allegedly false or misleading nature of a statement can be easily verified, then the fact that the determination of the truth of that statement was made by the FDA is immaterial so long as the party can also show the other requirements for establishing a Lanham Act claim, that is, that the false or misleading statement is likely to deceive consumers.

Defendants essentially argue that all of Mutual's claims are nothing more than attempts to "shoehorn" private enforcement of FDCA approval and labeling violations through the Lanham Act and related state unfair competition laws. In making this argument, defendants cast Mutual's false advertising claims into three categories: The marketing of an unapproved product in violation of the FDA and the Orphan Drug Act, the failure to include certain safety and dosage information on package inserts and price lists as required by the FDA, and the false impression created that defendants' product was safe, effective and FDA-approved by marketing it on price lists and distributing the product to internet retailers who explicitly stated that defendants product was FDA-approved. (Opp. at 8-9).

Defendants quickly dismantle these arguments by noting, not surprisingly, that vindication of such a claim would require interpretation of the FDCA and its accompanying regulations. The Court will address in turn each type of false advertising claim pressed by Mutual viewed through the prism of the interplay between the FDCA and the Lanham Act.

1. Labeling Claim

The substance of Mutual's labeling claim is that the labels used by Ivax omit 21 of the FDA-required adverse drug interactions, and the ones used by Zenith in connection with its quinine sulfate omit 24 of the adverse drug interactions. Mutual also notes that the dosage and administration information contained on defendants labels "recommends incorrect (and potentially dangerous) dosages" when compared with those required by the FDA to be placed on Mutual's product label.

(Decl. Joseph M. Vinetz ¶ 10). For instance, the FDA-approved instructions for use of Mutual's 324-mg quinine sulfate capsule provide the following dosage schedule: "648 mg (2 pills) three times a day for a total daily dose of 1,944 mg/day," with "the recommended course of treatment" being "7 days," resulting in "the total course of treatment call[ing] for 13,608 mg." (Id. ¶ 11). By contrast, the dosage schedule on Ivax's 260 mg tablets would result in a total course of treatment "of 10,920 mg — 2,688 mg below the FDA-approved dosage"; its dosage schedule for its 200 mg capsule falling 1,008 mg below the FDA-approved total course of treatment dosage; and its dosage schedule for its 325 mg capsule exceeding the FDA-approved total course of treatment by 42 mg. (Id. ¶ 12). Zenith's dosage schedule is similarly mistaken: The dosage schedule for its 200 mg tablets is 5,208 mg below that required by the FDA, the one used for its 200 mg capsules results in a total course of treatment dosage that is 1,008 mg below FDA-required levels, and the one for its 325 mg capsule exceeds the FDA-required levels by 42 mg. (Id. ¶13). Mutual also claims that defendants' instructions on their products label convey the impression that their product is FDA-approved because it is "printed in the same format and have the 'look and feel' as those which have FDA approval" (Compl. ¶ 84), including usage of the "Rx only" prescription drug symbol. (Decl. Jospeh M. Vinez, Exs. 2 & 3).

Mutual further takes issue with some of the information contained on defendants' labels regarding instructions for using quinine. Mutual notes that the FDA required that it place on its label that quinine sulfate is "indicated for treatment of uncomplicated Plasmodium falciparum malaria," and that is neither "approved for prevention of malaria" nor is it "approved for patients with severe or complicated P. Falciparum malaria." (Id. ¶ 14). In contrast, Ivax's product labels simply state that its quinine sulfate is "for treatment of malaria as a supplement" to other anti-malarial drugs, "e.g. with primaquine in relapsing vivax malaria, or the treatment of malaria due to strains of P. Falciparum resistant to chloroquine and other antimalarial

drugs." (Id, Ex. 2). Mutual argues that this conveys the mis-impression that Ivax's product is approved for "species [of malaria] other than [uncomplicated] plasmodium falciparum [malaria]." (Id. ¶ 15). Furthermore, Mutual objects to Ivax's label representing that its quinine sulfate "is effective as a malarial suppressant and in control of overt attacks" because the "the FDA has not approved quinine sulfate for use as a malarial suppressant." (Id.) Zenith's product label contains the same challenged representations as those noted in connection with Ivax's label.

