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I. INTRODUCTION

Food labels have been called informative, straightforward and crucial to consumers. At the same time, critics argue that food labels are confusing, overly complex and irrelevant. As a result, federal and state legislators and regulators have struggled for several years to update food labeling standards.

The debate surrounding new food labeling involves a variety of important concerns, such as human nutrition and health, misleading advertising and consumer perceptions. The debate is further complicated by the question of whether federal or state standards should dominate. Those affected by the debate range from the legislators and regulators who attempt to set the appropriate standards, to the food industry, which propounds the virtue of uniform federal laws, to consumers who are increasingly conscious of the relationship between diet and health.

Twenty years ago, when the United States Food and Drug Administration (“FDA”) established the current regulatory framework, diet and health issues revolved around the need for vitamins and minerals. Today, scientific evidence makes it clear that diet and health are even more closely related than previously understood by experts. Consequently, the biggest areas of concern now are not riboflavin and niacin, but fat, fiber, cholesterol and sodium.

In 1989, FDA began working in earnest on a variety of regulations to update the food label. Congress, ostensibly impatient with FDA’s progress, began to address food labeling legislation, thus creating a “race to regulate.” Congress won the race by passing the Nutrition Labeling and Education Act (“Labeling Act”) which President George Bush signed into law on November 8, 1990. The Labeling Act calls for the first major changes to food labels in approximately two decades. However, not all of the consequences of that victory are yet clear.

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This article analyzes the new federal law in historical context and explores the interplay between recent legislative and administrative activities. After a review of the history of food labeling law, the current regulatory scheme is explained. A discussion follows of recent efforts at change, including FDA’s proposed new regulations and the recently enacted Labeling Act. Finally, the article concludes with an explanation of the most knotty legal issue in this area, the debate over national uniformity.

II. THE HISTORY OF FOOD LABELING

In the early part of this century, widespread abuses in the food and drug industries inspired a combination of activists, most notably Dr. Harvey W. Wiley, to press for government controls. The resulting 1906 Pure Food and Drugs Act (“1906 Act”) prohibited misbranded and adulterated foods and drugs from interstate commerce, and provided for seizure of violative product and criminal sanctions. The 1906 Act required the government to prove a violation was committed with fraudulent intent. It also provided for the formation of the Bureau of Chemistry, the precursor to today’s FDA.

Efforts to strengthen the 1906 Act were underway in the 1930s when tragedy struck. Over one hundred people, mostly children, died after ingesting Elixir of Sulfanilamide. The tragedy gave new impetus to efforts to write a tougher law. That law, the Federal Food, Drug & Cosmetic Act of 1938 (“FD&C Act”), is the centerpiece of FDA enablement today. The FD&C Act added cosmetics and medical devices to the agency’s jurisdiction, and removed the intent requirements for misbranding violations. Under the FD&C Act, FDA was granted authority to provide pre-approval of drugs for safety, conduct factory inspections, and to enjoin violations of the Act.

Significant amendments have been made to the 1938 law. For example, the 1954 Pesticide Amendment gave FDA the power to set and enforce pesticide residues. The Environmental Protection Agency currently sets tolerance levels but FDA enforces them. Also, the 1958 Food Additives Amendment set up the pre-approval system for food additives, in which sponsors bear the burden of proving safety. Two years later, a pre-approval system for colors was established. Since 1938 FDA has promulgated a raft of regulations to implement its various programs. These regulations now comprise about 3,700 pages.

FDA exercises central authority over food labels and labeling through the FD&C Act, which gives FDA the power to act against “misbranded” food. However,
the United States Department of Agriculture, through the Federal Meat Inspection Act\(^1\) and the Poultry Products Inspection Act,\(^2\) and the Federal Trade Commission, through the Fair Packaging and Labeling Act,\(^3\) also participate in food labeling regulation.

III. FOOD LABELING UNDER THE CURRENT FDA REGULATIONS

In 1969, the White House Conference on Food, Nutrition and Health transformed concerns with vitamin deficiency diseases, among other things, into new regulations on topics such as nutrition labeling and ingredient labeling.\(^4\)

Current FDA regulations dictate label requirements for packaged foods.\(^5\) FDA requires that food labels include a statement of identity (the name of the food),\(^6\) the net quantity of the contents,\(^7\) a list of ingredients,\(^8\) and name and address of the manufacturer.\(^9\) Placement and type size specifications are part of the requirements as well.\(^10\)

In addition, one of the central features of the current framework is to require nutrition information on labels when the manufacturer makes a nutritional claim or when vitamins, minerals or protein are added to the product.\(^11\) Otherwise, nutrition labeling is optional.

