ZACKLER & ASSOCIATES

Food & Marketing Law Update

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Inside this Edition of Food & Marketing Law Update....

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FDA Implements the Recordkeeping Authority in the Bioterrorism Act

On December 9, 2004, the FDA issued the last of the four regulations that it has promulgated pursuant to the Bioterrorism Act of 2001. (In the Winter 2003 and Summer 2004 issues of FMLU, we discussed the first three regulations pertaining to facilities registration, import notification, and product detention.)

Virtually all businesses involved in the processing, manufacturing, transporting, or storage of food will be required to maintain records that can be produced, essentially upon demand, to FDA employees in the event that FDA has a reasonable belief that food handled by the business might present "serious adverse health consequences or death to humans or animals" (a.k.a. "SAHCODHA" to avid FMLU readers). Note that "food" includes ingredients, dietary supplements, alcoholic beverages, animal feed, as well as finished raw or processed food products.

This rule requires that domestic businesses establish and maintain the records to be discussed below if they engage in any one or more of the following activities involving food:

- manufacture
- process
- pack
- transport
- distribute
- receive
- import, or
- placement directly in contact with its finished container.

The final rule also applies to foreign businesses that transport food within the U.S. It does not apply to foreign owned businesses that operate outside the U.S.

In general, businesses covered by this rule must have available records that show the immediate previous sources (e.g. ingredient suppliers) and immediate

FDA Recordkeeping Authority *(cont'd on p.3, col. 1)*

New Web Portal

www.zacklerlaw.com

In order to meet the needs of our clients, Zackler & Associates has created a new web portal for you and your business. The new portal has many new resources such as information on starting a business, domestic & international business practice, and registering & maintaining your trademarks. The new portal also provides legal resources for businesses in the food and dietary supplement industries. Please go to www.zacklerlaw.com to take advantage of these new resources.

In the News

To read more about how the FTC targeting CortiSlim and CortiStress for false and unsubstantiated claims and how your business can prevent the FTC & FDA from sending you warning letters about your marketing please check our website, www.zacklerlaw.com, and click on "Current News" on the sidebar menu. Also, currently in the news are articles about Atkins Nutritionals changing their food labels and the FDA withdrawing proposed actions over 5 years old. New articles are being added frequently.

Is Obesity the Public Policy Wave of the Future or a Dying (No Pun Intended) Issue?

Readers of *FMLU* have undoubtedly noticed that our lead articles over the past 18 months or so, including the one in this issue, have been about the FDA's Bioterror Rules. However, there is still plenty of buzz about the obesity "epidemic." Although we have commented about the obesity issue in a few past issues (Winter 2003 and Winter 2004) in light of a recent development, we think its time to reexamine the issue.

The recent development is the fact that the number of deaths from obesity related diseases may have been significantly overestimated by the NIH's Center for Disease Control and Prevention ("CDC"). According to an article in *The Wall Street Journal*, a new analysis by the CDC has concluded that its original estimate of about 400,000 obesity related deaths a year was inflated by more than 200,000.

Does this mean that obesity is no longer the public policy issue de jour? While the issue may get a somewhat lower profile, we think that the genie is out of the bottle and revisions in CDC estimates will not cause it to go away. And although we don't expect the "trial lawyers" to fold up their tents and all move on to the next big thing in public health issues (e.g. VIOXX), we think that the issue of obesity is as likely, if not more likely, to be resolved by regulatory fiat (particularly in some states such as California) than the creative theories of plaintiffs' counsel which, even if accepted by some courts, may be legislatively overturned.

In this regard, is the real issue not obesity but nutrition in general? (There are plenty of "average" foods in the market place that would not win any nutritional awards from even the most pedestrian dietitian.) If so, then the analogy may not be the often-cited tobacco cases, but the U.S. Endangered Species Act ("ESA"). Environmental litigants (with the able assistance of some sympathetic federal judges) have essentially turned the ESA into a national land use (or as the critics would complain non-use) planning law, especially where land owned by the federal government is involved. (The U.S. government owns about 1/3 of the landmass of the United States.) Could obesity also be proxy for a much broader agenda concerning the regulation of the U.S. food supply?

We also see three basic scenarios or outcomes pertaining to obesity as a public policy issue. They are: repair, notice and ban. The "repair" scenarios are illustrated by the approach McDonald's has taken. Pay lip service to the critics by ending supersizing (I'll take two orders of fries instead of one), offer some "healthy" alternatives (most of which are nutritionally worse than the standard fare) and encourage people to exercise (Ronald McDonald now does Pilates).

The notice scenario would expand traditional labeling disclosures to notices on labels and at restaurants that the particular food (in the case of packaged food products) or a particular item on a restaurant menu is "bad" for you because of fat, cholesterol, trans fat, high calories, etc.