Finally, Mutual notes that the FDA required that it place on its label "a six paragraph warning about the danger for potential prolongation of the QT/QTc interval" from use of quinine sulfate, a condition that can lead to arrhythmia, a heart attack, or sudden cardiac death. Defendants' label fails to mention QT/QTc prolongation as a possible adverse reaction from use of quinine sulfate, instead listing only "anginal symptoms" as a possible adverse reaction. (Id. ¶19, Exs. 2 & 3) In connection with this latter point, Mutual has submitted a survey report wherein 11% of pharmacists surveyed did not believe, and 20% did not know, that the quinine sulfate they dispensed using the clinical/price lists has a potential life-threatening side effect of QT prolongation. (Decl. Joseph A. Matijow, Ex. D at 10).

Mutual contends that all of the foregoing regarding defendants labeling of its quinine sulfate is both "literally false" and "misleading" to the consuming public, the former proven by reference to the FDA's actions regarding what is required in the labeling of Mutual's Qualaquin. (Mot. Prelim. Inj. at 18). For their part, defendants argue that allowing such a claim to proceed would be to allow Mutual to use the Lanham Act to privately enforce the FDCA, as Mutual is simply seeking to "enforce the FDA's labeling and advertising standards," and that regardless in adjudicating the falsity of its labeling claims the court would be required to interpret and then apply FDA regulations. (Opp. at 14-15). Neither of defendants' assertions withstands scrutiny.

The Court finds instructive the Third Circuit's decision in Sandoz

Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3rd Cir. 1990), that also involved a labeling claim. There a cough syrup maker was sued concerning its representations about its product, Pediatric 44, that it "starts to work the instant it is swallowed." In connection with this advertising claim, the cough syrup maker listed demulcents, the ingredient that "theoretically effectuate the immediate [cough] relief [after being swallowed]," as an "inactive" ingredient. The plaintiff argued that FDA standards concerning when an ingredient is an "active ingredient" required that the cough syrup maker label demulcents as an "active" ingredient. Id. at 230 (citing 21 C.F.R. § 210.3(b)(7)(noting that an ingredient is considered "active" if it "is intended to furnish . . . direct effect in the . . . mitigation [or] treatment . . . of disease")). The court found that such a labeling claim was an effort to do indirectly through the Lanham Act what the plaintiff could not accomplish directly through the FDCA. In arriving at this conclusion, the court noted the peculiar procedural posture of the case, namely, that the FDA had yet to determine whether or not demulcents were active ingredients. The court focused on this point in concluding that plaintiff's method for establishing the falsity of the labeling claim was inappropriate.

The peculiar regulatory posture of the case gave the court pause in allowing a Lanham Act claim to go forward because it would "require[] original interpretation of the[FDCA] or [its] accompanying regulations"; that is, for the court to "determine preemptively how a federal agency will interpret and enforce its own regulations." Id. at 231-32. The court explained that reference to general FDA standards to adjudge the falsity of a labeling claim is an inappropriate method for establishing a Lanham Act claim in the absence of any action by the FDA concerning the specific applicability of those standards to the claim at issue:

> Sandoz cannot prevail on its labeling claim because it has not proved that Vicks's labeling is false. Sandoz's counsel argued to the district court that "[i]f [the demulcents] relieve coughs they're active. That's true as a matter of common sense and normal English." App. at 175, Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., (D.Del.1989) (No. 89-3654). Such an interpretation of FDA regulations, absent direct guidance from the promulgating agency, is not as simple as Sandoz proposes.