Whenever nutrition labeling is used, the label must meet a specified format which provides a breakdown of a food's content of specified nutrients.\(^12\) There must be declarations of the content of specified food components in relation to a declared serving size. The label must state: (1) the serving size, (2) the number of servings per container, (3) number of calories (4) protein content, (5) carbohydrate content, (6) fat content, and (7) the percentage of the Recommended Daily Allowance of vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium, and iron.\(^13\) A recent FDA survey revealed that about 60% of food products now feature nutrition labeling.\(^14\) One of the most common objections to the current food labeling regulations is that nutrition labeling is not mandatory for most foods. In addition, consumer advocates, legislators and others complain that the nutritional information required by the current regulations is incomplete. For example, the current regulations do not require the listing of cholesterol or fiber content of foods, in spite of the fact that nutritional and medical authorities increasingly advise consumers to monitor their intake of these components.\(^15\)

Another trend putting pressure on the current system is the food industry's continuing innovation. New and innovative products quickly make descriptions, categories and regulatory schemes anachronistic.

Additionally, during the 1980s more manufacturers sought to take advantage of claims that consumption of certain foods provided health benefits.\(^16\)

IV. RECENT FDA PROPOSALS TO UPDATE THE FOOD LABEL

FDA made piecemeal efforts, had a few false starts, then finally launched into an overhaul in 1989. The agency sought comments on five primary issues: (1) nutrition labeling, (2) label format, (3) ingredient labeling, (4) food descriptors such as "light", and (5) health messages on labels.\(^17\)

The agency held four public hearings in different locations around the country before making its food labeling proposals. Approximately two hundred consumers, health professionals, trade associations and food industry representatives, and state and local health officials testified at these hearings.\(^18\) In addition, fifty local "consumer exchange meetings" resulted in participation of about 1500 more persons.\(^19\) Seven thousand written responses to the August 1989 notice were received.\(^20\) FDA characterized the public response as demonstrating "broad public support for a thorough modernization of food labeling."\(^21\) Based on its August 1989 advance notice and the comments and hearings, FDA proposed four sets of regulations in July 1990.\(^22\) These dealt with nutrition labeling,\(^23\) cholesterol labeling,\(^24\) nutrient content labeling (a system to replace the Recommended Daily Allowance system),\(^25\) and serving sizes.\(^26\) In addition, the July 1990 proposals included notices that FDA planned future proposals on fat descriptors, ingredient labeling, food descriptors such as "light", and finalization on health claims. The nutrition labeling format proposals were expected in late 1991; the time-consuming chore of conducting consumer preference surveys may have inspired this delay.

V. CONGRESS PASSES A FEDERAL LABELING LAW

Paralleling FDA's efforts, several legislative proposals were introduced in Congress to update food labeling standards.\(^27\) During July 1990, at about the same time FDA issued its advance notice, a bill passed the House of Representatives to address food labeling.\(^28\) Then, in late October, the Senate passed the House bill with minor amendments and the House approved the amendments by voice vote. President Bush signed the Labeling Act into law on November 8, 1990.\(^29\)

This unusual two-track state of affairs may have been the result of congressional impatience with FDA efforts to update food labels. FDA, however, had attempted to adhere to a strict schedule in its food labeling overhaul. The race to regulate may have been the result of the popularity of the food labeling issue and a desire by both regulators and legislators to take credit for helping the American consumer.

The Labeling Act mandates that

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FDA promulgate a variety of food labeling regulations. The major topics covered by the Labeling Act are nutrition labeling, food description claims, disease-related claims and preemption of non-identical state laws in these and other areas.

The race to regulate may have been the result of the popularity of the food labeling issue and a desire by both regulators and legislators to take credit for helping the American consumer.

Under the new law, most foods must be labeled with statements of their serving size, number of servings, number of calories per serving, number of calories from fat per serving, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein, and any vitamins or minerals which were required label information before October 1, 1990. In contrast, current FDA regulations only call for labeling of serving size, servings per container, calories, protein, carbohydrates, fat, sodium, and a list of vitamins and minerals. The Act also includes a provision for FDA to designate additional nutrients.

