Advertising Law @ manatt

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## In This Issue



# SPECIAL FOCUS:
# Dietary Supplements on the Hill - New Legislation Introduced

By Ivan Wasserman

**There was a flurry of activity on Capitol Hill during the last week of May with respect to dietary supplements, including new legislation introduced by Senators Harkin (D-IA) and Hatch (R-UT), the two principal sponsors of the Dietary Supplement Health and Education Act of 1994 (DSHEA).**

Also, the Senate Special Committee on Aging held a hearing where it heard a report by the Government Accountability Office (GAO) on its investigation into the marketing practices of dietary supplement companies targeting seniors, and the presence of contaminants in the supplements it analyzed.

**Legislation**

The new legislation is S. 3414, the "Dietary Supplement Full Implementation and Enforcement Act of 2010." As the name of the bill suggests, it does not create new rules or restrictions; rather, it is intended to ensure that the law the two Senators championed in 1994 is fully implemented and enforced. It does so through several means. First, it would allocate funds to the FDA to implement and enforce DSHEA - $20 million (from funds appropriated to enhance food safety) in 2010, and a $30 million additional appropriation in 2011. Further, it would appropriate funds to the Office of Dietary Supplements at the National Institutes of Health for research and consumer information - $40 million in 2010.

Second, it would require the FDA to make annual reports to Congress on its implementation and enforcement of DSHEA. The reports would include, among other things: (1) the number of inspections of dietary supplement manufacturers for Good Manufacturing Practice (GMP) compliance; (2) a summary of all enforcement actions; (3) the number of dietary supplement claims the FDA determined to be false, misleading or unsubstantiated; and (4) recommendations for administrative or legislative actions to improve the regulation of dietary supplements.

Third, 180 days after the enactment of S. 3414, the FDA would be required to publish a guidance document on New Dietary Ingredients ("NDI"). An NDI is an ingredient that was not sold as a dietary supplement prior to the enactment of DSHEA in 1994. As an important safety measure included as part of DSHEA, with certain exceptions, prior to marketing an NDI, companies must submit a notification to the FDA with information showing why the ingredient is reasonably expected to be safe. This has been the cause of considerable confusion in the industry as it is often unclear whether an ingredient is an NDI, and what information the FDA expects to be in a notification. The mandated guidance should help increase compliance by addressing both sources of confusion.

**Senate Hearing**

At the May 26 hearing of the Senate Special Committee on Aging, the Senators heard testimony from the dietary supplement industry, consumer groups, the Federal Trade Commission, the FDA, and others. Perhaps the most compelling testimony came from the GAO, which reported the findings of its "undercover" investigation into the marketing practices of dietary supplement companies targeting seniors. The GAO found that the marketers it investigated illegally claimed that their supplements could treat diseases (such as Alzheimer's) and made claims not supported by current science. Moreover, the GAO found that companies, through telephone sales representatives, retail store sales clerks, and otherwise, often gave inappropriate medical advice, such as that the supplements were safe to take with certain medications, or that the consumer would be able to stop taking medications.

In addition to investigating marketing practices, the GAO analyzed 40 dietary supplement products and found that 37 had "at least one potentially hazardous contaminant … though none in amounts considered to pose an acute toxicity hazard." Among the trace contaminants were lead (found in all 37 samples) as well as cadmium, arsenic, and pesticide residues. The levels found did not exceed any FDA regulations, and FDA officials did not express concern about negative health consequences from consuming these supplements.

