

False Advertising Litigation Under the Lanham Act for Pharmaceutical Companies



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This article examines lessons learned from Lanham Act false advertising cases in the pharmaceutical sector.

Pharmaceutical companies regularly become involved in lawsuits with competitors over whether promotional claims are “deceptive.” The “Lanham Act”² provides a private cause of action permitting a company to sue its competitor whenever the competitor uses a promotional claim that is likely to mislead customers (here, physicians or patients).

Section 43 of the Lanham Act prohibits any company from making any statement that “misrepresents the nature, characteristics [or] qualities” of its own or a competitor’s products or services. A successful Lanham Act plaintiff can obtain an injunction (stopping the use of a claim and/or requiring corrective advertising) as well as money damages (including disgorgement of profits, attorney’s fees, and treble damages). Only competitors have standing to sue. The Lanham Act addresses competitive injuries—it is not a consumer protection act; therefore, the actual targets of promotional claims (patients, doctors, formularies, hospitals, and the like) lack standing to sue.

The scope of the Lanham Act is broad. Anything a pharmaceutical company writes or says potentially is the subject of a Lanham Act claim. The Lanham Act is not limited to traditional advertising but instead reaches a wide range of “statements,” including statements to physicians (detail aids and verbal statements by sales representatives to doctors) and direct-to-consumer materials

(website postings, patient brochures, patient testimonials, and verbal statements made by a call center representative). As one court held, “even a *single* promotional presentation to an individual purchaser may be enough to trigger the protections of the Act.”³

Examples of Pharmaceutical Company Violations. Pharmaceutical companies run afoul of the Lanham Act for many types of claims, including minimizing risks, broadening indications, overstating efficacy, and making comparative claims in the absence of supporting head-to-head clinical data. For example:

- Johnson & Johnson was found to violate the Lanham Act because its slogan “Night Time Strength” for antacid product Mylanta implied that the product was specially formulated for nighttime heartburn, but Johnson & Johnson did not have substantiation for that claim.⁴
- Procter & Gamble’s claim of “24 Hours” relief for heartburn medication Prilosec was deceptive because it implied 24 hours of relief after ingestion; in fact, the product provided relief only after it became “effective,” about 5 hours after ingestion.⁵
- Pharmacia’s television campaign for nicotine patch Nicotrol was enjoined because the commercial conveyed a superiority claim over competitive product Nicoderm regarding sleep disturbance, but Pharmacia lacked head-to-head clinical data to support this comparative claim.⁶

- Rhone-Poulenc’s ad for hypertension drug Dilacor XR was enjoined because it implied that Dilacor XR could be substituted for a competitor’s (Marion Merrell Dow’s) treatment (Cardizem), which, unlike Rhone-Poulenc’s drug, had been approved for additional indications, namely the treatment of both hypertension and angina.⁷

An area of heightened exposure for pharmaceutical advertisers is comparative claims. A plaintiff’s burden to obtain emergency injunctive relief is reduced whenever a claim is comparative,⁸ and comparative claims may trigger an obligation to disclose related but unfavorable differences.⁹

A Lanham Act defeat may also serve as a springboard to further litigation. For example, after a federal court enjoined Pfizer’s claim for mouthwash Listerine “as effective as” dental floss in reducing the risk of gingivitis,¹⁰ consumer class actions were filed around the country, targeting the same advertising under state law. In *Zeneca, Inc. v. Eli Lilly & Co.*,¹¹ Eli Lilly was found to violate the Lanham Act by promoting its osteoporosis therapy Evista off label for the prevention of breast cancer. Several years after the Lanham Act defeat, Lilly faced a Department of Justice criminal investigation into the same conduct, and ultimately pled guilty to a misdemeanor count of misbranding and agreed to pay \$36 million in fines, forfeiture, and disgorgement.

Recent—and huge—penalties paid for improper promotion (such as the \$2.3 billion

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² 15 U.S.C. § 1125.

³ Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1384 (5th Cir. 1996) (emphasis added).

⁴ Novartis Consumer Health v. Johnson & Johnson Merck Pharms., 290 F.3d 578 (3d Cir. 2002) (affirming preliminary injunction).

⁵ J & J-Merck Consumers Pharms. v. The Procter & Gamble Co., 285 F. Supp. 2d 389 (S.D.N.Y. 2003).

