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Pharmaceutical Companies Face Increased False Advertising Risk

Pharmaceutical companies need to take prophylactic measures to mitigate the increased risk of false advertising claims.
By J. Kevin Fee and Michael F. Clayton

Recent developments in the law and the pharmaceutical marketplace mean that pharmaceutical companies face a greater risk of false advertising claims than ever before. Until recently, many assumed that FDA-approved drug labels, and promotional materials repeating statements made in FDA-approved drug labels, were immune from false advertising challenges by competitors. But as explained below, a recent U.S. Supreme Court decision calls that assumption into question. Moreover, as more and more government and private payers demand competitive effectiveness research, pharmaceutical companies face an increased risk of claims by competitors alleging that the competitive effectiveness research is false or misleading. Against this backdrop, it is important that pharmaceutical companies understand the increased risks and take steps to mitigate their exposure.

Addressing the Risk that the U.S. Supreme Court Opened the Door to False Advertising Claims Based on Statements Made in FDA-Approved Drug Labels

Until recently, pharmaceutical companies reasonably assumed that the statements made in their FDA-approved labels, and advertising and promotional materials that repeated statements made in their FDA-approved labels, were immune to false advertising claims by their competitors. However, the Supreme Court's recent decision in *POM Wonderful LLC v. Coca-Cola Co.*[1] arguably undermines that assumption. As a result, the pharmaceutical industry should expect an increase in false advertising claims, at least until the impact of the Supreme Court's decision on the pharmaceutical industry is clarified.

Background on the Supreme Court's *POM Wonderful* Decision

In *POM Wonderful,* the Supreme Court unanimously held that regulations promulgated pursuant to the Federal Food, Drug and Cosmetic Act (FDCA) regarding food and beverage labeling do not preclude Lanham Act false advertising claims based upon the labeling. Although the case involved a dispute regarding food labeling, its impact may extend well beyond the food industry.

POM Wonderful, which sells a pomegranate-blueberry juice blend, filed a Lanham Act claim against Coca-Cola, alleging that Coca-Cola's name, label, marketing, and advertising for one of its juice blends misled consumers into believing the product consisted predominantly of pomegranate and blueberry juices when, in fact, it consisted of 0.3% pomegranate juice and 0.2% blueberry juice. The Coca-Cola label displayed the words "pomegranate blueberry" in all capital letters on two separate lines. Below those words, Coca-Cola placed the phrase "flavored blend of 5 juices" in much smaller type.

The FDA has promulgated detailed regulations for the labeling of juice blends and food flavoring, including the use of images of fruits and vegetables in vignettes, pursuant to the FDCA. In light of the substantial FDA regulations in this area, both the district court and the U.S. Court of Appeals for the Ninth Circuit held that, in the realm of labeling for food and beverages, a Lanham Act claim like POM's was precluded by the FDCA, which forbids misbranding of food, including by means of false or misleading labeling. The Court of Appeals explained that "for a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority."[2]

The Supreme Court reversed, holding that nothing in the text, history, or structure of the Lanham Act or the FDCA demonstrated a congressional intent to forbid such claims. In fact, the Supreme Court concluded that the Lanham Act and the FDCA complement each other in the federal regulation of misleading food and beverage labels. The Court explained that "[a]lthough both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety."[3]

The Court rejected the argument that the FDCA precluded Lanham Act claims based on the labeling of food and beverages because such a holding would lead to a result that Congress likely did not intend. Because the FDA does not preapprove food and beverage labels (unlike drug labels), and does not necessarily pursue enforcement measures against all objectionable labels, "if Lanham Act claims were precluded, then commercial interests—and indirectly the public at large—could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated indus-

tries."[4] The Supreme Court concluded that it was unlikely that Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than in competitive markets for other products.

The Impact of *POM Wonderful* on the Pharmaceutical Industry

Because the facts in the *POM Wonderful* case involved food labeling, the decision's impact on the pharmaceutical industry remains to be seen.

Some pharmaceutical companies will argue that the holding of *POM Wonderful* is limited to food products and does not apply to drugs. After all, the Supreme Court noted more than 20 times in its decision that it was addressing the Lanham Act's intersection with the legal framework that applies to "food and beverage labeling." Moreover, the Supreme Court repeatedly acknowledged the differences between the regulatory schemes for food labels and drug labels. For example, the FDA sets minimum standards for food labels, but it does not review or preapprove food labels. On the other hand, the FDA actually preapproves drugs and their labels. Therefore, one could argue that although *POM Wonderful* did not involve an attempt to use the Lanham Act to relitigate a decision that Congress specifically assigned to the FDA, any attempt to bring a Lanham Act claim based on a drug would conflict with Congress's decision to entrust the FDA with decisions related to drug approval and labeling.

