# Food Law UPDATE

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## NEW STUDY CONFIRMS THAT TRANS FATTY ACIDS ARE VERY BAD AND LACK ANY REDEEMING NUTRITIONAL VALUE

## New Labeling Regulations Coming Your Way

***By Allan Zackler***

The National Academy of Science has released a report confirming earlier studies that trans fatty acids in food present a significant health risk for coronary disease. The publication of the report will probably cause the FDA to speed up issuance of its long pending proposal to require mandatory labeling of trans fatty acids.

Trans fat is created when vegetable oils are partially hydrogenated. An estimated 40% of all processed food products contain trans fatty acids including baked goods, snacks, candy, dairy products, and meat. The report concluded that there is no safe level for trans fat consumption and that trans fat had no positive dietary benefits.

The FDA published a proposed rule on trans fat labeling in November 1999. (The public comment period ended in 2000.) The rule is currently scheduled to be issued in final form by September 2003. Under the proposal, references to trans fat will have to be included in the "Nutrition Facts" required by the NLEA. The proposal also includes limits on both health and nutrition content claims based upon the amount of trans fat in a food. For example, a low cholesterol claim could only be made if a serving of a food contains 2 grams or less of saturated and trans fat combined instead of 2 grams or less of saturated fat as permitted by the current rule. Foods that have more than 4 grams of saturated and trans fat combined per serving could not make any on-label health claims. The labels could still make nutrient content claims, for example a "good" or "excellent" source claim if a special legend is included on the PDP.

The FDA believes that adoption of the proposed rule will prevent 6,300 to 12,800 cases of coronary heart disease annually and 2,100 to 4,200 deaths annually with much of the reduction resulting from food processors reformulating their products to reduce or eliminate trans fat from their ingredients.

*Comment.*

*Although one professor at the University of California Medical School has compared trans fat to nicotine, given the ubiquitousness of trans fat in the food supply an outright ban seems unlikely.*

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*Undoubtedly, many manufacturers of food products containing trans fatty acids will now start to think a lot about the advantages and disadvantages of reformulating their products. Similarly manufacturer's of products that contain little or no trans fatty acid may see the new labeling requirements as a marketing opportunity.*

*Zackler & Associates provides proactive expert legal advice on FDA, USDA and other labeling requirements as well as on and off label marketing issues. We can review with you how the proposed FDA trans fatty rule will affect the current labeling and marketing of your products and help you develop strategies to comply with the rules as well as use them to your commercial advantage whenever possible.*

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# DIVIDED CALIFORNIA SUPREME COURT HOLDS STATE UNFAIR PRACTICES AND FALSE ADVERTISING LAWS CAN BE APPLIED TO CORPORATE "IMAGE" ADVERTISING

## Are "Happy Cows" Next?

***By Steve Weinstein***

In a 4-3 decision the California Supreme Court has reinstated a private attorney's general lawsuit against Nike alleging that Nike's public communications concerning its labor practices are false and misleading in violation of both the state's strict liability unfair practices and false advertising statutes. Both a trial court and a state court of appeal had previously dismissed the action on First Amendment grounds.

The majority opinion in *Kasky v. Nike* determined that Nike's public statements concerning its labor practices constituted commercial speech and based upon current United States Supreme Court decisions were not entitled to the absolute First Amendment protection. The majority used a three part test that looked at the identity of speaker, the speaker's intended audience and the content of the message. The Court based its conclusion on the fact that the speakers were Nike officers and directors who were acting in furtherance of the company's commercial interest, the intended audience included purchasers of Nike's products and the company's statements concerned its own business operations. While conceding that commercial speech frequently addresses issues of public policy, the majority concluded that speech is still commercial if it is likely to influence consumers in their commercial decisions.

Three justices dissented. The dissents disagreed with the majority's conclusion that Nike's statements about its labor practices were commercial speech. The dissents stated that even if Nike's statements had a commercial aspect, they were so intertwined with public debates on globalization and labor practices that non-commercial aspects had to outweigh any restrictions that might be imposed on them as commercial speech. The dissenters also noted that the decision means that the playing field in public policy debates will now be uneven with business critics enjoying the First Amendment's absolute protection while businesses will be subject to an onerous strict liablity standard.

Nike has stated that it intends to seek review of the decision by the United States Supreme Court.

Among the parties filing friend of the court briefs were California Attorney General Bill Lockyer and the Sierra Club on behalf of Kasky and the ACLU on behalf of Nike.