⁶ Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, 292 F. Supp. 2d 611, 619 (D.N.J. 2003).

⁷ Rhone-Poulenc Rorer Pharms. v. Marion Merrell Dow, Inc., 93 F.3d 511, 516 (8th Cir. 1996) (affirming corrective advertising order to “explain[] the differences in the two products” where original advertising claimed the products could be “indiscriminately substituted”).

⁸ McNeil Lab. v. Am. Home Prods., 848 F.2d 34, 38 (2d Cir. 1988).

⁹ Am. Home Prods. v. Johnson & Johnson, 654 F. Supp. 568, 579-80 (S.D.N.Y. 1987) (rejecting defense argument that “the law does not require that they disclose the disadvantages of the product as well as the advantages”).

¹⁰ McNeil-PPC, Inc. v. Pfizer Inc., 351 F. Supp. 2d 226, 256 (S.D.N.Y. 2005) (preliminarily enjoining defendant from using that claim because consumers perceived this claim to be an overall claim of superiority not limited to gingivitis).

¹¹ Zeneca, Inc. v. Eli Lilly & Co., No. 99 Civ. 1452, 1999 WL 509471 (S.D.N.Y. 1999).

penalty Pfizer paid for improper promotion¹² and \$1.42 billion Lilly paid for off-label promotion of Zyprexa¹³) underscore the exposure in this area.

FDA Authority Over Advertising Is Not Typically a Successful Defense.

A common misconception within pharmaceutical companies is that compliance with applicable FDA guidelines and regulations is sufficient to avoid advertising challenges. However, FDA consideration of (or failure to object to) a claim is not ordinarily a defense to a Lanham Act false advertising case, and the fact that FDA has overlapping jurisdiction does not block a Lanham Act suit.¹⁴ The only exception is when a court conclusively determines that a Lanham Act plaintiff's true goal is to circumvent the bar on private enforcement of the Federal Food, Drug and Cosmetic Act ("FDCA"); however, as long as the case turns on whether a claim is false or misleading, the fact that FDA may have authority to consider the same issue is not a defense.¹⁵ Companies should be prepared to litigate these issues: FDA's broad authority particularly over prescription pharmaceutical labeling and advertising make primary jurisdiction issues more plausible than in other industries.¹⁶

Surveys of Patients and Doctors Are Core Evidence in Lanham Act False Advertising Cases.

Lanham Act false advertising cases are typically proven by surveys. With regard to verbal statements of sales representatives to physicians, surveys of doctors are used and accepted as reliable and trustworthy evidence of what a sales representative said. A survey of a doctor recently detailed on a pharmaceutical product allows the doctor to report to the surveyor the content and impression given

by a sales representative. If a "not insubstantial"¹⁷ portion of doctors surveyed (15% or more) are "misled" (i.e., they report a statement that is misleading), that may be enough to show a Lanham Act violation.

Writing for a panel of the Second Circuit, Judge (now Justice) Sonia Sotomayor wrote that surveys asking for doctors' "memories" and "impressions" of detail sessions are reliable, including to prove "a pattern of implied falsehood."¹⁸ *Schering v. Pfizer*¹⁹ involved an allegation that antihistamine Zyrtec was promoted as "nonsedating." Zyrtec, a second generation antihistamine that was relatively low-sedating, did in fact cause sedation at a rate statistically higher than placebo. In surveys of doctors detailed on Zyrtec, about 15-20 percent of the doctors reported that the sales representative said or implied that Zyrtec was essentially "nonsedating."

Judge Sotomayor ruled that this level of survey response was sufficient to trigger the Lanham Act. Likewise, in *Zeneca v. Eli Lilly*, which involved the off-label promotion of osteoporosis therapy Evista for the prevention of breast cancer, survey evidence as well as other sales representative data such as call notes, demonstrated that the sales representatives were making the breast cancer claim.²⁰

Surveys of patients likewise are powerful evidence in lawsuits over direct-to-consumer advertising and for over-the-counter products marketed to consumers. Survey data can reveal the presence of unanticipated implied claims. For example, in the Listerine case,²¹ Pfizer had clinical data to support its claim that Listerine was as effective as floss, but only with respect to reducing the risk of gingivitis. The survey data showed that

consumers were taking away a much broader "replacement" message; that is, one could replace flossing with Listerine and receive all of the same benefits. It was the truthfulness of this implied claim that Pfizer was forced to defend. Pfizer's defense was that it did not make this broader "replacement" claim and, in fact, the advertising specifically encouraged consumers to "floss daily."²² Notwithstanding Pfizer's protests, the court found that the presence of a "replacement" take-away in a minority (25-30%) of survey responses was sufficient to demonstrate the presence of the implied claim and therefore, a Lanham Act violation.²³

FDA Advertising Principles Are Potentially Useful in Lanham Act Cases.

