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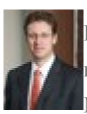
SPECIAL FOCUS: The FDA and Zicam



Recently, Zicam hit the news in a big way when the FDA warned consumers not to take certain products. This week our newsletter editors interview Manatt partner and FDA specialist Ivan Wasserman on what happened and what it means from a marketing standpoint.

Editors: What is the problem with Zicam?

Wasserman: There have been many reports that people who used the Intra-Nasal forms of Zicam lost their sense of smell. For some, the loss is apparently permanent.

Editors: What did the FDA do?

Wasserman: The FDA did two things. First, it issued a public notice warning consumers not to use these Zicam products. Second, it sent a Warning Letter to Matrixx Initiatives, Inc., the company that markets the products, informing the company that the products, which are homeopathic, are unapproved new drugs and therefore cannot be marketed. The FDA also expressed concern that Matrixx had apparently not told the FDA about hundreds of reports of loss of smell that it had received.

Editors: What is a "homeopathic" product?

Wasserman: Homeopathy is a type of medical practice that has been around for hundreds of years. It is based on the theory of "like treats like." If a patient has a particular condition, the patient is given a homeopathic drug which contains a minute amount of a

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substance that is thought to cause that same condition when taken in larger amounts.

Editors: How are homeopathic products regulated by the FDA?

Wasserman: They are regulated as drugs. However, under a long-standing enforcement policy, the FDA generally does not require them to be approved prior to marketing. In the Warning Letter to Matrixx, the FDA took the position that if a homeopathic product presents a safety risk, the enforcement policy does not apply, and the product must go through the FDA drug approval process.

Editors: What is the takeaway from this for marketers?

Wasserman: There are several important lessons here. First, with this action and the recent Hydroxycut recall, it seems that the FDA is increasingly willing to take action when it perceives a potential safety issue with a product. It is therefore more important then ever to ensure the safety of your products. Second, and related to that, it is important to have procedures in place to monitor consumer complaints and know when such complaints must be submitted to the FDA. Third, while the Zicam case is not about advertising claims, it is important to know that just because a homeopathic product does not need to be approved by the FDA, claims for the product are subject to FTC enforcement and therefore must be supported by competent and reliable scientific evidence.

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FDA To Take Over Tobacco Regulation

Federal lawmakers have passed a landmark bill that grants the Food and Drug Administration wide-ranging regulatory control over the packaging, manufacturing, and marketing of tobacco products.

President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act into law on June 22. President Obama cosponsored the bill as a senator.

The new law will give the FDA sweeping oversight of the $150 billion tobacco industry. Specifically, the law provides for:

- Restrictions on marketing and sales to youth, including a ban on all outdoor tobacco advertising within 1,000 feet of schools and playgrounds; a ban on all remaining tobacco-brand sponsorships of sports and entertainment events; a ban on free giveaways of non-tobacco products with the purchase of a tobacco product; a limit to black-and-white text-only advertising in publications with significant teen readership as well as outdoor and point-of-sale advertising, except in adult-only facilities; and a restriction on vending machines and self-service displays to adult-only facilities.

June 25-26, 2009
Food and Drug Law Institute
Introduction to Drug
Law and Regulation:
A Program on Understanding
How the Government
Regulates the Drug Industry
Speaker: Ivan Wasserman
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Newsletter Editors

Jeffrey S. Edelstein
Partner
jedelstein@manatt.com
212.790.4533

Linda A. Goldstein
Partner
lgoldstein@manatt.com
212.790.4544

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- Granting the FDA specific authority to restrict tobacco marketing.
- Requiring detailed disclosure of ingredients, nicotine, and harmful smoke constituents.
- Requiring bigger and better health warnings on packaging.
- Funding FDA activity through a user fee on manufacturers of cigarettes, cigarette tobacco, and smokeless tobacco, allocated by market share, much like the user fee pharmaceutical companies pay.
- Strict regulation of "reduced harm" products, which would prohibit the use of descriptions such as "light," "mild," and "low" to characterize a product on labels or in advertising. A manufacturer must file an application and receive an order before it markets any tobacco product as presenting a "modified risk."

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The country's No. 2 and No. 3 tobacco manufacturers, R.J. Reynolds and Lorillard, opposed the bill, arguing that it helps market leader Philip Morris, which is owned by Altria Group. The bill was reportedly drafted, in part, with the input of Philip Morris, which earned $25 billion in revenue in 2008, compared with RJR's $8.8 billion and Lorillard's $4.2 billion 2008 revenue.