*Comment:*

*Unless and until the United States Supreme Court reverses the decision in Kasky v Nike, companies doing business in California should recognize that the State Supreme Court decision has effectively eliminated any distinction between the advertising of products and services and statements pertaining to company business practices. In addition to being subject to actions by private parties as well as public agencies, plaintiffs in Unfair Practices and False Advertising actions do not need to prove either that consumers relied upon a defendant company's public statements or that they were damaged by purchasing the defendant's products. Furthermore, because of the statute's strict liablity standards, conventional methods of documenting information, sometimes referred to as a "paper trail," may not be adequate.*

*Zackler & Associates provides legal services concerning all aspects of marketing and is available*

*to review with you any communications that may raise issues under Kasky.*

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## FDA ASKS FOR COMMENTS ON COMMERCIAL SPEECH ISSUES

***By Steve Weinstein***

Although it appears that the California Supreme Court majority in *Kasky v. Nike* needs a remedial course in Constitutional Law, the FDA appears to be at least willing to learn. Citing the United States Supreme Court decision in *Thompson v. Western States Medical Center*, which held that the FDA could not restrict otherwise truthful advertising of compounded drugs, the FDA has issued a Federal Register Notice requesting comments concerning its regulation of commercial speech.

Although the FDA has not limited its request to any specific topics, it has listed several areas of particular interest in the notice including:

What should be the standards for speech pertaining to drugs?

Should FDA change its policies concerning direct advertising of drugs to consumers?

Should the FDA has different regulations for nutritional claims for food and dietary supplements?

How should the disclaimers be presented relative to the claims they modify?

How should warnings be stated?

Is there any empirical evidence to support different standards for on and off label claims?

Do public statements by persons in a drug distribution channel concerning off-label uses undermine the FDA's authority to approve new uses?

Do the FDA speech related regulations address the public health?

Should the FDA change any of its regulations in order to comply with First Amendment requirements?

The FDA has extended the comment period to September 13, 2002 any responses to those comments are to be submitted by October 28, 2002.

*Comment:*

*After its losses in Thompson as well as Pearson v. Shalala, the FDA has apparently become much more sensitive to First Amendment claims and now wants to develop a factual matrix to either support its restrictions or modify its advertising restrictions so they pass muster as the least intrusive method of protecting the public. This notice represents a great opportunity to go on record with the FDA concerning any advertising regulations that fail to protect the public welfare in the most legally appropriate manner.*

*Zackler & Associates can review any FDA regulations that impair the truthful advertising of any goods or services offered by your business and prepare a statement for submittal to the FDA.*

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## COUNTRY OF ORIGIN LABELING REQUIREMENTS EXPANDED

***By Matt Frank***

The 2002 Farm Bill has substantially revised and expanded country of origin labeling requirements. Of particular concern to retailers will be the bill's record keeping requirements.

Under the new law, beef, lamb, pork, fish, peanuts and fresh produce will have to be labeled at retail with the product's country of origin which includes the United States. For example, under prior law only imported pre-packed produce had to be labeled by country of origin. Grocery stores will now have to also post signs identifying the country of origin (including the US) for produce received in bulk that is unpacked and not sold directly from its container.

The bill directs the Secretary of Agriculture to issue voluntary country of origin labeling guidelines by September 30, 2002 and mandatory labeling rules by September 30, 2004. Grocery stores must maintain country of origin records and suppliers are required to provide retailers with county of origin

information. Grocers could be fined up to $10,000 for violations of the regulations.

*Comment:*

*The country of origin labeling requirement is one small part of the 492 page Farm Bill which formalized the effective repeal of the short-lived "Freedom to Farm Act."*

Zackler & Associates provides advice on labeling, distribution and similar issues subject to USDA regulation and can review with you how the Farm Bill might affect marketing and labeling of your products.

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## NEW ORGANIC LABELING RULES TO GO INTO EFFECT

***By Matt Frank***

As provided in the final rules that were published by the USDA on December 21, 2000, effective October 21, 2002 all packaged food products sold as organic must comply with the labeling requirements of the National Organic Program ("NOP"). The only exception is for products that have already entered the "chain of commerce." Consequently, any unshipped organic food products that have not been labeled in compliance with NOP standards as of October 21 will have to be relabeled prior to shipment.

The labeling requirements for organic foods depend upon whether the product is "100% Organic," "Organic," or made with identified organic as well as non-organic ingredients. In each case, the organic certifier must be identified on the label by name. The certifier's address, Internet address or telephone number may also be included on the label. Products that can be labeled as "100% Organic" or "Organic" may also use the USDA "Organic" seal.