> The FDA has not found conclusively that demulcents must be labelled as active or inactive ingredients within the meaning of 21 C.F.R. § 210.3(b)(7). We decline to find and do not believe that the district court had to find, either "as a matter of common sense" or "normal English," that which the FDA, with all of its scientific expertise, has yet to determine. Because "agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise." McKart v. United States, 395 U.S. 185, 194, 89 S.Ct. 1657, 1662-63, 23 L.Ed.2d 194 (1969). Thus, we are unable to conclude that Vicks's labeling of Pediatric 44's demulcents as inactive is literally false, even if Vicks concurrently claims that these ingredients enable its medicine to work the instant it is swallowed.
>
> Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations. Jurisdiction for the regulation of OTC drug marketing is vested jointly and exhaustively in the FDA and the FTC, and is divided between them by agreement. See FDA/FTC Memorandum of Understanding, 36 Fed.Reg. 18,539 (1971). Neither of these agencies' constituent statutes creates an express or implied private right of action, see, e.g., Alfred Dunhill Ltd. v. Interstate Cigar Co., 499 F.2d 232, 237 (2d Cir.1974); American Home Prods. Corp. v. Johnson & Johnson, 436 F.Supp. at 797-98, and what the FD & C Act and the FTC Act do not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of these Acts or their accompanying regulations. Cf. L'Aiglon Apparel, Inc. v. Lana Lobell, Inc., 214 F.2d 649, 651 (3d Cir.1954) (noting that the Lanham Act created a distinct and separate federal cause of action).
>
> [There is] no support for the theory that it is appropriate for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations. See Cutler v. Kennedy, 475 F.Supp. 838, 856-57 (D.D.C.1979) (stating that it is not for a court to force the FDA to interpret, apply and enforce its regulations in a manner determined by the court to fairly effectuate the FD & C Act's policies).

Id. at 230-31. In making this statement, it is clear that the Sandoz court would have viewed the matter differently if the plaintiff had been able to present evidence that the FDA had specifically determined that demulcents were required to be listed as "active" ingredients. Id. at 232 n.12 (noting that the policy against allowing plaintiff's Lanham Act claim to proceed was "to protect [the FDA] from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way" (emphasis added)). In short, it was not the fact that the Lanham Act claim involved or made reference to the FDA labeling standards itself that made litigating the claim problematic, it was that, in adjudging the falsity of the label, the court

would have to, in the first instance, interpret those general label standards and then apply it to whether the particular ingredient at issue on defendant's label was an active one, something which the FDA itself had yet to do. If, however, the FDA had already taken a position on whether a demulcent was an active ingredient (thus confirming the falsity of defendant's contrary labeling), the court clearly indicated that it would have no trouble in allowing the Lanham Act claim to proceed.

This is precisely the nature of Mutual's claim in the present case. They are not seeking for this Court to interpret and then apply FDA standards governing the labeling of drugs in general to prove the falsity of the particular representations contained on defendants' drug labels. Rather, they are arguing that the FDA has already determined what must be included on the label for quinine sulfate specifically, and that defendants' labels are not conforming to those requirements. In adjudging this claim the Court need not interpret and then apply any FDA regulation; instead, it need only verify whether defendants' label conforms to what the FDA has already determined is required to be listed for quinine sulfate, something which the Court can do "without any need to interpret [and then apply] FDA regulations." Summit II, 933 F.Supp. at 933 n.7.

In this respect Mutual's claim is no different than those where courts have allowed a Lanham Act claim to proceed based on a defendant's express false statement that its product was FDA approved when, in fact, that was not the case. Such a claim did not require the interpretation and application of the FDCA because it was a fact that was readily verifiable — either the FDA had issued a letter of approval for the defendant's product or it had not.

Accordingly, the Court finds that the FDCA does not stand as a bar against Mutual litigating its false labeling claim. As this is the only argument raised by defendants as to why Mutual lacks a probability of success on this claim, the Court finds that Mutual has shown a likelihood of success as to its false advertising claim to the extent that claim is based upon defendants' false representations contained

on its product labels.

2. Price Lists

Mutual has submitted survey reports demonstrating the specialized meaning a drug's presence on clinical/price lists has with pharmacists and large pharmacy chain stores. One survey conducted before Mutual's Qualaquin was widely available to pharmacists revealed that 91% of the pharmacists surveyed believed that all of the drugs contained on the clinical/price lists were FDA-approved, including 89% who believed that the quinine sulfate they dispensed using the clinical/price lists were FDA-approved. (Decl. Joseph A. Matijow ¶ 8; Decl. Rich Foster ¶ 8). Another survey showed that 48% of pharmacists who use such private clinical/price lists commonly mistake the fact that a drug appears on the list means the drug was approved for use by the FDA, and that anywhere between 28 to 38% of pharmacists thought that the usage and other labeling information listed in connection with the drug on the private clinical/price list description is complete. (Decl. Martin Buncher ¶ 6 & Ex. 1).