Why it matters: The law will subject the tobacco industry to a host of new regulations, some of which will probably face First Amendment challenges in court. Supporters, however, say they took care to meet free speech requirements in drafting the law. You can read more about the controversy being generated by the legislation by clicking here.

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Marlboro Wins Gift Certificate Lawsuit

In a key win for the promotion industry, the U.S. Court of Appeals for the Ninth Circuit has ruled that California's gift certificate law does not cover on-pack proofs of purchase as part of a Marlboro Miles loyalty program by brand owner Philip Morris.

The June 2, 2009, decision in *Reynolds v. Philip Morris USA Inc.* arose from a complaint claiming that Marlboro Miles were "gift certificates" regulated by California law, and that Philip Morris's termination of the program violated California law, which dictates that gift certificates distributed under a loyalty program may expire only if the expiration date is printed on the gift certificate. No such expiration date was printed on Marlboro Miles.

In its motion to dismiss, Philip Morris argued that Marlboro Miles were not gift certificates, but proofs of purchase that are commonly used in connection with consumer loyalty programs. On June 5, 2007, the district court denied Philip Morris's motion, finding that Marlboro Miles were gift certificates as defined by California law. The Ninth Circuit has now reversed the lower court, finding that the Marlboro Miles were proofs of purchase, "just like a cereal box top," and not a "gift certificate," as the term would ordinarily be understood.

Why it matters: If the lower court's decision had stood, it could have severely restricted the ability of marketers to offer loyalty programs where points are obtained through product purchases. To preclude having to accept such points forever, promoters would have had to print an expiration date on each proof of purchase in capital letters in 10-point font. With the Ninth Circuit's ruling, companies may continue to offer point certificates in connection with a loyalty program, without having to worry that they will bump up against California's gift certificate law.

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Helmet Maker Sues Google Over AdWords Program

For the fourth time in less than two months, Google has found itself on the receiving end of a complaint over its AdWords program.

Motorcycle helmet manufacturer Soaring Helmet sued Google for trademark infringement, alleging that a competitor, Leatherup.com, uses the trademarked name of one of its helmets to trigger Leatherup.com ads on search result pages. Soaring Helmet also alleges that Leatherup.com has used the mark – Vega – in the text of its ads.

Soaring Helmet argues in its complaint, filed in federal court in Seattle, that Leatherup.com's use of "Vega" as a keyword is likely to cause consumer confusion. The company also alleges that a Leatherup.com ad for "50% off Vega Helmets" has cost it revenue. "At least one retailer refused to do business with Soaring Helmet due to the fact that the Leatherup.com advertisement falsely stated that Leatherup.com sells Soaring Helmet's products at a deep discount," the lawsuit alleges.

For years, trademark owners have made sporadic – and largely unsuccessful – attempts to prevent Google and other Internet search companies from allowing marketers to buy trademarked "key words" that trigger their ads on search result pages. In the last couple of months, however, at least four trademark infringement lawsuits have been filed against Google. The first, filed in May, was a potential class action suit by software development company Firepond. The same plaintiff lawyers filed another class action suit a few days later on behalf of real estate investment advisor John Beck. Several weeks later, a Connecticut plaintiff firm brought a similar lawsuit against the company.

The latest wave of lawsuits may have been set off by an April 3, 2009, ruling by the U.S. Court of Appeals for the Second Circuit in the closely watched case, *Rescuecom Corp. v. Google Inc.* Until that decision, the prevailing wisdom had been that trademark owners were facing an uphill battle in proving that keyword search ad programs violate federal trademark law, because they could not establish the narrowly defined "use in commerce" required by the statute. In *Rescuecom*, however, the Second Circuit ruled that using a trademark to trigger an ad is the type of "use in commerce" that can potentially infringe on the trademark.

Why it matters: Although *Rescuecom* is a major win for trademark owners, it does not mean that Google will lose the lawsuit – or any of the spate of complaints that have followed in its wake – because the trademark owners must still prove likelihood of consumer confusion at trial. Google prevailed in the only case that actually went to trial on this point, when a federal district judge in Virginia found that insurance company Geico failed to prove that consumers were confused when its name triggered rival ads on search result pages.