One of the significant changes in the new law is the requirement that most foods, including bulk containers of many fruits, vegetables and raw fish, be labeled with nutrition information. Current regulations only require nutrition labeling when a food label makes a nutritional claim or when the food is fortified with vitamins, minerals or proteins. Restaurants or places where food is intended for immediate consumption or for take-out are exempted, as are small businesses. In addition, the Act provides FDA with discretion to exempt foods that have no significant amounts of any required nutrients.

The Labeling Act combines into a single section provisions governing both description-type claims such as "light" and health-related claims. Under the law, food makers will be required to follow regulations FDA will promulgate when their label characterizes the level of any required nutrient or describes the relationship between a nutrient and a disease or a health-related condition. Other limitations on types of claims made, such as when the absence of a nutrient can be stated, are also specified. The Act also requires a statement on the label directing the consumer's attention to additional nutrition information.

The Labeling Act exempts claims made in the brand name of a product used before October 25, 1989. In particular, the exemption applies to the use of the word "diet" in soft drink brand names.

At a minimum, FDA must make rules to govern use of the words free, low, light or lite, reduced, less and high. These descriptors are largely unregulated now. Currently, light or lite is used on a variety of products, to refer to a reduction in calories, fat, sugar, alcohol, color or sodium. FDA presumes "light" refers to a reduction in calories; therefore, the agency in the past has tried to require manufacturers to make explicit label statements when the word refers to anything else.

The legislators hope this new set of requirements will finally result in a clear program for management of disease-related claims for foods.

As for disease-related claims, the law requires that FDA make regulations allowing such claims when it finds there is "significant scientific agreement" on a particular diet-to-disease relationship. At a minimum, the agency must evaluate claims for the relationship between calcium and osteoporosis, dietary fiber and cancer, dietary and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease.

FDA has announced that it will not reopen or extend comment periods on existing proposals. It will issue instead a series of announcements seeking comments on limited aspects of the existing proposals and on supplementary proposals to assure that the regulations it makes comport with the law's requirements.

The legislators hope this new set of requirements will finally result in a clear program for management of disease-related claims for foods. The saga of FDA's recent efforts in this area is long and tortured.

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If a food's label or advertising reveals that the food is intended to cure, mitigate, treat or prevent disease, or affect the structure or a function of the body, it thereby makes a drug claim, and legally the product becomes a drug. FDA's traditional approach to health claims associated with foods was a strict prohibition, largely because most such claims were little more than quackery.

However, advances in medicine and increasing knowledge about the effect of diet on health have led to a number of widely accepted links between food components and disease prevention. For example, lowering cholesterol has been connected to reducing the risk of heart disease, and high calcium intake is associated with preventing osteoporosis. As a result, FDA has struggled for several years with formulating an appropriate regulatory scheme for permitting health claims.

Most recently, in February of 1990, FDA issued a proposal which established six criteria for permissible health messages; health claims must be (1) truthful
and not misleading, (2) limited to describing the value of ingestion or reduction "of a dietary component, as a part of a total dietary pattern," based on all publicly available scientific evidence, (3) consistent with generally recognized medical and nutritional principles for a total dietary pattern, (4) consistent with an FDA-accepted scientific summary and consumer health message summary, (5) accompanied by a reference to the applicable consumer health message summary which provides more complete information, and (6) accompanied by complete nutrition labeling.68

In the proposal, FDA said manufacturers could continue to include health messages on products, but the agency would, as an interim enforcement policy, evaluate them on a case-by-case basis, with four considerations for guidance. Among the considerations was a list of six topic areas for health messages that were "least likely to run the risk of regulatory action," because they were those "about which significant evidence and general scientific agreement exists."69 These topic areas are those which the Labeling Act now requires FDA to explore: calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and heart disease.70 Carrying out its enforcement policy, FDA in September 1990 warned six food companies about health claims on cereals, baked goods and other foods.71

VI. THE ROLE OF STATE GOVERNMENT IN REGULATING THE FOOD LABEL

A. Preemption of State And Local Regulations

Interestingly, food industry leaders sometimes seem less concerned with the specifics of any new labeling rules and more concerned with whether those rules will be uniform throughout the nation. Indeed, there has long been a good deal of agreement that FDA's food labeling regulatory scheme is outdated and needs improvement. However, the food industry, like all national industries, prefers not to battle fifty different state requirements, and possibly even more local requirements, because differing requirements necessitate much more complex packaging, marketing and distribution systems, and raise costs. Any changes, they argue, should be accompanied by preemption of state and local laws on the same topics. State officials prefer the flexibility that comes without preemption.