Moreover, a similar survey of 11 chain pharmacy stores found that ten either frequently or always refer to clinical/price lists when dispensing or ordering prescription drugs, and that nearly half thought that "all of the prescription drugs listed" on the clinical/price lists "were FDA approved." (Decl. Martin Buncher, Ex. 1). One pharmacist has stated that "if an 'Rx-only' drug is listed on the price lists," pharmacists "assume" that the drug "on those lists are FDA approved." (Decl. Robert Graul ¶¶ 10-11). Finally, it is asserted that before a clinical/price list provider will list a particular drug on its database, it requires the drug's manufacturer to provider it either an "FDA approval letter or IND number." (Decl. Robert Graul ¶ 11; Suppl. Decl. Rich Foster ¶ 6).

Mutual argues that use of the clinical/price lists marketing channel misleads the relevant consumers into believing that defendants' quinine is FDA-approved. Defendants contend that such a claim is nothing but a clever means on Mutual's

part to simply hold them liable for marketing a drug that happens to lack any FDA approval. As they contend, "false implications of FDA approval are not actionable." They point to the Fourth Circuit's decision in Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993), where the court refused to allow a Lanham Act claim to proceed when the only evidence proffered to demonstrate such false implications of FDA-approval consisted of nothing more than defendant's "act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs." (Opp. at 15-16). Defendants mischaracterize the nature of Mutual's claim and miscomprehend the type of falsehoods governed by the Lanham Act.

Mutual's argument concerning the particular marketing channel used by defendants as conveying the false impression of FDA approval is not insubstantial. Defendants argue that this misrepresentation consists of nothing more than a veiled argument that defendants are simply marketing a non-FDA approved drug. The Court reads the substance of Mutual's claim differently. It is not the simple act of defendants marketing a non-approved drug that Mutual seeks to combat, but the particular form that marketing has taken; a form that Mutual contends carries certain implicit false suggestions in the minds of the consumer that defendants' drug is FDA-approved. With no evidence to suggest that clinical/price lists are anything but a specialized and unique marketing channel used by drug manufacturers for FDA-approved medications (something that appears to be the case given that such clinical/price lists require the drug maker to submit an FDA approval letter or NDA number — that carry the indicia of FDA approval — in order to get the drug listed on the database), then use of such a marketing mechanism could create an implicit false impression of FDA-approval.

To prove that use of this particular marketing channel conveys such a false impression of FDA-approval, Mutual cannot, as noted above in reference to the difference between literal falsehoods and implied ones, "obtain relief by arguing how consumers could react; it must show how consumers actually do react."

Sandoz, 902 F.3d at 229 (emphasis in original). For purposes of the present motion, Mutual has met this burden through the surveys they have submitted indicating that a significant number of pharmacists and chain pharmacy stores — the relevant audience in question, see Pediamed Pharmaceuticals, Inc. v. Breckenride Pharmaceutical, Inc., 419 F.Supp.2d 715, 729 (D. Md. 2006)("The relevant audience is pharmacists, drug wholesalers, distributors and chain drug stores, to whom defendants sent their advertising materials") — view all the drugs listed on such clinical/price lists as having been FDA-approved. This evidence has not been rebutted by defendants.

Instead, defendants argue that "false implications of FDA approval are not actionable," again citing to the Fourth Circuit's decision in Mylan. There the plaintiff argued that the maker of generic drugs falsely represented that its drugs had been properly approved by the FDA. 7 F.3d at 1139. Nowhere did defendant make any explicit statement or representation declaring its generic drugs as being FDA-approved. Id. Instead, the only evidence presented of such a statement was that "the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs," falsely implied that the defendants' drug had been "properly approved by the FDA." Id. The Fourth Circuit rejected such a theory as "too great a stretch under the Lanham Act" as it "would, in effect, permit [plaintiff] to use the Lanham Act as a vehicle by which to enforce the . . . FDCA." Id.