*Comment:*

*After years of waiting and wrangling the U.S. finally has national organic standards. Zackler & Associates can assist you in determining how to advertise and label your products that are "100% organic," "organic" or contain organic ingredients. We can advise you about alternative nomenclature for products that cannot be labeled "organic."*

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## FTC EXTENDS "SLIDING SCALE" COPPA CONSENT RULE; FINES COMPANY FOR VIOLATIONS

***By Steve Weinstein***

The FTC has extended the COPPA rule allowing sliding scale parental consent. The sliding scale rule was scheduled to expire on April 21. The FTC's action extends the rule until April 21, 2005.

COPPA requires that a website operator obtain verifiable parental consent when collecting personal information from children 12 and younger. Under the sliding scale rule, if the website operator is not going to release the child's information to a third party, then verifiable parental consent can be obtained by email, or obtaining the parent's address or telephone number and confirming the parent's consent by letter or telephone call. Once the rule expires, consent can only be obtained by a written consent form, credit card verification, calling a toll free number, digital certificate or use of a PIN.

Separately, Ohio Art, the maker of the Etch-A-Sketch toy, has agreed to pay a $35,000 penalty for collecting personal information from children without obtaining verifiable parental consent, collecting more information than was necessary, not providing parents with the opportunity to review the child's personal information and not providing opt out alternative.

*Comment:*

Expect to see continued strict enforcement of COPPA by the FTC. Zackler & Associates can audit your on-line marketing for COPPA compliance.

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## Table Scraps™

- The European Union has asked the WTO to issue regulations to prohibit the use of geographical names on foods produced outside their area of origin. This prohibit already applies to wine and spirits. For example cheeses labeled "parmesan" could only come from the Parma region of Italy. Under the proposed rule

domestic "parmesan" products would have to be labeled something such as hard aged cheese." Not surprisingly, the Grocery Manufacturers of America isn't in favor of the idea.

- Slicing and dicing apparently won't be covered by the EU's region of origin labeling proposal. An EU judge has rejected complaints by Parma ham producers that objected to the labeling of their ham as "Parma Ham" after it had been sliced and packaged in British supermarkets.

- Is it Stoli or _____? A dispute has arisen concerning the ownership of the Stoli trademark. SPI Spirits Group, which says that it purchased the mark, claims that elements in the Russian government are trying to take over the trademark and have refused to allow export of 150 containers of mostly Stoli product. SPI has sought the support of the US Congress in the dispute. Our guess is that they won't settle this dispute over a glass of beer.

- It looks like the fast food industry better watch out. While fast food companies have been attacked over the years from everything ranging from poor quality food, poor nutrition, low employee pay and tasteless architecture, it looks like the attacks are going into high gear with publication of books such as Eric Schlosser's *Fast Food Nation,* proposals for special soda pop or fast food restaurant taxes and a recent report attacking "super sizing" by the Naderite Center for Science in the Public Interest. (And we always thought that paying less for more increased consumer welfare.) With the birth of social cause litigation such as tobacco, guns, and managed care health insurance, we think it only a matter of time before some mega lawsuits are filed against the industry targeting advertising, nutritional disclosures, ingredient sourcing, etc. There may be a future for tofu burgers. Meanwhile, any industry responses in California to the critics will have to keep *Karsky* in mind.

- In response to a Citizen's Petition, the FDA has reclassified nicotine water from dietary supplement to drug based upon claims on the manufacturer's web site and the fact that nicotine is an active ingredient in drugs that the FDA has approved for anti-smoking therapies. The reclassification means that nicotine water cannot be legally sold until the FDA approves a new drug application. For further comment concerning the legal differences between dietary supplements and drugs as well as food, see our new "Ask Allan" feature below.

- FDA has published a regulation listing as GRAS a new sweetener manufactured by Nutrasweet called Netome which is about 10,000 times sweeter than sugar. The approval came after FDA reviewed 113 animal and human studies for toxic effects.

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# ASK ALLAN

With this issue Zackler & Associates is adding a new column by Allan Zackler to replace the void left by the death of Ann Landers. Like Ann, Allan will responding to questions concerning your relationships. Unlike Ann, who wrote about relationships between spouses and children and relatives and employees and bosses, Allan will be writing about your relationship with the regulators by responding to commonly asked questions. Just remember, children grow up and marriages breakup, but your relationships with regulatory agencies are forever.

Submit via email your questions concerning regulatory policies, public policy developments, or other legal/business matters. Allan will respond to those questions that will be of general interest to our readers.

*What's the difference between a food, a dietary supplement and a drug?*

I assume that what you mean is what is the *legal* difference between these products. Obviously, the physical impact of consumable substance upon a human or animal body does not depend upon its classification. Vitamin A doesn't affect you any differently whether you consume it from a cereal, a vitamin pill or as part of a prescription drug.