The Labeling Act's preemption and state enforcement sections are the result of extensive lobbying and compromise. Under these provisions, states are prohibited from making any non-identical requirements for foods subject to federal standards of identity, nutrition labeling or claims requirements, or for a variety of basic labeling requirements not specifically covered by the new law, but already in place.72 The law also specifically says that it is intended to be expressly preemptive only, and that it is not intended to change the express or implied preemptive effect of any other sections of FD&C Act.73

Food industry members, beleaguered by California's chemical warning initiative, Proposition 65,74 would have preferred that new food labeling laws or regulations explicitly preempted such health warnings by states. Proposition 65 requires that products, including foods, that contain even trace amounts of chemicals that California has determined cause cancer or birth defects, include warnings to that effect.75 The new law does not preempt regulations such as Proposition 65 that involve warnings "concerning the safety of the food or component of the food."76

Interestingly, FDA's four July 1990 announcements stopped short of deciding whether to make the rules explicitly preemptive. Instead, each of the four documents described the preemption issue as "complex and divisive," and asked for public comment on the issue.77 It was widely reported that FDA had originally called for some measure of preemption of state laws on the same topics, and had even

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hand, point to the severe added costs and complications that non-uniform state laws will foster. If burdensome enough, an unusual state requirement might even lead to the disappearance of products from the state. Because a lack of uniformity can result in higher prices to consumers, state officials ostensibly trying to protect consumers may defeat their own purposes. Nonetheless, advocates of state regulation press on. Many who agree with the states would concede that uniform national food labeling is a good idea, but still would prefer to let states decide about safety warnings like those called for by Proposition 65.

B. State Enforcement of Federal Law

The Labeling Act permits state enforcement of select portions of federal law.79 States are given au-
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authority to bring actions in their own name, within their own jurisdiction, for violations of a long list of FD&C Act provisions, as well as provisions created by the Labeling Act governing nutrition labeling and claims.80 A state must first give notice to FDA of its intent to pursue such an action and wait thirty days for informal or formal action to be started by the federal government.81 The state must refrain from acting if FDA diligently pursues or settles a court action against the violator, or has settled another formal or informal proceeding.82 Precisely how this will work in practice is unclear. For example, there may be disputes over what constitutes an informal or formal regulatory action.

A special provision appears to have been added to keep FDA from beginning an enforcement action within the first thirty days and then dropping it; the state may commence its own action after ninety days if FDA begins action within the first thirty days after notice,83 but then does too little to activate the "diligently prosecuting" clause.84

It remains to be seen whether FDA will have the resources to respond to state prodding. Moreover, conflicts in enforcement approaches may result, as state actions, guided only by federal legislation, begin to conflict with FDA action, which is guided by both law and enforcement policy. The state enforcement clauses may prove the undoing of the apparent protection against non-uniformity afforded by the preemption provisions.

VII. CONCLUSION

The dictates of the new law, combined with FDA regulations, will result in new and different food labels. Nutrition labeling, which has been largely optional until now, will be required for most foods. Further, the new nutrition label will include information on more food components, such as cholesterol, dietary fiber and saturated fats.

The new law also requires FDA to make rules governing the use of the descriptive terms like free, low, lite or light, reduced and high. New rules in this area should help eliminate confusion about what these terms mean when they are used to describe food. The agency must also formulate rules that will allow manufacturers to make health claims for their products when there is significant scientific agreement about a relationship between a dietary component and disease. Finally, although the new law will surely create some national uniformity, it will not be complete, and the unknown effect of the state enforcement provisions may lessen industry enthusiasm and make uniformity, in practice, illusory.

Unless manufacturers begin to change their labels before the new regulations are effective, and unless FDA acts more quickly than expected in making these regulations, consumers will probably not see widespread changes in their food labels for at least two years. The major portions of the new law require new regulations to be effective thirty months after passage, by May of 1993. With the fast pace of change in medical and nutritional science, let us hope the new requirements are not obsolete as soon as they appear.