The false implication noted in Mylan is different than that at issue in this case. Mylan addressed the false implication of FDA approval conveyed by the simple fact that the product is being marketed and sold, a contention that was unaccompanied (as it must in order to prove a false implication (as opposed to a literally untrue) claim under the Lanham Act) by any consumer survey evidence indicating that such an act carried in the eyes of the purchasing public the imprimatur of the FDA. Here, as explained above, it is not so much the false impression of FDA-approval conveyed by the marketing and sale of the drug in

general that Mutual seeks redress unadorned with any survey evidence to substantiate such a claim, but the peculiar form that marketing has taken as having a specialized, implicit meaning in the eyes of the consumer (as substantiated by consumer surveys) that the drug is FDA-approved.

In this sense, the present case is more akin to that of the Tenth Circuit's decision in Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248 (10th Cir. 1999). There, a manufacturer of hard surface cleaners and disinfectants used in medical and dental facilities was sued by a competitor under the Lanham Act for making false advertisements regarding its product. The products in question were subject to regulatory oversight by the EPA, who is charged by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") with "reviewing and approving the text of all labels on or accompanying the products before they can be sold." Id. at 1250 (citing 7 U.S.C. §§ 136 & 136a). It is unlawful under FIFRA to sell a product subject to EPA oversight using labels that have not been approved by the agency. Id. (citing 7 U.S.C. §§ 136a(c)(1) & 136j(a)(1)(B)). And like the FDCA there is no private right of action to enforce FIFRA and its implementing regulations. Id. at 1255. The alleged false statements consisted of (1) marketing its product using labels that claimed its product continued to be an effective cleaner and disinfectant for seven days when it knew full well the label had not been approved by the EPA, (2) its advertising materials contained on its labels deceive consumers "by implying that EPA approval or clearance has been obtained [for the seven-day efficacy claim]," and (3) making the "false label claims that defendants' products can be used for seven days after mixing." Id. at 1254. The Court found the first type of Lanham Act claim as precluded by FIFRA, but not the second. Although admitting that the two were "closely related," the Court found them "distinct" in that the first was simply predicated liability on the fact that the label "violated FIFRA, related regulations, and EPA actions," while the second was predicated on the particular "representations" defendant "directed at consumers." Id. at 1254 n.6. As the court

further explained: "[Claim two is distinct] because in addition to alleging that the label claims did not comport with FIFRA regulations and EPA approval, claim #2 adds an allegation that [defendant]'s label claim, in the context in which the product is advertised, deceives consumers into believing, erroneously, that the EPA has approved [defendant]'s one-week efficacy claim. If [plaintiff] can establish by consumer surveys or other means that [defendant]'s advertising is likely to confuse or actually confuses consumers, then the effect of the false 'implication' of EPA approval that [plaintiff] now asserts could be as damaging for Lanham Act purposes as an express false claim of EPA approval." Id. at 1255-56 (emphasis added).

The manufacturer argued that the court should, nonetheless refuse to consider such a claim as it "touches on issues covered by FIFRA"; the court disagreed, finding that courts "are capable of resolving . . . [an] issue" that defendants "falsely imply that the EPA has approved their claim that [its product] is effective for seven days after mixing when in fact the EPA has not given such approval." Id. at 1256.

This is precisely what Mutual is arguing here. Defendants are using a specialized marketing channel to sell its quinine sulfate that, through its use, conveys the false implication its drug is approved by the FDA. In support of this contention Mutual has submitted market surveys demonstrating that the relevant consumer group, pharmacists and retail pharmacy chains, consider use of this particular marketing mechanism as implictly informing them that the product is FDA-approved; a belief that is all the more reasonable given that only drugs that have been FDA-approved or received a NDA are allowed to be placed on such private clinical/price lists.

Given the submission of these consumer surveys to substantiate their contention that defendants' use of clinical/price lists conveys the misleading impression of FDA-approval, the Court finds that Mutual has sustained its burden of demonstrating a likelihood of success on its Lanham Act false advertising claim to

the extent that claim is based upon defendants' use of the clinical/price lists to market its quinine sulfate.