At the hearing, Senator Kohl, the Chairman of the Special Committee, stated: "Let's be clear that no one is suggesting that consumers should

**UPCOMING EVENTS**

June 10-12, 2010
**Natural MarketPlace 2010**
**Topic:** "The Claim Game- Vegas Edition"
**Speaker:** Ivan Wasserman
Las Vegas, NV
Las Vegas Convention Center
for more information

June 10-12, 2010
**American Advertising Federation**
**Topic:** "Let's Get Digital"
**Speaker:** Linda Goldstein
Orlando, FL
for more information

June 10-12, 2010
**American Advertising Federation**
**Topic:** "Truth in Advertising: Can You Handle It?"
**Speaker:** Jeff Edelstein
Orlando, FL
for more information

June 15-16, 2010
**American Conference Institute Litigating and Resolving Advertising Disputes**
**Topic:** "The Realities of Bringing and Defending a Lanham Act case in Federal Court Part 2: Litigating and Proving the Case"
**Speaker:** Tom Morrison
New York, NY

not be able to take vitamins or other dietary supplements. Our concern is that they be able to do so safely. American consumers should have access to comprehensive, accurate information about these products, so they are empowered to make the best decisions about their own health."

**Why it matters:** From the numerous stories of steroids and other substances being found in dietary supplements, to stories of adverse health effects and "quack" science, calls for an increase in the regulation of dietary supplements have been loud and this hearing is another sign that they are not abating. Much of the debate has been divided into two camps: (1) those that think DSHEA should be amended; and (2) those that think the FDA should just increase enforcement of the laws currently on the books. This new bipartisan legislation is a sign of hope for the second camp. We will continue to monitor the Hill and inform you of new developments.

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## EVENT REMINDER:
## Advertising Litigation Conference is June 15-16

**Linda Goldstein, chair of Manatt's Advertising Division, and Tom Morrison, partner in the firm's False Advertising Practice Group, will serve among the faculty of ACI's "Litigating and Resolving Advertising Disputes" Conference on June 15 and 16 in New York City.**

The 2-day program will cover: challenges faced by in-house counsel, how to determine the appropriate forum for competitive challenges, preparing effective strategy, proving the case, utilizing the NAD, securing preliminary relief, the interplay between regulatory activity and private litigation, taking the case to the TV networks, and effective settlement strategies.

To take advantage of our friend-of-the-firm $300 discount off the registration fee, click here.

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## Milk Producers Seek Labeling Enforcement for Dairy Terms

**The National Milk Producers Federation (NMPF) recently petitioned the Food and Drug Administration to stop producers of nondairy food from using terms like "milk," "cheese," "yogurt," and "ice cream" on their labels.**

"The traditional retail dairy case has become a chaotic center of misbranded products and false and misleading labeling," according to

The Helmsley Park Lane Hotel

for more information

June 15-16, 2010

**American Conference Institute**

**Litigating and Resolving Advertising Disputes**

**Topic:** "Pushing the Envelope: Case Studies Examining Advertising that has been the Focus of Recent Adversarial Proceedings"

**Speaker:** Linda Goldstein

New York, NY

The Helmsley Park Lane Hotel

for more information

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the petition. "This expansion in the number of falsely-labeled products has now reached epidemic proportions and an 'anything goes' attitude now pervades the marketplace, making a mockery of existing federal food standard and labeling regulations for dairy products."

Using terms like "milk" and "sour cream" on labels for nondairy products confuses consumers and FDA regulations, which define milk products, the petition argues.

The NMPF included a list of hundreds of products it claims are mislabeled in a variety of ways.

The most common example: a product that uses the word "milk" as part of its standardized food name, such as "soymilk," even though the product does not meet the legal standard of identity for standardized dairy products, the petition states.

The NMPF argues that any product that does not meet the standard of identity for milk as defined by the FDA should not be permitted to use the term "milk" in its labeling.

The petition also references "misbranded, nondairy, plant-based beverages and powders" labeled as milk products.

Products such as "almond milk" are not dairy milk flavored with almonds, but food substances ground and filtered to remove solids, and the resulting liquid should not be labeled as a milk product, the petition argues.

Nondairy products marketed as an alternative but that use a dairy name – such as "sour cream alternative" – are also deceptive, according to the petition.

To read the petition, click here.

**Why it matters:** Although the NMPF cited recent warning letters sent by the FDA to producers of dairy-free products cautioning them about mislabeling products, the petition requests that the agency "significantly" increase its enforcement efforts. It also suggests that nondairy beverages and products should be renamed to more accurately reflect their contents as "drinks," "beverages," or "imitation milk."

