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GILEAD made HIV history.

But in its fledgling efforts to diversify, the biotech is having trouble finding its feet. *Pharm Exec* sits down with Kevin Young, head of commercial operations, to discuss the firm's strategy to outgrow its extraordinary early success

AN ADVANSTAR ★ PUBLICATION

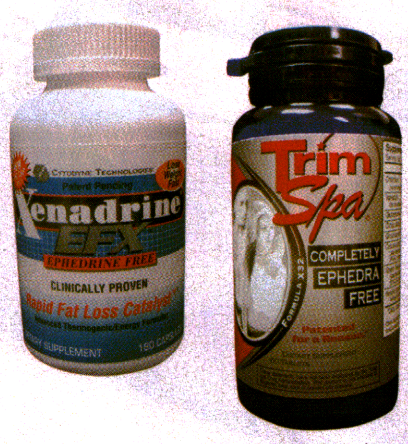
Three Little Pigs of Deceptive Advertising

If companies aren't careful with their marketing spend, they could, in fact, wind up getting too much bang for their buck

Even the best marketing campaign can cause a headache if it precipitates false advertising allegations. Allegations of false advertising are generally addressed by either the FDA (for prescription drugs) or the FTC (for OTC drugs, medical devices, dietary supplements, and medical foods). But FTC enforcement can be severe, so it is of utmost importance to insulate against potential liability.

The Federal Trade Commission Act requires that advertising fulfill three requirements: First, advertising must be truthful and non-deceptive; while "puffery" is allowed, misleading statements are not. Second, advertising cannot be unfair. Third, therapeutic claims must be supported by "competent and reliable scientific evidence"—that is, clinical testing, laboratory studies, and other scientific evidence, which has been "evaluated by people qualified to review it."

Violations can be expensive, both financially and in reputation. For example, in June, Teva admitted to including false or misleading statements in the physician-prescribing information for its Gianvi oral contraceptive. To remedy this, Teva agreed to not ship any inventory until it could remove the false claim from package inserts and other materials. Adding embarrassment to this financial injury, however, Teva also agreed to directly notify every known wholesaler, distributor, and chain retailer that received Gianvi of the labeling change, and agreed to send e-mail or fax messages with corrected prescribing information to US pharmacies nationwide, once a week, every week, for three months.



In another false advertising case (involving Acella Pharmaceuticals' generic version of Merck KgA's prescription-strength l-methylfolate), the Louisiana Attorney General is demanding the manufacturer refund its entire gross sales of the product.

Read Between the Lines

In evaluating whether advertising is deceptive or not, blatant lies are relatively rare. More common are ads that are subtly misleading. The distinction between "subtly misleading" claims and legitimate puffery, however, can be difficult to define. For example, Donald McLemore, the vice president of advertising standards at New Hope Natural Media, commented, "Generally, the types of ads that end up on my desk and end up for review ... are ads that are subtly misleading. For example, just last month, we received an ad for a product that compared itself to three pharmaceutical drugs ... It was a dietary supplement that said it had the same effects as the pharmaceuticals without any side effects ... The advertiser said that, in fact, that product was FDA-approved and had been cleared by the FTC. And, they felt that we had no right to ask them to remove those claims. So, therefore, we lost about $50,000 worth of advertising for that particular ad."

Deceptive advertising allegations are particularly important in direct-to-consumer (DTC) advertising. For example, weight-loss products have been a particularly attractive target for scrutiny; given the numerous new obesity products in the pipeline (for example, Vivus' Qnexa, Arena's Lorcaserin, and Orexigen's Contrave), this trend should continue.

Adverse events can understandably precipitate scrutiny. For example, in February 2003, a 23-year-old pitcher was in spring training with the Baltimore Orioles. He was not, however, apparently in top physical condition; another Orioles pitcher was quoted as observing, "He wasn't able to finish his running the day before; he was really distraught." Fighting a losing battle for a highly competitive spot on the team, the young pitcher apparently tried to help his performance by taking three Ephedra weight-loss pills on an empty stomach. That, along with "other medical issues" and the high temperature that day "converged in a catastrophic event," according to the coroner. The aspiring athlete collapsed and died.