The ban scenario would do exactly as stated. It would be illegal to sell foods that exceed certain parameters of bad nutrients. We view this third alternative as neither practically nor politically feasible. After all, cigarettes have not been banned and the noble experiment (prohibition) was a complete flop.

On the other hand, the nutritional window dressing by the food industry may not work either. The most likely outcome, if the obesity issue continues to gain momentum, are requirements for more affirmative disclosures of "bad" nutrients in foods and more warning requirements. Of course, warning requirements on consumer products are nothing new. Tobacco products have had them for years. Non-food products have them all the time in order to avoid products liability claims. Currently there are alcoholic beverage warnings on product labels, in stores and in restaurants. In the past, the FDA had a cancer warning requirement for products that contained cyclamates as an artificial sweetener. Currently, FDA policies and congressional legislation are requiring enhanced labeling of allergens. Why not a label on the PDP that says "Warning: This product contains excessive amounts of fat that may be [or "are"?] harmful to your health" or a notice at fast food restaurants that states "Warning: The milk shakes served at this establishment are high in fat, calories, and cholesterol that may be [or "are"?] harmful to your health"? For obesity advocates, a warning might be enough to force a back door ban by forcing the industry to reformulate. This is exactly what is happening in the case of the new mandatory trans fat nutritional disclosure.

Third, we think that there are at least three specific areas where regulatory action might be taken or which merit examination as cross over issues.

<u>Advertising to Children</u>

This is a "mom and apple pie" issue and it's our opinion that this is not going to go away even with a "conservative" administration and a Republican Congress, the latter of which may change in 2006. There is a long-standing tradition of public policy giving special recognition

Obesity *(cont'd on p.3, col. 1)*

Obesity *(cont'd from p.2, col. 1)*

to "protecting" children. For example, the Children's On-Line Privacy Protection Act ("COPPA").

FDA Regulation of Restaurants

When the FDA was formed in 1906, there were no fast food restaurants and eating out was an activity limited to an affluent minority. Although we don't have any statistics at hand, restaurant meals are obviously an enormous and growing part of the American diet. Interestingly, one of McDonald's unsuccessful defenses in the *Perman* lawsuit was that the labeling of its products was subject to FDA regulation and therefore, it was not subject to prosecution under New York state law. The *Perman* lawsuit was filed in federal court in New York by two obese teenagers who alleged that their obesity was McDonald's fault. Given the fact that some states may become much more aggressive than the FDA in dealing with the obesity issue, it's possible that the restaurant industry may seek FDA regulation in order to avoid more onerous state regulation.

Cross Over Issues

We're not quite sure how the following issues might play with obesity. However, consideration should be given to whether there is any relationship between the political economy and legal posture of obesity and the "low carb" marketing movement that food processors and retailers have taken and run with despite the lack of official FDA sanctions, and/or organic regulation by the USDA and GMO's.

All three of these issues involve or potentially involve labeling, which, as we have suggested above, is the most likely public policy outcome. Of course, organic regulation includes a comprehensive set of labeling rules.

In the case of GMO's, short of an outright ban, industry critics want foods that contain GMO's to be labeled as such, preferably with the words "ruins the environment" and "will kill you." You might want to note the anti-capitalist leanings (the real issue?) of a number of GMO opponents which is well expressed in a letter we reprinted in the Winter 2004 issue of FMLU.

FDA Recordkeeping Authority *(cont'd from p.1, col. 2)*

subsequent recipients of food (e.g. purchasers of finished product). The types of records that businesses must maintain depends upon whether they are "transporters" or "nontransporters." Transporters include truckers, railroads and public warehouses. Nontransporters include manufacturers, processors, packers and importers.

Transporters must maintain records of:

- the immediate previous source and immediate subsequent recipient of food
- the origin and destination of the food
- the dates the food was received and released
- a description of the food, and
- the quantity of food.

When nontransporters receive food, they must maintain records of:

- contact information for the transporter
- contact information of the immediate previous nontransporter source (e.g. supplier) of the food
- a description of the type of food
- the date the food was received
- the quantity, and
- how the food was packaged.

When nontransporters ship food, they must maintain records of:

- contact information for the transporter who receives the food
- contact information for the immediate subsequent nontransporter recipient of the food
- a description of the type of food
- the date the food was released
- the quantity, and
- information that identifies the specific source of each ingredient in the finished product.

Depending on the type of food, the rule has different standards as to how long records must be kept. The retention period depends upon the spoilage (i.e. shelf life) of the food. Food subject to spoilage:

- within 60 days after shipment–the record retention period for both transporters and nontransporters is six months.
- between 60 – 90 days after shipment–the record retention period for both transporters and nontransporters is one year.
- no less than 6 months after shipment–the record retention period for nontransporters is two years while for transporters is one year.