Other pharmaceutical companies will advocate a broader interpretation of the *POM Wonderful* decision. These companies will note that in the *POM Wonderful* case, the Supreme Court engaged in a typical statutory interpretation analysis, evaluating the text, histories, structures, and purposes of the Lanham Act and the FDCA. After conducting this analysis, the Supreme Court concluded that "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA."[5] Extending *POM Wonderful* to the pharmaceutical industry would also be consistent with the Supreme Court's recognition that the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety. In this circumstance, the Supreme Court held that "it would show disregard for congressional design to hold that Congress nonetheless intended one federal statute to preclude operation of the other."[6] Those advocating extending *POM Wonderful* to the pharmaceutical industry will argue that *POM Wonderful* held that the FDCA does not create a ceiling on the regulation of a product, and that *POM Wonderful* confirms that pharmaceutical companies can pursue Lanham Act claims based on competitors' advertising and promotion of drugs regulated by the FDA.

To date, no court has addressed the implications of *POM Wonderful* on the pharmaceutical industry. Until there is a clear resolution of this issue as a result of numerous appellate court decisions reaching the same conclusion or a Supreme Court decision, pharmaceutical companies are likely to face more false advertising claims under the Lanham Act.

Recommendations to Mitigate Risks in Light of *POM Wonderful*

Therefore, pharmaceutical companies should take appropriate steps to confirm not only that their labels, product names and other promotional materials comply with the relevant FDA regulations, but also that the labels and promotional materials do not expose them to liability for claims of false or misleading advertising in violation of the Lanham Act. For example, companies should carefully analyze their labels and promotional materials to determine whether a competitor could argue that they make false or misleading claims by implication based on the relevant context, including the images, font sizing, and placement of claims. In certain instances, additional steps, such as consumer surveys, may be appropriate when developing labels for pharmaceutical products. To the extent that the labels and promotional materials contain express or implicit claims, pharmaceutical companies should ensure that those claims have adequate substantiation and should not presume that the statements are immune from challenge even if the statements are included on the FDA-approved label.

Mitigating the Risk of False Advertising Claims Based upon Comparative Effectiveness Research

The Increased Importance of Comparative Effectiveness Research

Government and private payers, both in the United States and globally, are increasingly demanding competitive effectiveness research as a requirement for reimbursement and placement on product formularies to allow selection by physicians. Inevitably, any comparative effectiveness research that one pharmaceutical company is interested in publicizing will be detrimental to a competitive product, and litigation predictably follows.

The *ONY v. Cornerstone* Decision

One recent appellate court decision provides that pharmaceutical companies, at least in certain circumstances, may be shielded from liability for false advertising based on competitive effectiveness research, and provides insight as to how other pharmaceutical companies can limit their exposure to similar claims.

ONY v. Cornerstone Therapeutics[7] involved two of the biggest U.S. producers of naturally derived surfactants, biological substances that line the surface of human lungs and promote the transfer of oxygen from inhaled air into the blood stream. ONY alleged that Chiesi and/or its U.S. subsidiary, Cornerstone, commissioned a retrospective study to support the claim that the Chiesi product was superior to ONY's product. ONY alleged that Chiesi hired defendant Premier Research Services to provide a database to support the desired conclusion, and hired the defendant authors to submit the findings to pediatric medical societies. The authors subsequently submitted an article for publication in the *Journal of Perinatology*, a peer-reviewed scientific journal. According to the complaint, the article included allegedly false claims, including a claim that even after adjusting for factors such as patient and hospital characteristics, the ONY product "was associated with a 49.6% greater likelihood of death than [the Chiesi product]."[8] ONY's primary objection to the article was that the authors omitted any mention of the length-of-stay data from the article. ONY alleged that the omission of length-of-stay

data was intentional and designed to mask the fact that the neonatal infants treated with Chiesi's product were healthier than the group treated with ONY's product. According to ONY, if the length-of-stay data had been included, "it would be obvious to readers that the differences in the results were a result of differences in the groups of patients treated, not of any differences in the effect of the particular lung surfactant administered."[9] Based on these allegations, ONY brought claims for false advertising in violation of the Lanham Act and related state laws.