Prompted by adverse event concerns, the FTC initiated false advertising cases against three weight loss product manufacturers. Comparing these similar cases provides a unique insight into how to protect against false

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advertising liability, because the three defendants had similar products, similar advertising claims, and similar clinical substantiation for their advertising claims. But much like the houses of The Three Little Pigs—the results came to dramatically different ends.

The case against the first defendant was nothing if not effective: It forced the company into bankruptcy. Putting the best spin on the situation, the company's CEO explained, "Chapter 11 provides to [the company] a vehicle for resolving its past problems with the FTC ... We have made this difficult but necessary decision [to file for bankruptcy protection]."

The case against the second defendant was similarly effective: The FTC obtained a financial settlement not only from the company, but also from the corporate officers personally, collecting nearly $13 million in cash, a boat, a truck, a "real estate interest," and proceeds from a tax shelter, among other assets. The company was soon put on the block and sold off.

In contrast, the third defendant was able to settle its suit for a nominal payment—basically what it would have cost in legal fees to litigate the case. The FTC's rapid retreat against the third company is exceptional because the three defendants had similar products, advertising, and claim substantiation. What could make the same marketing campaign disastrous for two companies, while giving the third company little more than a slap on the wrist?

Preparation: The Silver Bullet

The answer lies in how the third company prepared in advance. That preparation didn't require more modest advertising claims, nor expensive clinical studies. The preparation, however, enabled the third company to respond in a very convincing way. Further, the preparation not only reduced the company's downside false advertising liability risk, it also increased the product's sales nearly 30 percent.

Like the proverbial third little pig that took the pains to build a house of brick, the third defendant, by taking the effort to pursue a patent, built itself a stable legal home. ... Doing so meant the difference between corporate failure and survival

Recall the fair-advertising standard: Therapeutic claims must be supported by "competent and reliable scientific evidence" which has been "evaluated by people qualified to review it." The FTC enjoys significant expertise in law and in economics. In contrast, scientific expertise is not generally considered one of the FTC's comparative strengths. Another Washington agency, however, enjoys significant scientific expertise, employing scores of medicinal chemists, toxicologists, and pharmacists who are qualified to review scientific evidence and, based on that review, decide whether the evidence supports therapeutic claims. That agency, of course, is ... The United States Patent & Trademark Office (PTO).

Patent Office to the Rescue!

The Patent Office has that expertise, and the third defendant used it—and used it well. The company gathered scientific evidence for its advertising claims, and submitted that evidence to the Patent Office, asking the PTO to evaluate it and make a legal ruling on whether that evidence supports the advertising claims. The Patent Office evaluated the evidence and concluded that the evidence did support the claims, awarding the company a patent (U.S. Letters Patent No. 6420350) in the process.

Several years after the patent was issued, the FTC demanded the company substantiate its advertising claims. The approved US patent, however, was confirmation that the company had indeed produced the necessary scientific evidence evaluated by proper reviewers. Put simply, the patent showed that the US government had already investigated the issues at hand and found the evidence adequate to support its claims. Thus, like the proverbial third little pig that took the pains to build a house of brick, the third defendant, by taking the effort to pursue a patent, built itself a stable legal home.

Manufacturers may, of course, use internal research (or hire a contract research organization) to substantiate advertising claims. Adding a patent to the mix, however, has several unique advantages. For example, the FTC may argue that internal research or external sponsored research is improperly biased in favor of the sponsor. In contrast, it would be difficult to credibly allege that the PTO is biased in favor of particular companies.

Similarly, corporate research does not legally bind the FTC unless and until the FTC actually accepts that research. In contrast, where the Patent Office accepts certain research as cogent on a particular issue, that legal conclusion can be binding not only on the Patent Office, but also, thanks to a 1940 Supreme court case (*Sunshine Anthracite Coal Co. v. Adkins*), on the FTC.

The difference between the three defendants was a seemingly minor one: the first two defendants did not bother to get patents on their advertised indications; the third one did. That seemingly minor difference, however, made the difference between corporate failure and survival—and boosted product sales to boot. PE