The new rule contains numerous qualifiers and exceptions. For example, it does not cover farms or retail sales, it does not include products regulated exclusively by the USDA, and in the case of packaging materials, it distinguishes between direct food contact and indirect food contact packaging.

FDA Recordkeeping Authority *(cont'd on p.4, col. 1)*

FDA Recordkeeping Authority *(cont'd from p.3, col. 2)*

Records may be maintained in either paper or electronic form and they must be retained either onsite or at a reasonably accessible location offsite. Depending on the size of the business, the final compliance date with this new recordkeeping regulation ranges from December 9, 2005 to December 9, 2006. Violators of the rule are subject to both criminal and civil actions.

COMMENT: Don't try to figure out compliance at home! The rule is complicated and convoluted. The online version of the new rule and its accompanying comments is ***344 double-spaced pages****. Zackler & Associates strongly recommends that you examine your business operations to determine how you will be affected by these recordkeeping requirements. If you are uncertain how this rule or any other aspects of the Bioterrorism Act will impact your business, we are available to assist you in auditing and modifying your current business practices to assure compliance with all of the new Bioterrorism Rules.* ■

Ask Allan (cont'd from p. 6)

will you outsource: production (e.g., use a co-packer), storage and delivery (e.g., a logistics firm), advertising, sales, bookkeeping? If you will be hiring employees, what skills will they need and how much in wages and benefits will you be able to afford to pay them? Keep in mind that carelessly outsourced functions or hired employees can cause you real grief.

5. Protect your intellectual property rights. Should you patent it or maintain it as a trade secret? Have you made sure that employees, business associates, customers, and suppliers sign non-disclosure agreements whenever necessary. Have you developed a trademark? Do you want to register your trademark with the United States Patent & Trademark Office? How about overseas?

6. Document and administer your transactions. Casual agreements are not a good business practice. Get it in writing may sound trite, but a little extra work upfront can save you a lot of grief later especially when dealing with important suppliers and accounts. The documentation doesn't have to be elaborate, but it should be clear and complete so that strangers will agree on its meaning. Also, don't forget that agreements are living documents. Refer to them from time-to-time in order to be sure that both you and the other party are complying with the terms of the agreement. This is especially important when circumstances of either party change and might affect the agreement.

7. Have a working knowledge of the regulations that affect your business. There are two types of regulations. The first type is the ubiquitous variety that apply to virtually every business (e.g. wage and hour laws, worker's comp., OSHA, business licenses, zoning, etc.) and then the regulations that are unique to your business (e.g., FDA, USDA, EPA). Correcting regulatory problems after the fact can be very expensive.

8. Develop a risk management strategy. What business practices can you adopt to mitigate potential losses? How much can you afford to self-insure? What types and how much insurance will you buy for casualty losses and liability coverage?

9. Be prepared to delegate. Many entrepreneurs unnecessarily try to do everything themselves or micromanage the business. Details are important, but if you spend all of your energy on them, you'll never have time to address the big picture items. Furthermore, many aspects of creating and running a business require technical skills that can take years to learn and perfect. Therefore, hiring specialized consultants can offer the best way to get things done right the first time within a budget. It's several times more expensive to do things wrong and then have to hire someone else to correct it. The cheapest way to do something right the first time is hire an expert.

10. Work out a tax compliance strategy. Although you and your business should be separate legal entities, the choice of a legal form can involve significant tax issues. Furthermore, failure to comply with our monumentally complex tax code not only may cost you money in terms of back taxes but also missed tax saving opportunities.

If you have any further questions that you would like answered, submit your inquiries via email to ***AskAllan@foodlaw.com***. Your question may be answered and published in the next issue of Food and Marketing Law Update! ■

In Defense of Trial Lawyers

We hear a lot of complaining from some members of the political class, pundits, business people, the *The Wall Street Journal* editorial page and even some of our clients about "trial lawyers." The term "trial lawyer" is code talk. What these people really mean is plaintiffs' trial lawyers. (What do they think the lawyers on the other side of the courtroom do?) Some of our readers may agree with the complaining, except when they need the services of a "trial lawyer."

Well, we've got news for the complainers. LAWYERS DON'T MAKE THE RULES. The rule making process is a three legged stool that the trail lawyers only sit on. Legislators make the rules, judges make the rules and, at least in California under our initiative and referendum system, the people (voters) make the rules. For an example, see the article on *Karsky v. Nike* and Prop 72 at zacklerlaw.com. So if any of our readers think that killing all of the trial lawyers will solve their legal problems, they will have killed the wrong (if not innocent) people.

Now we expect that most of our readers understand the legislative process and the process of going to the voters. For example, see Proposition 72 which was the barely successful business backed effort to repeal legislation requiring most employers to provide health care benefits. What we have out doubts about is the complainers' understanding of the role of the judiciary.