The legal difference between these three categories is dependent on how they are marketed. The FDA does not pre-review or pre-approve the marketing of food products. However, foods must be composed of ingredients that are GRAS (Generally Recognized as Safe) and any health claims are strictly limited to those permitted by FDA regulation. On the other hand, drugs (both OTC and prescription) cannot be marketed without prior FDA approval. In the case of OTC drugs, the FDA has a series of monographs (essentially standards of identity) which allow any drugs meeting

the standards in those monographs (e.g. aspirin) to be marketed after receiving routine FDA approval. Of course, new drug therapies are rigorously tested for efficacy and safety prior to being approved.

Dietary supplements fall in a category that is between food and drugs. At one time the FDA classified what we now call dietary supplements as food. Because of the limitations placed upon the ingredients that can be used in food products and the limitations on health claims that can be made for those products, the Dietary Supplement Health and Education Act of 1994 created a separate category for supplements.

Unlike food, supplements can contain non-GRAS ingredients. Unlike drugs, supplements do not need prior FDA approval to be marketed although manufacturers of new supplement products may have to submit literature to the FDA demonstrating the supplement's safety. As is true of any claim on any product, all supplement health claims have to be factually sustainable

Because supplements cannot be marketed as either food or drugs, their advertising is limited to "structure function" claims. For example, supplements cannot be advertised with descriptive terms commonly associated with food such as like "delicious," "refreshing," or "great as a salad dressing." After all, the stuff is supposed to be medicinal. On the other hand, supplements cannot be advertised as drugs either. Therefore words like "cures" or "treats" cannot be used while terms such as "maintains" can be used. As our supplement clients know, despite hundreds of pages of commentary pertaining to the FDA's supplement regulations, the demarcation lines between food/supplement marketing and between supplement/drug marketing can be very unclear.

*Is it true that the USDA has legally defined sandwich?*

Yes. In fact, Office of Policy of the Food Safety & Inspection Service of the USDA has issued a tome called the "Food Standards Labeling Policy which provides separate definitions of "sandwich—open" and "sandwich-closed" along with hundreds of other helpful definitions such as chili, pizza (currently subject to review) and salami.

The sandwich definition is particularly important because closed sandwiches can be made in a facility that is not USDA inspected, but open sandwiches have to be made in a USDA inspected facility. So is a rolled sandwich open or closed?

Note: USDA jurisdiction is limited to products containing meat or poultry. Products subject to USDA jurisdiction must be made in a USDA licensed facility and unlike products under the jurisdiction of the FDA, labels on meat and poultry products, must receive prior USDA approval.

Finally, we heard a rumor that USDA is revising the definition of pork to "2002 Farm Bill."

*When we discuss labeling of foods and supplements you often refer to the "NLEA." What does it stand for?*

NLEA refers to the Nutrition Labeling and Education Act of 1990, which is the law that directed the FDA to enact its current regulations on the labeling of nutrient content of food and dietary supplements (i.e., the "Nutrition Facts" box part of the label). NLEA is our short hand reference to this required information as well as other information that is required to be on the label such as ingredient statement, net contents, and food name.

*What are the "PDP" and the "IP" and how do they differ?*

PDP stands for the Principal Display Panel and IP stands for Information Panel. Both are legally required items on a label. The PDP is the front and/or top portion of a product's label that identifies the product by either its standard of identity or, if it has no standard of identity, its common or usual name, and states its net weight. Various disclosures may also need to appear on the PDP such as the use of artificial flavorings or colors. The IP, which normally appears on the right side of a label, contains the NLEA information discussed above and an ingredient statement. In addition to the information required to be published on either the PDP or IP, other information such as the manufacturer's signature is required to appear on the label. By the way, marketing type copy on a label is referred to as "romance copy."

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Zackler & Associates provides a full range of legal services to clients in the food, nutrient supplement, consumer products, advertising and marketing consulting industries and importers/exporters. Our involvement in the areas of consumer packaged goods labeling and other food regulatory requirements dates to the mid-1970's. We look forward to serving your legal needs in the future. Please call us at (510) 834-4400:

- Packaging and Labeling/NLEA Compliance
- Food Regulatory Matters-Federal & State Agencies
- Dietary Supplement/Vitamin Regulation
- Marketing and Promotion Programs
- Advertising Review
- Trademarks Registration and Protection
- Technology Licensing Agreements
- Contract Negotiation and Preparation
- Incorporations, Partnerships & L.L.C.'s
- Customs Law; International Trade Regulation
- New Product Development/Regulatory Concerns
- Antitrust and Corporate Compliance Review
- Drug, Cosmetic & Medical Device Issues
- Energy Issues
- Distribution Law