3. Third-party internet retailers

Similarly, the use of third-party internet retailers who explicitly make such a representation of FDA-approval would likewise be cognizable under the Lanham Act. Mutual notes that one internet retailer's (buygeneric.com) masthead contains the tag line "FDA Approved Generic Prescription Drugs," that it contains statements throughout its web site that it "offer[s] FDA approved generics," and that it further states that "all generic drugs have been approved for use by the Food and Drug Administration." (Decl. Brendan J. Hughes, Ex. 3).

Defendants make the argument that Mutual's claim that such broad statements contained on third-party internet retailer's web sites simply goes too far. They argue that a pharmaceutical company should not be responsible for policing the advertising activities of retailers to whom they distribute their products. (Opp. at 16 n.12 ("To impose Lanham Act liability and issue a preliminary injunction based on the way a product appears on a website over which the defendant has no control extends liability too far. Any company that advertises on the internet would be forced to spend millions on its defense because of the way a marketer displayed its [product on] its web-site")). That, however, is not exactly what Mutual is arguing. It does not so much seek to require defendants to police all third-parties who employ false advertising in marketing its products as it seeks to hold defendants liable for such false advertising that it "knows or reasonably should know" is taking place in connection with its products. (Mot. Prelim. Inj. at 13). Such an argument does have some basis in other aspects of trademark law.

For instance, the Supreme Court has long held that a manufacturer or distributor can be held liable to the owner of a trademark if it "continued to supply a product which could readily be passed off to a particular merchant whom it knew was mislabeling the product with the trademark owner's mark." Inwood

Laboratories v. Ives Laboratories, 456 U.S. 844, 855 (1982). Thus, even if a maker of a product sells a good to a third party that, when it is sold does not contain infringing material on it, the maker can still be held liable for the subsequent infringing activity of the third party if it knew that the third party was engaging in such infringing activity with its product and nonetheless continued to supply the third party with its wares. By the same reasoning, it is not much of a stretch to impugn liability on defendants if they knew that these third party internet retailers where making such false advertisements in connection with the sale of their quinine sulfate and nonetheless continued to sell their products to those internet retailers. The problem with Mutual's argument, however, is one of proof, not the law. Its complaint merely alleges that defendants knew or should have known that these third-party internet retailers were equating its products with FDA approval. As Inwood makes clear, only proof that defendants knew their products were being falsely advertised by third party retailers is enough to trigger liability. Other than the allegation in the complaint, Mutual has come forward with no evidence indicating that defendants did in fact know of these false statements contained on these third party retailers web sites. With this lack of proof, the Court cannot find at this time that Mutual is likely to succeed on the merits of its Lanham Act false advertising claim with respect to defendants' marketing of its quinine sulfate via third-party internet retailers.

4. Defendants' web site

Finally, Mutual challenges various representations contained on defendants' web sites promoting their quinine sulfate as falsely implying that it has been FDA-approved. For example, Ivax "represents that its quinine sulfate product is to be compared to an NDA holder product." (Compl. ¶ 85). By making such a comparison to a product with an NDA, which are approved by FDA, Mutual asserts that Ivax "affirmatively and falsely representing that its product should be compared to an FDA approved product." (Id.) Furthermore, Teva's web site states that its

quinine sulfate product received a TEE (Therapeutic Equivalence Evaluation) rating of a DESI drug, meaning that it was approved prior to 1962 on the basis of safety alone, something that can only be granted by the FDA. (Decl. Robert Dettery ¶ 10 & Ex. 1). This statement is assertedly false as only a DESI product that has undergone a subsequent effectiveness evaluation and received an NDA can be sold legally in the United States, and only Mutual's quinine sulfate was subjected to such an evaluation; defendants' product was not. (Id. ¶10). Finally, Mutual objects to a link to "Facts About Generic Drugs" wherein it is noted that generic drugs are "monitored by FDA" for "same standards of quality and consistency" as a brand-name drug and as having met "the FDA standards of safety" on that part of Teva's web site that discusses its quinine sulfate product. (Decl. Brendan J. Hughes, Ex. 2). As with the marketing of their products through placement on clinical/price lists, it is asserted that defendants' web sites, by innuendo or suggestion, sought to tie defendants' quinine sulfate products as being FDA-approved by making comparison to other such FDA-approved quinine products.

