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A new normal in the pharmaceutical industry: How to fight back when your competitor can't stop fibbing

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Speaking in September at a discussion hosted by the Alliance for a Stronger FDA, Dr. Janet Woodcock provided some candid insight into FDA's enforcement priorities in the area of prescription drug advertising and promotion. Acknowledging a recent decline in untitled and warning letters targeting prescription drug advertising and promotion, she remarked that the agency is "very wary of wading into the First Amendment" and so it is focusing on advertising violations "where health and safety might be involved" and where the advertiser's behavior is particularly "egregious." Dr. Woodcock suggested that competitors could "duke it out" when it came to disputes that do not involve threats to human safety, as reported by the *Pink Sheet*.

These remarks affirm what we have seen from the Center of Drug Evaluation and Research (CDER) in recent years: there has been a marked decline in enforcement efforts following a series of legal challenges by pharmaceutical companies that called into question the limits of FDA's authority over truthful and non-misleading communications about unapproved uses of approved products. In 2017, FDA's Office of Prescription Drug Promotion (OPDP) sent only five enforcement letters regarding potential pharmaceutical marketing violations, notably fewer than the 51 letters it sent in 2010. OPDP's more recent letters have been limited to cases where the alleged marketing violations would be clear regulatory violations, such as pre-approval promotion and outright failures to include risk information.

FDA opened the door for pharmaceutical companies to promote their prescription drug products more broadly when it issued draft guidance in early January 2017 and finalized that guidance in June 2018 (which we analyzed here). In this guidance, FDA expanded what promotional statements may be considered "consistent with" the FDA-required labeling (CFL) by noting that "evidence other than that which meets the new drug approval standard of 'substantial evidence' of effectiveness could be used to support certain representations or suggestions about a prescription drug in a CFL promotional communication."

Dr. Woodcock's recent remarks further reflect the agency's disinclination to police run-of-the-mill advertising violations.

Yet, pharmaceutical companies facing inappropriate statements by a rogue competitor are not left without recourse. There are a number of legal options that might be available to an aggrieved pharmaceutical company if FDA does not pursue enforcement action against a competitor engaging in false or misleading promotion or advertising or unfair competition.

Cease-and-desist letter

Sometimes, a strongly worded cease-and-desist letter that puts a competitor on notice of its unlawful, false, or misleading conduct is enough to induce the receiving party to correct the wrongful behavior. In addition, a well-drafted demand letter can create a framework for future litigation, in the event the letter does not cause the competitor to voluntarily comply with the law.

Litigation in court

In the event that litigation becomes necessary, the most popular forum for false advertising disputes between pharmaceutical companies is a court of law. Possible causes of action include federal claims for false advertising and unfair competition under the Lanham Act, similar state law false advertising and unfair competition claims, and claims for tortious interference, trade libel, unfair trade practices, and product defamation under state common law.

Section 43(a) of the Lanham Act, 15 USC 1125a, contains a false advertising provision, which allows companies to challenge a competitor's false and misleading advertising. Generally, the elements of a false advertising claim under the Lanham Act are

- the defendant made a false or misleading statement of fact in a commercial advertisement about its own or another's product;
- the misrepresentation is material (i.e., likely to influence a purchasing decision);
- the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
- the defendant placed the statement in interstate commerce; and
- the plaintiff has been or is likely to be injured as a result.

In addition to the federal Lanham Act, most states have their own false advertising, unfair competition, and deceptive trade practices laws. Some of these state laws mirror the false advertising provisions of the Lanham Act. Other states, including California and Massachusetts, have fairly broad unfair competition statutes that permit a relatively wide range of claims challenging a competitor's unlawful conduct.

Whatever the cause of action, it is important to remember that there is no private right of action under the Federal Food, Drug, and Cosmetic Act (FDCA). As a result, false advertising claims that merely seek to challenge violations of the FDCA, FDA regulations, or agency guidance have been rejected by courts as improper efforts to create a private right of action under the FDCA. However, if a pharmaceutical company can articulate an independent basis for relief – i.e., a false or misleading claim made by the defendant about its (or another company's) product that is separate and distinct from a mere violation of the FDCA – the resulting claim can often survive dismissal.