In order to understand the role of the judiciary, keep in mind that there are two aspects to each lawsuit: issues of law and issues of fact. Issues of fact are determined by the triers of fact, usually a jury, or in the case of a bench trial, a judge. We'll be the first to admit that a smart, devious, articulate, slick, well prepared attorney with first rate expert witnesses and a sympathetic or maybe just a pathetic client can change a sow's ear lawsuit in a jackpot jury award, which (by the way) the trial and appellate judges can (and frequently do) take away. We'll also note that jackpot jury verdicts can also be the result of lousy defense work, particularly when the defense attorney isn't given the necessary resources by the defendant's insurance carrier.

Guess what? Judges are also a part of the legal process. First, trial judges can make bad rulings that favor one side or the other. Sometimes a ruling may force a settlement. Others may significantly influence a jury's decision or just flat out throw the plaintiff out of court. For obvious reasons defendants are very hard to throw out of court. And, believe it or not, trial judges have been known to give out very large awards in bench trials.

Second, trial judges and most importantly judges on the courts of appeal decide issues of law. They decide constitutional issues of law, statutory interpretations and make common law. Trial lawyers (both plaintiff and defense) may develop novel legal theories but it's up to the judges to decide whether these theories become new law or if old theories remain the law. Don't like a judicial decision? Quit wasting your time blaming the trial lawyer, he or she is only doing their job, and start blaming the judge. (By the way, we don't agree with the legal fiction that judges don't make the law, they only figure out what it really is (e.g. what the U.S. Constitution really means). These guys and gals MAKE public policy. Period. End of discussion.)

Who is the judge? You frequently hear that the California Supreme Court decided this and the Ninth U.S. Circuit Court of Appeals decided that. Well "courts" don't make decisions; the individual judges that make up the courts make decisions. As noted elsewhere in this issue, Karsky was a 4 to 3 decision by the California Supreme Court. So, if you don't like Karsky, then your dismay should be directed at the four majority judges.

Now, of the three methods by which the legal rules can be changed for good or ill, we would agree that changing the judges once they are on the bench, is undoubtedly the toughest. In regard to the federal bench, judges are appointed for life. So there, you're stuck with the judges you don't like. State court trial judges are elected or appointed and then elected. Very seldom are incumbent trial judges opposed, and to be frank, we don't think that state court trial judges significantly influence the legal rules in California. Judges of the California Supreme Court and the Courts of Appeal are appointed and are subject to retention elections every 12 years. This may sound academic, but retention was not an academic subject in the 1980's as far as Chief Justice Rose Bird and Associate Justices Joe Grodin and Cruz Reynoso were concerned.

Of course, the complainers can try to change the members of the legislature, although we'll admit with the gerrymander in California that's going to be very tough to do as the Governator found out in the November election. As explained above, they have limited opportunities to change judges on the courts. But they will never be able to change the membership of the third leg of the rule making stool, the voters.

COMMENT: Although the attorneys at Zackler & Associates have seen the inside of a few courtrooms and know how to spell judge, they do not litigate. However, Zackler & Associates does help its clients to determine whether they have a legal problem that requires the engagement of litigation counsel, and if so, help them obtain representation from appropriate attorneys, assist clients in working with litigation counsel and monitor the work of litigation counsel for quality and cost.

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The information in *Food & Marketing Law Update* is general in nature and not intended to be relied upon as legal advice. Zackler & Associates will be pleased to privately discuss with you in greater detail the information in this newsletter including its application to your specific business needs. Of course, we welcome your comments and suggestions.

Zackler & Associates
Provides the Following Legal Services:

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

ASK ALLAN

For years, my family has used an old family recipe to make a food that guests have continually suggested we sell commercially. How would I go about converting this recipe into a business?

So you have perfected the greatest idea since sliced bread and now you want to turn your idea into a business. Well, this is a list of 10 big-ticket items that you need to keep in mind in moving the product from being an idea in the kitchen to being a business. Note that none of these items works in isolation from the other and that none of them are static. You'll need to remake your business as markets, laws and the commercial environment change.

1. Have a written business plan. Without one you'll never know what you're doing, where you are going or how you are going to get there.

2. Create a legal form for your business. It can be a corporation, limited liability company ("LLC"), limited partnership or even a general partnership. LLC's are the preferred form today because (as the name implies) they offer limited liability (one of the main reasons for doing business as a corporation) with the income tax benefits enjoyed by partnerships. (Note: one person LLC's are now legal in California.)

3. Determine how to finance your venture on a sustainable basis. Will you use personal savings, the bank of mom and dad, mortgage your house, an SBA loan, bank loan, venture capital, sale of equity? If a loan, how you will repay it? If a sale of equity, how much control will you give up and for what price? Also, don't forget about those pesky security laws.

4. What resources will you need to run your business? Which functions

Ask Allan (cont'd on p. 4)