The substance of this false advertising claim, however, has been rendered moot by the defendants' subsequent act of removing the offending material from their web sites. Defendants have since removed all these portions of their web site (indeed, Ivax has deleted quinine sulfate entirely from its web site) except the placement of the hyperlink to generic drugs on Teva's website on the web page concerning its quinine sulfate product. (Decl. David Marshall ¶ 12). With nothing left to enjoin, Mutual will not likely succeed on this claim.

In sum, Mutual has shown a probability of success with respect to defendants' false and/or misleading representations that they have conveyed both in marketing their product using the clinical/price lists and the information contained on their products label inserts.

However, even with a showing that it is likely to succeed in proving that

defendants' representations are false or misleading, Mutual must also show that such acts will cause it irreparable harm.

B. IRREPARABLE HARM

Mutual argues that defendants' false or misleading advertising (label claim) and promotional activity (use of the clinical/price lists marketing channel) will cause it irreparable harm as consumers will associate defendants' quinine sulfate as being safer (in that it has less adverse effects and consequences on its label than Mutual's quinine sulfate), and more effective (because its dosage regimen requires the consumption of less milligrams over the course of the treatment than Mutual's Qualaquin) than its Qualaquin, and as bearing the same seal of FDA-approval as given to its Qualaquin (by its placement on clinical/price lists). (Mot. Prelim. Inj. at 22-23). For this argument to hold there must exist a "link in [Mutual's] proof [of] evidence that [defendants'] advertising will have the effect on consumers that [Mutual] says it will — in other words, that consumers will see [defendants' quinine sulfate as a safe (perhaps safer)] substitute[] for [Mutual's Qualaquin]." Ortho Pharmaceutical Corp. v. Cosprophar, Inc., 32 F.3d 690, 695 (2nd Cir. 1994). Such a causative link between the false or misleading advertising and a plaintiff's potential lost sales is normally "supplied by consumer surveys or consumer witnesses"; conjecture and common sense, no matter how persuasive, do not suffice. Id.

Mutual, however, argues that it need not supply such market studies because injury is presumed when a showing of probability of success on the merits is established. (Reply at 13). Although such a presumption would apply if this were a trademark infringement case, such a presumption of injury is applied differently in the context of false advertising claims. When an advertisement draws an explicit comparison between the competitor's product and plaintiff's, then such a caustive link of irreparable injury is presumed because "[a] misleading comparison to a specific competing product necessarily diminishes that product's value in the minds

of the consumer." McNeilab, Inc. v. American Home Priducts Corp., 848 F.2d 34, 38 (2nd Cir. 1988). Outside the context of comparative advertisements (that is, those that make no direct reference to a competior's product), a presumption of irreparable injury to a party is unwarranted because the injury caused by such a false or misleading advertisement "accrues equally to all competitors; none is more likely to suffer from the offending broadcasts than any other. The Lanham Act, however, only authorizes actions by one 'who believes that he is or is likely to be damaged.'" Id.; see also 4 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:37 at 27-75 to 27-76 (4th ed. 2006)("Where the challenged advertising makes a misleading comparison to a competitior's product irreparable harm is presumed. But if the false advertising is non-comparative and makes no direct reference to a competitior's product, irreparable harm is not presumed").

Here, although the parties are direct competitors in the quinine sulfate market, defendants' false and misleading advertising and promotional activities do not make a direct comparison with Mutual's Qualaquin. Defendants implicitly tout FDA approval and wrongly place connotations in the consumer's mind that its quinine sulfate has fewer side effects or requires less treatment regimen, but they never mention or compare their product to Mutual's Qualaquin.