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## Report: Alcohol Companies Using Social Media to Market to Minors

**Alcohol companies are reaching underage drinkers through online games, social media, and other digital marketing, according to a report issued by consumer groups**.

"Alcohol Marketing in the Digital Age," released by the Center for

Digital Democracy and Berkeley Media Studies Group of the Public Health Institute, requests that the Federal Trade Commission investigate digital marketing by alcohol companies.

The report claims that alcohol companies are targeting consumers through the use of mobile phone applications, virtual online communities, online video, and social media to "harvest behavioral and other data on consumers."

"Today, alcohol brands (like other major advertisers) are promoting their products across a wide spectrum of new platforms – from social networks to mobile phones to immersive, virtual communities," the report states.

The report argues that the current self-regulatory advertising standards for the alcohol industry are outdated in the constantly burgeoning world of social media.

"Marketing is now fully integrated into daily communications and social relationships, not cordoned off in a special category of 'advertising,'" the report states.

It cites examples of companies marketing their products in arenas dominated by underage consumers, such as a recent Smirnoff "Tea Partay" ad which received millions of hits on YouTube, the creation of a virtual word by Heineken where consumers play branded games and earn points, and an Absolut iPhone app that allows users to create or order the perfect drink and share it with friends through a social network.

The report also expressed concern about the growing practice by companies of using "brand ambassadors" as well as the ease of underage consumers to get around alcohol companies' age-verification processes online.

A simple math calculation enables those under 21 to change their date of birth, and "in the new digital environment, such mechanisms are not only inadequate but increasingly irrelevant," the report argues.

To read the report, click here.

**Why it matters:** The report notes that the Food and Drug Administration is considering promulgating guidelines for the Internet-related marketing of drugs and health products as an illustration of the growing concern by regulators about online marketing, and it urges the FTC to undertake a similar investigation. "The FTC and other regulators need to determine whether alcohol beverage ad targeting is reaching specific young people and their networks, providing a complete picture of the industry's online data collection practices – including whether their privacy policies are accurate," the report states. The report offers several suggestions, including the collection by the FTC of annual expenditure and exposure metrics by leading alcohol companies in the

realms of digital media and advertising to include social media (similar to the current requirements for tobacco companies). In addition, the report suggests that alcohol companies and trade associations should be required to publish annual "transparency reports" of their actions in digital and virtual marketing as well as the data they collect about Internet users. And alcohol companies should also be required to observe a 15 percent maximum youth audience standard based on users aged 12 to 20 for placing advertising in digital media, the report recommends.

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## L.A. Sues Grocery Store Over Prepackaged Products, False Advertising

**The Los Angeles City Attorney's Office filed a criminal case against Ralphs Grocery and its parent company alleging that it overcharged consumers for prepackaged and weighed products and engaged in false labeling and advertising.**

The complaint alleges that Ralphs and the Kroger Company engaged in 18 violations of unlawful computation of value, 14 counts of false and misleading advertising, 18 violations of false labeling, and 9 violations of selling prepackaged commodities in less quantity than represented.

Total fines could reach $256,000.

The complaint came as a result of undercover inspections at 14 grocery stores in Los Angeles over a six-week period earlier this year, when inspectors found 27 violations of overcharges to customers, according to the Los Angeles City Attorney's Office.

The majority of the violations were for illegal charges of the weight of the package, or for including the ice glaze on frozen products in the net weight, and many prepackaged items were also found to be under the labeled weight posted, the complaint alleges.

To read the press release from the Los Angeles City Attorney's Office, click here.

**Why it matters:** The Los Angeles City Attorney's Office noted that Ralphs was previously issued notification of multiple violations in 2008 and 2009 and paid fines both years. The suit serves as an important reminder to comply with all laws and local regulations on packaging and labeling, as well as weights and measures, to avoid continuing violations and fines.

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