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2nd Circ. Creates Confusion For FDA-Vetted Marketers


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Law360, New York (September 29, 2016, 11:17 AM EDT) -- While advertising off-label claims for medical devices and pharmaceuticals may be like sailing into stormy waters, companies might assume that advertising their products based on U.S. Food and Drug Administration-vetted labeling is, if not a safe harbor, at least a reasonably sheltered cove. The recent Second Circuit decision in Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics GmbH, Dkt. No. 15-241, 12016 (2d Cir. Sept. 9, 2016), affirming a finding of Lanham Act false advertising liability based on an over-the-counter (OTC) home pregnancy test's "Weeks Estimator" advertising, challenges this seafaring assumption:

> The fact that the FDA has satisfied itself that a product's labeling is sufficiently accurate to secure FDA approval gives no assurance that the intervention of a competitor would not reveal problematic misleading messaging that is harmful to the competitor's interests...

The Second Circuit's ruling that FDA approval "gives no assurance" that advertising claims based on approved labeling are not "misleading" appears contrary to another unanimous Second Circuit decision issued less than four months earlier. Apotex Inc. v. Acorda Therapeutics Inc. Dkt. No. 14-4353, ___F.3d___, 2016 (2d Cir. May 16, 2016), held "that representations commensurate with information in an FDA label *generally cannot* form the basis for Lanham Act liability." (emphasis added).

Given these contradictory directions from the Second Circuit, advertisers of products whose promotional and labeling claims are subject to FDA vetting and oversight — including the manufacturers and distributors of foods, medical foods, drugs, cosmetics, medical devices and biologics — must navigate cautiously even when basing their advertising on FDA approved labeling.

Church & Dwight v. SPD Swiss Precision Diagnostics

New Jersey-based Church & Dwight markets the leading OTC home pregnancy test kit, First Response. In direct competition, Swiss Precision Diagnostics (SPD) also markets home pregnancy test kits, including ClearBlue. Like most OTC home pregnancy tests, both First Response and ClearBlue detect the human chorionic gonadotropin (hCG) hormone in a woman's urine. When present hCG signals pregnancy.

While First Response offers a "yes" or "no" (two lines, or one) signal, SPD's ClearBlue goes a step further and also provides the customer with a "weeks estimator" calculation based on the amount of hCG in the sample tested. The formula SPD uses measures pregnancy duration from the time of ovulation. However, the medical profession generally calculates pregnancy duration based on the weeks since the expectant mother's last menstrual period.

While SPD's methodology is arguably a more scientifically accurate means of expressing pregnancy duration, it is not a method generally used in the field of obstetrics and gynecology, and provides a "weeks estimation" that understates pregnancy duration — as it is commonly measured — by about two weeks.

Both First Response and ClearBlue are FDA-regulated Class II medical devices, cleared by the FDA as substantially equivalent to predicate devices already recognized as safe and effective. During clearance of ClearBlue, the FDA expressed concern about SPD's pregnancy duration calculation, and imposed limitations on SPD's advertising and labeling of the product. The FDA's clearance letter required, among other things, that SPD "include a specific 'conversion chart' explaining how a doctor would date the pregnancy compared to [ClearBlue's] results," using language provided by the FDA. It also specified that the pregnancy duration results not be expressed as 'weeks pregnant,' but only as the number of weeks since ovulation." SPD also was required to include a specific "indications for use statement" provided by the FDA detailing the meaning and limited value of the weeks estimator, including the caveat: "This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy."

While SPD's "launch package" complied with the FDA's clearance letter, Church & Dwight nevertheless complained to the FDA because word size and placement on the packaging obfuscated the limitations of the product's pregnancy duration calculation ("ovulation," for example, was allegedly placed in small print and only on a side panel, while the front panel included a row of boxes with "Pregnant" above the time estimates of "1-2 weeks," "2-3 weeks," and "3+ weeks"). Similarly, while SPD's television advertising included disclaimers, they were fleeting, with "ESTIMATED WEEKS SINCE OVULATION" appearing for only two seconds.

In response to this complaint, SPD negotiated a "mitigation proposal" with the FDA, requiring SPD to replace the word "weeks" with the phrase "weeks along" in all instances. For example, when promoting its kit as "The ONLY pregnancy test that estimates weeks," SPD now was required to state: "The ONLY pregnancy test that estimates weeks along." SPD also had to clarify that the calculation involved "weeks since ovulation." After SPD's negotiations with the FDA, Church & Dwight sued for injunctive relief.

Following a bench trial, the district court held that both SPD's "launch package" and its revised advertising were misleading and false by necessary implication in violation of § 43 (a) of the Lanham Act. The court found a reasonable consumer would understand the challenged advertising's "weeks estimator" to communicate the same pregnancy duration as would a doctor's advice. Along with evidence that SPD knew its advertising was likely to confuse or mislead consumers, this finding also was bolstered by a consumer survey conducted by the plaintiff, showing that almost 20 percent of consumers believed that SPD's expression of the number of weeks a woman has been pregnant is the same as a doctor's estimate of duration. The trial court issued a sweeping permanent injunction, both

mandatory and prohibitory, requiring, in part, that SPD:

- Remove all current products from points of sale within 45 days;
- Refrain from communicating in any advertising that SPD's product provides an estimate of weeks pregnant that is the same as a doctor's estimate;
- Refrain from using certain phrases in its advertising, including "weeks pregnant," "weeks along" or "weeks estimator";
- Include with its products a specified statement clarifying the difference in the estimates;
- Deliver within a week to all retailers and distributors a specified written corrective notice with a copy of the injunction, and for the next year to make these materials available at all U.S. trade shows and professional meetings attended by SPD or its representatives;
- Set up and maintain for a year a stand-alone webpage with a specified message about the lawsuit and its history of providing misleading information, and to publish a similar statement in retailer circulars and in full-page ads in three parenting magazines;
- Publish an internet banner advertisement prominently displaying its logo and stating that a federal court has determined that it "engaged in false advertising";
- Produce and post on SPD's website, YouTube and Facebook a video explaining the difference between SPD's and the medical profession's pregnancy length estimates, along with a statement that a federal court found it engaged in false advertising.