FDA advertising principles, such as "fair balance,"²⁴ can be useful in Lanham Act cases, but only to the extent that the principles are used to shed light on the issue of falsity. However, over-reliance on these principles may lead to FDA primary jurisdiction arguments. For example, in a case involving competing proton pump inhibitors Nexium and Prevacid, the parties debated the FDA concept that an advertiser should not disseminate a claim that has only statistical significance without clinical significance. The court commented that this FDA principle was inapplicable to the Lanham Act inquiry, which is focused on the truth or falsity of the advertising message:

"[I]t is not sufficient for a Lanham Act plaintiff to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public." Thus, citation

¹² News Release, U.S. District Attorney's Office for the District of Massachusetts, Justice Department Announces Largest Health Care Fraud Settlement in Its History, (Sept. 2, 2009), available at www.usdoj.gov/usao/ma/press.html; see also Gardiner Harris, "Pfizer Pays \$2.3 Billion to Settle Marketing Case," N.Y. Times (Sept. 3, 2009).

¹³ Press Release, U.S. Dep't of Justice, Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa, (Jan. 15, 2009), available at <http://www.usdoj.gov/opa/pr/2009/January/09-civ-038.html>.

¹⁴ See, e.g., Ethex Corp. v. First Horizon Pharm., 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) ("false statements . . . are actionable under the Lanham Act even if they involve FDA-regulated products.").

¹⁵ On the question of whether a plaintiff seeks to circumvent the bar on private rights of action under the FDCA, or whether a case encroaches on FDA's primary authority to such an extent as to warrant dismissal, see generally *Alpharma, Inc. v. Pennfield Oil*, 411 F.3d 934 (8th Cir. 2005); *Mylan Labs. v. Malkari*, 7 F.3d 1130 (4th Cir. 1993); *Axcan Scandipharm Inc. v. Ethex Corp.*, 2007 WL 3095367 (D. Minn. 2007); *Solvay Pharms. v. Global Pharms.*, 298 F. Supp. 2d 880 (D. Minn. 2004); *Summit Tech. v. High-Line Med. Instruments*, 933 F. Supp. 918 (C.D. Cal. 1996); *Grove Fresh Distrib. v. Flavor Fresh Foods*, 720 F. Supp. 714 (N.D. Ill. 1989).

¹⁶ *Cf. Sanderson Farms v. Tyson Foods*, 547 F. Supp. 2d 491 (D. Md. 2008) (preliminary injunction ordering Tyson to halt its national advertising campaign that its chicken was "raised without antibiotics," when evidence showed that the chickens were fed a product proven to function as an antibiotic, despite prior approval for the claim by the USDA).

¹⁷ *Sanderson Farms v. Tyson Foods*, 547 F. Supp. 2d 491, 504 (D. Md. 2008) (quoting *Johnson & Johnson * Merck Consumer Pharms. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992)).

¹⁸ *Schering v. Pfizer*, 189 F.3d 218 (2d Cir. 1999).

¹⁹ *Id.*

²⁰ No. 99 Civ. 1452, 1999 WL 509471 (S.D.N.Y. 1999).

²¹ *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d 226 (S.D.N.Y. 2005).

²² *Id.* at 254.

²³ *Id.* at 252-57.

²⁴ See 21 C.F.R. § 202.1(e)(5) (pharmaceutical promotional materials must present a "fair balance" of information between the effectiveness and risks).

to the FDA guidelines, in the absence of proof of literal falsity or misleading of the public, is insufficient to show that the claims in the [advertising] campaign are false.²⁵

The core question in Lanham Act cases remains whether a claim is deceptive, not whether FDA regulations have been followed.