Given the form that defendants' misleading advertisments have taken, Mutual must come forward with some evidence indicating that consumers are misled into believing that defendants' product is superior to its own. See Vidal Sasson, 661 F.2d at 278 (noting that, "although the likelihood of injury and causation cannot be presumed," plaintiff had come forward with sufficient evidence indicating that "it is quite likely that the apparently effective suggestions of competitive superiority, if repeatedly communicated to consumers, would eventually result in loss of sales to" plaintiff); Telebrands Corp. v. The Media Group, Inc., 45 U.S.P.Q.2d 1342, 1345 (S.D.N.Y. 1997)("a finding of irreparable harm is warranted

in a context where the parties are direct competitors and some evidence is adduced to suggest that consumers are misled by defendant's advertising"); see also 4 MCCARTHY § 27:31 at 27-58 (although rejecting "the theory of presumed damage in non-comparative advertising cases, [such] damage . . . . will ordinarily be almost automatic if the parties are competitors and the advertising has a tendency to mislead some consumers, as demonstrated by evidence of either actual confusion or a consumer survey").

Mutual, however, has not submitted any evidence on this point with respect to its false labeling claim. There is no evidence in the record demonstrating that consumers are misled by defendants' particular labeling representations. The most Mutual has proffered is the declarations of certain business and marketing executives who opine that consumers "may" be confused or "it is logical to conclude" that they would be so deceived. (Decl. Martin Buncher ¶ 9; Decl. Rich Foster ¶¶ 15-16). Such speculative beliefs are insufficient to establish irreparable harm. See Telebrands, 45 U.S.P.Q.2d at 1345 ("plaintiff must offer something more than a mere subjective belief that it is likely to be injured as a result of the false advertising"). Mutual has submitted no evidence, be it consumer surveys or a declaration of a consumer witness, demonstrating that consumers have been so misled.

The only evidence that can be said to demonstrate such a tendency or likelihood of actual consumer deception is a survey report submitted by Joseph Matijow that documented that, among 500 pharmacists surveyed, 11% did not believe that quinine sulfate poses "a specific potentially life threatening side effect of QT prolongation." (Decl. Joseph A. Matijow, Ex. D). From the discussion above it is clear that the FDA does believe that quinine sulfate has such a potential side effect. The suggestion would be that this 11% of pharmacists had been deceived into believing otherwise on account of the incorrect label inserts on defendants' quinine sulfate. This is a slim evidentiary reed upon which to build such a

suggestion. The survey was conducted in July, 2006, shortly after Mutual began marketing its Qualaquin that contained label inserts with the proper warning about QT prolongation. Thus, presumably many of the pharmacists in question had not even been exposed to the proper label insert long enough to demonstrate that it was defendants' misleading label that had impacted their perception of the two products' effectiveness.

The same, however, cannot be said of Mutual's false advertising claim regarding the clinical/price lists. There it has submitted survey reports documenting that anywhere from a third to nearly ninety percent of pharamacists view defendants' quinine sulfate as being FDA-approved because it is marketed on the clinical/price lists. Assuming these surveys are reliable (something which defendants have not challenged in this case), then a significant portion of the relevant consumer market are getting the misleading impression that defendants' quinine sulfate is approved by the FDA. The false impression imparted by defendants' marketing activities would make their quinine sulfate appear more favorable than it otherwise would be in the eyes of the consumers and induce those consumers to dispense the quinine sulfate when presented with a prescription for the drug. Such a result would thereby cause Mutual to suffer irreparable harm.[3] See Telebrand, 45 U.S.P.Q.2d at 1345-46 ("[I]f consumers are misled by defendant's advertising into believing something about the product that makes it more desirable than it would otherwise be, and if plaintiff and defendant are direct competitors, then it is likely that plaintiff will lose business because consumers will unfairly choose defendant's product over plaintiff's").

Accordingly, the motion for preliminary injunction is **GRANTED IN PART** and

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[3] Defendants' argument that no irreparable harm is shown given Mutual's long wait before seeking a preliminary injunction is disingenuous. Mutual did not introduce its Qualaquin to the marketplace until July 18, 2006. The same day it introduced Qualaquin to the market, Mutual filed the instant action, and less than a month thereafter brought the instant motion for a preliminary injunction.

DENIED IN PART.

Specifically, defendants are hereby enjoined from placing and are ordered to remove information regarding their quinine sulfate products on any "Price List" drug dispensing system in the United States.

IT IS SO ORDERED.

DATE: 10-17-06.

STEPHEN G. LARSON
UNITED STATES DISTRICT JUDGE