Affirming the trial court's judgment and injunction, the Second Circuit rejected SPD's argument that the FDA's vetting of the ClearBlue labeling, or the fact its advertising was consistent with this labeling, precluded SPD's false advertising liability under the Lanham Act.

Relying on POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014), the court of appeals reasoned that "the subjugation of the defendant's product labeling to FDA regulation through the § 510(k) process should [not] categorically immunize it from Lanham Act claims by competitors regarding the regulated labeling." In other words, "FDA approval of the accuracy of a subject's representations does not create a ceiling that bars still better protections against the capacity of the representations to mislead."

Accordingly, irrespective of FDA consideration, "[i]f an advertising message means something different from what reasonable consumers would understand it to mean, that message can be considered false." The Second Circuit affirmed the district court's finding "that a reasonable consumer would have assumed from the text of the launch package, TV commercial and other associated advertising that the product was not giving a different number than a medical professional would give," and that SPD's advertising message therefore was false.

Apotex Inc. v. Acorda Therapeutics Inc.

The Second Circuit issued its Apotex decision on May 16, 2016, less than four months before deciding Church & Dwight. The prior decision issued after briefing closed in the subsequent case, however. No supplemental briefing filed with the Church & Dwight court,

and the Apotex decision was not referenced in the Church & Dwight opinion.

Apotex concerned Acorda's marketing of the drug tizandidine, under the brand name Zanaflex, in both capsule and tablet form. Approved for spasticity in Parkinson's and MS patients, the drug has a common side effect of inducing somnolence (that is, drowsiness). As described in the FDA-approved labeling, Zanaflex tablets and capsules are not bioequivalent to each other because, when taken with food, the amount of sleepiness is different between the two. Specifically, "there is a 30 percent increase in Cmax when the tablets are administered with food, but that when the capsules are administered with food, Cmax decreases by 20 percent."

Following successful patent litigation against Acorda, competitor Apotex sought FDA approval of a generic tizandidine for both the capsule and tablet form of Zanaflex. Acorda filed a citizen petition objection with the FDA, which the FDA denied on the same day it approved Apotex's generic. Apotex then sued Acorda, claiming both antitrust violations and false advertising under § 43(a) of the Lanham Act. Following a bench trial, the district issued a defense judgment on all claims.

Among Apotex's false advertising claims was its contention that, while consistent with Zanaflex's FDA-approved labeling, Acorda's advertising of Zanaflex capsules was nonetheless misleading. The Second Circuit styled this "question" as "whether representations that are wholly consistent with an FDA label are subject to Lanham Act liability."

Citing "a number of district courts in this circuit [which] have sensibly adhered to this principle," the Apotex court agreed and held "that representations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability." As the court explained:

> Such a rule reflects proper "deference to the expertise" of the FDA as the regulatory agency responsible for issuing the label by respecting the exhaustive process preceding the issuance of a label. This principle rightfully insulates pharmaceutical companies from liability when they engage in First Amendment speech that is consistent with the directive of the regulatory body having oversight of product labels. (citations omitted).

Thus, "in order to avoid chilling speech that ought to be protected, Acorda's advertisements cannot form the basis for Apotex's claims to the extent they were in line with the FDA-approved label."

Making Sense of Church & Dwight and Apotex

Typically, circuit courts treat prior published authority as stare decisis to which they are bound, barring some intervening U.S. Supreme Court or legislative change in the law. U.S. v. King, 276 F.3d 109, 112 (2d Cir. 2001). After the Apotex panel concluded the FDA should have the final word on the truthfulness of advertising claims based on an FDA-approved label, the Church & Dwight panel nevertheless held that the FDA's consideration carried no weight in a court's determination of whether advertising claims based on FDA-approved labeling is false or misleading.

Appellate courts faced with such an apparent intra-circuit split may refer the issue for en banc consideration, or adopt one of several competing approaches to inconsistent precedent. See Walker v. Mortham, 158 F.3d 1177, 1188 (11th Cir. 1998) (analyzing cases adopting different approaches to resolving intra-circuit split, including those applying earliest precedent, applying most recent precedent and applying precedent most consistent with Supreme Court authority and common sense). Here, it is unclear how future Second Circuit panels will reconcile these two apparently incompatible rulings.

In the meantime, these competing decisions impact companies potentially at risk of false advertising litigation in the jurisdictions comprising the Second Circuit, notably New York, and which are involved in the "one-fifth to one-quarter of U.S. gross domestic product" directly regulated by the FDA. Marc T. Law, History of Food and Drug Regulation in the United States, EH.Net Encyclopedia (Oct. 11, 2004). Until these rulings are resolved or clarified, advertisers of products regulated by the FDA may wish to err on the side of caution, and assume that even advertisements based on product labeling can be scrutinized without deference to the FDA's approval, and could subject the advertiser to liability under § 43(a) of the Lanham Act.

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