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France's Anti-Piracy Plan Hits Yet Another Roadblock

The highest constitutional body in France has flung another obstacle in the path of the government's plan to block Internet access of repeat copyright pirates, finding that authorities had no right to act without court approval.

The Constitutional Council, which reviews and approves legislation passed by Parliament before it goes into effect, rejected an essential aspect of the legislation, which would have created a new agency with the authority to order Internet service providers to terminate the accounts of alleged copyright pirates who defied two warnings to stop downloading copyrighted content.

It wrote that giving an agency such authority was contrary to the French constitutional principle of freedom of speech. "[C]onsidering the development of the Internet, and its importance for the participation in democratic life and the expression of ideas and opinions, [this principle protects] the online public's freedom to access these communication services," the Council said. It also said the proposal was contrary to the constitutional presumption of innocence.

The decision is the latest setback for supporters of the legislation, which was first outlined a year and a half ago by President Nicolas Sarkozy. Parliament approved the proposal last month, but only after the government resubmitted it following a surprise rejection by the lower house, the National Assembly, in April.

Why it matters: The Council's ruling is a major stumbling block for music and film companies, which had held up the French law as a model for combating illegal file-sharing. French Culture Minister Christine Albanel said she would propose to President Sarkozy that the law be modified as the Council demanded, reserving to the courts the decision to block Internet access. Albanel added that the agency would start sending warning letters to downloaders in the fall as planned. Observers said that without the threat of disconnection, the new agency is largely powerless.

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In Ad Campaign, FedEx Accuses UPS of Taking a "Bailout"

With government bailouts on the public radar, FedEx is seizing the opportunity to

accuse its rival, United Parcel Service, of taking a bailout itself.

The FedEx-backed Web site BrownBailout.com (brown is UPS's color and nickname) claims that UPS is "quietly seeking a congressional bailout designed to limit competition for overnight deliveries." The site includes statements like "This is a bailout, plain and simple, and the American people won't stand for it." It also features a "bailout-o-meter" reflecting UPS's revenue and a parody of a UPS commercial.

The actual issue at stake is not government money for UPS, but the labor laws under which UPS and FedEx are classified. The House recently passed a bill that would make it easier for members of a particular FedEx division to unionize, and the company is opposing the legislation in the Senate. On the Web site, FedEx is basically claiming that, should the bill become law, it would be a bailout for UPS because it would hinder a rival.

FedEx is protesting a clause in a Federal Aviation Administration reauthorization bill passed by the House in May. The provision would classify non-airline employees of FedEx's Express division under the National Labor Relations Act rather than the Railway Labor Act, which currently has oversight of Express as well as airlines and railroads. The reclassification would make it easier to unionize Express, since under the NLRA, unions are allowed to form at a company's individual sites. In contrast, the Railway Act requires unions to have the support of a majority of a company's workers nationwide. UPS, which is governed under the NLRA and is heavily unionized, has been lobbying for the reclassification.

FedEx's description of a labor issue as a bailout has raised eyebrows at UPS and the Teamsters union, which said that it planned to respond with its own public relations campaign. The Teamsters represents 240,000 UPS workers.

"FedEx is appearing to spend millions of dollars to try to convince Congress that a FedEx driver delivering a package is different from a UPS driver delivering a package," said a UPS spokesperson. He added that FedEx's description of the bill as a bailout was misplaced. "There's clearly no way we're seeking a bailout. In fact, what we're doing is working to eliminate an earmark that has been given to FedEx for some years," he said.

A Teamsters executive also said the bailout description was incorrect. "It is just the height of hypocrisy for them to allege that there is a bailout of their competitor, when in fact, it's the company, it's FedEx, who has benefited from this misclassification of their workers," he said.

FedEx counters that the different classification makes sense, since it differs from UPS in its roots and ways of doing business. As for the bailout characterization, a FedEx spokesperson said the "piece of legislation only helps one company while hurting a main competitor — if that's not a bailout, we're going to have to redefine the word."

Why it matters: FedEx is taking a risk that its campaign will backfire. It will not take most visitors to the Web site very long to realize that FedEx is not referring to a bailout as most consumers and business people would define it. On the other hand, FedEx is obviously looking to draw traffic to the Web site and is counting on the fact that the publicity it will generate will outweigh any negative repercussions from its characterization of the dispute as a bailout.

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