The FDA and courts take a similar approach in evaluating promotional statements, but articulate the standard differently. For example, an FDA misbranding violation is shown where a efficacy or safety claim has not been demonstrated by substantial evidence (usually two adequate and well controlled clinical trials).²⁶ Analogously, a Lanham Act court will enjoin an “establishment” or “tests prove” claim—even without affirmative proof of falsity—where plaintiff proves that the supporting tests conducted (the clinical trials) do not reliably support the claim.²⁷ Some courts have held that that FDA’s gold standard of two adequate and well controlled studies “imposes a more stringent standard that that applicable under the Lanham Act.”²⁸

Discovery and Evidence in Lanham Act Cases. One difference between the FDA process and Lanham Act litigation is the availability of discovery and the potential that

internal company documents or emails can overwhelm the merits of the case. For example, it is common that Lanham Act litigants will discover marketing materials, which may be colorful because they are drafted by enthusiastic and creative marketers. So-called “rah rah” emails (i.e., “we are killing them”) may be influential in court, and such evidence can overshadow scientific data. In addition, documents related to the sales process will affect adjudication of a physician claim. For example, call notes, sales “scripts,” and other sales training materials have been used in Lanham Act cases²⁹ to prove that an advertising claim was actually conveyed to doctors.

Planning For Lanham Act Risk. The potential for Lanham Act litigation and significance of such litigation is something that pharmaceutical companies should consider when planning and deploying promotional campaigns.

Pharmaceutical companies should:

- (1) consider lessons learned from Lanham Act cases and conduct training sessions on the Lanham Act with key legal and marketing personnel;
- (2) carefully substantiate their claims with Lanham Act cases in mind, and keep well-developed records on such substantiation;

- (3) vigilantly monitor competitors’ claims and evaluate potential competitor vulnerabilities. If a competitor brings a Lanham Act lawsuit, the best defense frequently is a good offense, and counterclaims are common. Advance work on competitor vulnerability is crucial;
- (4) regularly update training for sales and marketing personnel (including on the discoverability of their emails); and
- (5) if Lanham Act litigation is threatened, quickly assemble a multi-disciplinary team in the following key areas: (a) science; (b) survey; (c) fraud litigation; (d) marketing; and (e) regulatory. These distinct disciplines have to coordinate in order to field an effective litigation presentation.

Lanham Act cases often proceed at a rapid pace and judicial decisions can be made after a few weeks or months of hasty preparation, but the impact can be significant and last for years. Pharmaceutical companies should plan in advance for litigation risk, consider offensive strategies for competitors who are breaking the rules, and make sure all claims (express and implied) are adequately substantiated, with both FDA guidance—and Lanham Act decisions—in mind.

Randy Miller is a Member of the Antitrust Section’s newest committee: the Private Advertising Litigation Committee.

Section members can join this new committee at no cost and will be entitled to receive timely and relevant announcements of developments in this area.

For more information, please visit the PAL Committee’s web site at <http://www.abanet.org/dch/committee.cfm?com=AT311570> or contact Amy Mudge at amy.mudge@aporter.com.

²⁵ AstraZeneca LP v. Tap Pharm. Prods., 444 F. Supp. 2d 278, 295 (D. Del. 2006) (evaluating the so-called “Better is Better” campaign, where the advertiser claimed superiority based on clinical data showing efficacy advantages only as to a subset of patients for a subset of conditions; however, consumers interpreted the ad as conveying overall superiority).

²⁶ Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc., 2008 WL 2053733, at *7 n.8 (S.D. Cal. 2008); accord Warner-Lambert Co. v. Heckler, 787 F.2d 147, 151 (3d Cir. 1986).

²⁷ Zeneca, 1999 WL 509471, at *31, 34 (enjoining therapeutic claims “on the ground that the underlying tests are irrelevant and/or unreliable to support them.”); McNeil v. Pfizer, 35 F. Supp. 2d 226, 248 (S.D.N.Y. 2005); Pfizer, Inc. v. Miles, Inc., 868 F. Supp. 437, 452 (D. Conn. 1994)

²⁸ Bracco v. Amersham Health, 627 F. Supp. 2d 384, 471 (D. N.J. 2009).

²⁹ *Id.* at 460 (collecting authority including *Zeneca, Pfizer v. Miles*, and *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6 (7th Cir. 1992)).