The trial court dismissed the case in its entirety, and the United States Court of Appeals for the Second Circuit recently affirmed the district court's ruling. The appellate court recognized that ONY's claims required ONY to identify a false statement of fact and that, generally speaking, statements of pure opinion, i.e., statements incapable of being proven false, are protected by the First Amendment. As the court noted, however, "[s]cientific academic discourse poses several problems for the fact-opinion paradigm of First Amendment jurisprudence."[10] The court further explained:

> Most conclusions contained in a scientific journal article are, in principle, "capable of verification or refutation by means of objective proof," *Phantom Touring, Inc. v. Affiliated Publ'ns*, 953 F.2d 724, 728 n.7 (1st Cir. 1992). Indeed, it is the very premise of the scientific enterprise that it engages with empirically verifiable facts about the universe. At the same time, however, it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation. Importantly, those conclusions are presented in publications directed to the relevant scientific community, ideally in peer-reviewed academic journals that warrant that research approved for publication demonstrates at least some degree of basic scientific competence. These conclusions are then available to other scientists who may respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn from the results. In a sufficiently novel area of research, propositions of empirical "fact" advanced in the literature may be highly controversial and subject to rigorous debate by qualified experts. Needless to say, courts are ill-equipped to undertake to referee such controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury.[11]

Consequently, the court concluded that the traditional dividing line between fact and opinion is not entirely helpful when analyzing statements made as part of an ongoing scientific discourse about which there is considerable disagreement. Nevertheless, the court concluded that statements about contested scientific hypotheses are more closely akin to matters of opinion for the purposes of the First Amendment laws and laws relating to defamation, and are so understood by the relevant scientific communities.

As a result, the court found it significant that ONY did not allege that the data presented in the article were fabricated or fraudulently created, because, if the data were falsified, the fraud would not be easily detectable by even the most informed members of the scientific community. Instead, ONY alleged that the inferences drawn from those data were the wrong ones, and that competent scientists would have included variables that were available to the authors but not taken into account by their analysis. As the court noted, "when the conclusions reached by experiments are presented alongside an accurate description of the data taken into account and the methods used, the validity of the authors' conclusions may be assessed on their face by other members of the relevant discipline or specialty."[12] Therefore, the court held that "to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act."[13] Based on this holding, the court affirmed the dismissal of ONY's claims based upon the publication of the article in the *Journal of Perinatology*.

In addition, the court affirmed the dismissal of ONY's claims arising from the alleged distribution of the article's findings for promotional purposes. In dismissing these claims, the court relied upon the fact that ONY did not allege that the promotional materials misstated the article's conclusions. The court indicated that the present case presented a much easier case than a case in which a plaintiff alleged that a defendant distorted an article's findings in its promotional materials.

Recommendations Regarding the Use of Comparative Effectiveness Research

The *ONY* case is an important decision for the pharmaceutical industry. Until recently, there were no cases alleging that a pharmaceutical company had engaged in false advertising based upon comparative effectiveness research. With increased demands in the last few years by government and private payers for such research as a prerequisite to reimbursement and placement on product formularies to allow selection by physicians, pharmaceutical companies can expect that more such cases will be filed. In order to mitigate exposure for claims relating to comparative effectiveness research, pharmaceutical companies should consider taking the following steps:

- In any scientific articles or presentations, disclose details regarding the data used and the methodology employed in any studies.
- Disclose any potential conflicts of interests or relationships between the authors and the relevant pharmaceutical companies.
- When issuing any press releases or comparative data in promotional materials, consider distributing the entire article or study with the press release or promotional materials.
- Consider limiting circulation of any press releases or other comparative claims to sophisticated consumers (i.e., physicians and not patients).
- Closely script any oral presentations regarding competitive effectiveness research to ensure accuracy.

Conclusion

Courts are likely to continue to grapple with the issue of whether and to what extent pharmaceutical companies are liable for false or misleading statements in their labels, promotional materials and comparative effectiveness research, but many of the trends

suggest that the this type of litigation is likely to increase in the foreseeable future. Therefore, pharmaceutical companies should assume that none of their materials are exempt from lawsuits based on allegedly false or misleading statements, and all of these types of materials should be closely scrutinized to limit potential exposure to such claims.

1 *POM Wonderful LLC v. Coca-Cola Co.*, No.12-761 (U.S. June 12, 2014).
2 *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1177 (9th Cir. 2012).
3 *POM Wonderful*, No. 12-761, slip op. at 11.
4 *Id.* at 12.
5 *Id.* at 9.
6 *Id.* at 11.
7 *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013). One of the authors and his firm are counsel for the manufacturer defendants in this action.
8 *Id.* at 494.
9 *Id.* at 495.
10 *Id.* at 496.
11 *Id.* at 496-97.
12 *Id.* at 497-97.
13 *Id.* at 498.