One area where pharmaceutical company plaintiffs have used the Lanham Act and similar state laws to challenge their competitors' behavior involves the marketing of unapproved drug products. While the mere act of marketing an unapproved drug product alone may not support a private cause of action, courts have routinely recognized claims challenging independently false and misleading statements or conduct associated with the marketing of unapproved drug products. For example, courts have permitted the following types of claims to survive dismissal in appropriate circumstances, such as

- claims based on a competitor's reference to an unapproved drug as "generic" or "therapeutically equivalent" to the plaintiff's drug product;
- claims based on a competitor's description of its unlawfully marketed products as lawful or compliant with applicable FDA regulations; and

- claims based on a competitor's placement of unapproved drug products on price lists viewed by pharmacists and other market participants as containing only lawfully approved drugs, especially if the competitor's products are linked to the plaintiff's drug product.

Under the doctrine of primary jurisdiction, courts retain the discretion to dismiss or stay lawsuits in order to permit FDA to address certain issues deemed best decided by FDA in the first instance. In applying this doctrine, courts sometimes express reluctance to delve too deeply into disputes that would require original interpretation of ambiguous provisions of the FDCA or agency regulations, especially where judicial intervention would create the risk of imposing obligations inconsistent with FDA requirements. As a result, plaintiffs must craft their claims carefully to avoid forcing the court to wade too far into disputed areas of regulatory law.

Another trend in Lanham Act pharmaceutical product jurisprudence involves so-called "establishment" or "tests show" claims, in which the plaintiff asserts that a competitor has disseminated false or misleading statements about its (or another party's) scientific studies. Establishment claims involving studies of pharmaceutical products may be actionable in either of two ways: (i) if the defendant inaccurately describes the outcome of the study in the advertising materials; or (ii) if the defendant accurately describes the study's outcome, but fails to adequately describe material defects in the study protocols, such that the study's reported conclusion is nonetheless misleading. Establishment claims relating to drug products often involve an overlay of science and public health that sometimes requires a court to distinguish between First Amendment-protected scientific discourse and actionable commercial speech. In framing these types of claims, careful attention must be paid to the context in which the statements were made.

Other creative dispute resolution options

Competitor disputes are not limited to litigation in federal or state court, of course. Depending on the circumstances, pharmaceutical companies faced with a rogue competitor might want to be creative about considering other legal forums. One potential option that might merit consideration is a complaint with the National Advertising Division (NAD), part of the National Advertising Review Council, which is administered by the Council of Better Business Bureaus. The NAD conducts voluntary, non-binding proceedings relating to competitor false advertising claims involving national advertisements, providing an objective forum for evaluation of a competitor's claims.

In appropriate circumstances, another option might be an unfair trade practices claim under Section 337 of the Tariff Act of 1930 before the U.S. International Trade Commission (ITC). Although an ITC case is not appropriate for every dispute, it might merit consideration if the competitor's product is imported from outside the United States, if the false and misleading statement does not rely too heavily on FDA regulatory issues, and if the plaintiff can establish the requisite domestic industry for its own product.

Although both of these alternatives are somewhat unconventional pathways for disputes involving prescription drug advertising, they might merit consideration in appropriate circumstances.

Thoughtful marketing efforts

Finally, aggrieved pharmaceutical companies may wish to give careful consideration to their own options to determine whether it is possible to lawfully provide some measure of counterbalance against offending messages from misbehaving competitors, particularly when those messages pertain to the aggrieved company's own drug product. FDA guidance has opened some avenues that might allow for an expanded scope of counterbalancing messaging, if done thoughtfully. However, this approach requires careful attention to both regulatory requirements and litigation risk.

Conclusion

We expect that FDA's declining enforcement efforts will put increased pressure on pharmaceutical companies to keep their competitors in line through litigation and other forms of private dispute resolution. Over time, pharmaceutical companies, doctors, and other stakeholders may also push for other formalized structures to maintain promotional standards and ensure a level playing field.

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