ENDNOTES
8 id. at §§ 351-353.
9 id. at §§ 355.
10 id. at § 372.
11 id. at § 332.
12 id. at §§ 321(q-r), 342(a)(2), 346a, 346b.
15 The terms "label" and "labeling" differ. "Label" means "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k) (1988); By contrast, "labeling" means all "labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article." 21 U.S.C. § 321(m) (1988). The "accompanying" clause has been relied on to prevent clever attempts to circumvent restrictions on labeling, such as by mailing product and labeling, in the form of pamphlets, under separate cover. See, Kordel v. U.S., 335 U.S. 345, 350 (1948)
17 See 21 U.S.C. § 343 (1988) for the various reasons food can be considered "misbranded.
20 15 U.S.C. §§ 1451, et seq. By a 1980 Memorandum of Understanding, FTC and FDA agreed that FTC would have primary responsibility over the truth or falsity of food advertising, while FDA would have primary responsibility over all matters concerning the regulation of food labeling. FDA CPG 7155m.01 (10/1/90).
24 Id. at § 101.105.
25 id. at § 101.4.
26 id. at § 101.5.
27 Id. at §§ 101.2, 101.15.
28 Id. at § 101.9(a).
29 Id. at § 101.9(c).
30 id.
34 54 Fed. Reg. 32610 (1989). FDA, like any regulatory agency, must follow the strictures of the Administrative Procedure Act, 5 U.S.C. § 551 et seq. (1982), 21 U.S.C. § 371 (1988), in making rules. When FDA makes rules, it plays a legislative role. Typically, "informal" rulemaking such as this begins with a petition from an outsider; it may also begin at the agency's own instance. A proposal is prepared and published in the Federal Register, and public comments on it are sought. Sometimes, as with the food labeling overhaul, an "advance notice" precedes the proposal to obtain input to help the agency formulate the proposal.
35 Once public comments are received, the proposal is altered as the agency deems appropriate based on the comments, and a final rule is published in the Federal Register. Typically, the final rule becomes effective after a specified period of time. Adversely affected parties may petition for FDA reconsideration of a final rule or for a stay of its effectiveness. 21 C.F.R. § 10.33 (1990).
36 55 Fed. Reg. 29487 (1990). Although public hearings and forums were held on the food labeling overhaul, they were only informal information gathering hearings. These were not evidentiary hearings (witnesses were not sworn) such that the process could be characterized as "formal" rulemaking.
37 id.
38 id.
40 Id. at §§ 29487, 29491.
41 Id.
42 Id. at §§ 29476, 29478.
43 Id. at §§ 29517, 29524.
47 Id. at § 2(a)(q)(1).
48 See supra notes 22-30 and accompanying text.
53 Id. at § 2(a)(q)(4)(D).
54 Id. at § 2(a)(q)(5)(C).
55 Id. at § 3.
56 Id. at § 3(a)(r)(2)(A)(i).
57 Id. at § 3(a)(r)(2)(A)(ii).
58 Id. at § 3(a)(r)(2)(B).
59 Id. at § 3(a)(2)(C)(vi).
60 Personal communication, F. Edward Scarbrough, Acting Director, Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, October 2, 1989.
61 Labeling Act, at § 3(a)(q)(1)(B).
62 Id. at § 3(b)(1)(A)(vi).
63 56 Fed. Reg. 1161.
65 See, U.S. v. 25 Jars, etc. of U.S. Fancy Pure Honey, 218 F. Supp. 208 (D. Mich. 1963), aff'd, 444 F.2d 288 (6th Cir. 1965) (honey was claimed to be a cure for a variety of ailments).
68 Id. at §§ 5179-5180.
69 Id. at §§ 5184.
70 Labeling Act, at § 3(b)(1)(A)(vi).
72 Labeling Act, at § 6(a).
73 Id. at § 6(c)(3).
75 Id. at §§ 25249.6, 25249.11(c).
76 Labeling Act, at § 6(c)(2).
78 Executive Order No. 12612, October 26, 1987.
79 Labeling Act, at § 4.
80 Id. at § 4(b)(1).
81 Id. at § 4(b)(2)(A).
82 Id. at § 4(b)(2)(C).
83 Id. at § 4(b)(2)(B).
84 Id. at § 4(b)(2)(C).

ANNOUNCEMENT
New Committee To Focus On Consumer Protection

The Section of Antitrust Law of the American Bar Association recently created a Consumer Protection Committee to focus on consumer protection developments and enforcement initiatives. State and private enforcement activities and counseling issues involving consumer fraud, deceptive advertising and marketing will be the principal interests of the Committee. The Committee’s membership includes state and federal agency lawyers, corporate counsel, and private practitioners involved in advertising and consumer protection matters.

If you wish to join the Committee or if you want further information about its activities, contact the Committee Chair:

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