

# Report for Congress

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## **Alcohol Beverages: Labeling and Health Claims**

**Updated April 10, 2003**

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# Alcohol Beverages: Labeling and Health Claims

## Summary

On March 3, 2003, the Alcohol and Tobacco and Trade Bureau published final rules that would prohibit manufacturers from making any substantive claims in labeling or in advertising regarding health benefits associated with alcohol beverage consumption, unless specific criteria are met. This publication follows several years of debate over whether statements of health benefits should be allowed to appear on alcohol beverages.

Regulation of alcohol beverages fell under the jurisdiction of the Department of Treasury's Bureau of Alcohol, Tobacco and Firearms (BATF) until it was renamed Alcohol and Tobacco Tax and Trade Bureau (TTB), following the creation of the Department of Homeland Security. All alcohol beverage labels must undergo premarket approval by the Bureau, which will be referred to as TTB throughout this report. The Food and Drug Administration (FDA) and the Department of Agriculture are responsible for the regulation of labeling on non-alcohol beverages, food and meat products. Since 1987, FDA and TTB have worked under a memorandum of understanding which clarifies and delineates the enforcement responsibilities of each agency with respect to regulation of alcohol beverages found to be adulterated.

In general, labeling requirements are specific to the food or alcohol beverage product being marketed. Since 1988, alcohol beverages have been required to carry government *warnings* about alcohol consumption and its impact on driving and/or pregnancy. In the last decade, food products have been allowed to carry nutrient content and health claims, if they meet certain regulatory requirements. Early in 1999, TTB announced that it would allow wine manufacturers to place health information on their labels for the first time. However, it subsequently proposed rules to prohibit such messages on alcohol beverages, unless specific criteria are met.

TTB's initial decision to allow health messages on wine labels was based on the message's reference to the U.S. Dietary Guidelines. The guidelines state that "if alcohol beverages are consumed, it should be done in moderation." The accompanying text outlines the hazards of excessive intake, individuals who should avoid drinking, and recent evidence that moderate drinking may be associated with lower coronary heart disease risk in some individuals.

Three bills were introduced in the 106<sup>th</sup> Congress in response to the initial TTB decision to allow health messages on wine labels. The Alcohol Beverage Labeling Act of 1999 (S. 431) would have transferred all authority for alcohol beverage labeling from TTB to the Department of Health and Human Services. The Alcohol Abuse, Prevention and Treatment Trust Fund Act of 1999 (S. 432) would have increased the rate of tax on wine and dedicated those revenues to programs for the prevention and treatment of alcohol abuse. The Alcohol Beverage Label Preservation Act of 1999 (S. 433) would have prohibited additional statements and representations related to alcohol beverages and health beyond the government *warning* already required. Two other bills, H.R. 2094 and H.R. 2161, were concerned with alcohol beverage shipments. No action was ever taken on these bills, and no alcohol labeling legislation has been introduced since the 106<sup>th</sup> Congress.

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# Alcohol Beverages: Labeling and Health Claims

On March 3, 2003, the Alcohol and Tobacco Tax and Trade Bureau (TTB) published final rules that would prohibit the appearance in labeling or advertising of any statement that makes a substantive claim regarding health benefits associated with alcohol beverage<sup>1</sup> consumption, unless specific criteria are met. This announcement followed several years of debate on whether to allow health benefit statements to appear on wine products. For more than a decade, mandatory health *warnings* have appeared on all alcohol beverages.

## Alcohol Consumption

Alcohol consumption is difficult to quantify accurately, and there is no universally acceptable classification system or standard for a safe level of drinking. The amount and type of alcohol beverages Americans drink, and changes in overall drinking levels, are generally determined by monitoring product sales. Per capita consumption is not possible to determine so it is derived from sales data to represent an estimate of the average amount of alcohol consumed per person. The result is “apparent per capita consumption,” which is calculated by dividing alcohol sales or shipment data from every state and the District of Columbia by the U.S. population aged 14 years or older, to determine the consumption expressed in gallons of pure alcohol. The estimates attribute average consumption to all individuals in the population, regardless of their actual consumption; thus the data have limitations in determining actual consumption.

Total annual per capita alcohol consumption rose from 1935, when consumption was 1.2 gallons, to 1982 when consumption reached a high of about 2.75 gallons, before falling to a level of 2.21 gallons by 1999 for the population 14 years and older.<sup>2</sup> Beer makes the greatest contribution to apparent per capita alcohol consumption in the United States, while wine has made the least. Almost all of the recent decline in alcohol use can be attributed to a reduction in the use of distilled spirits.

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<sup>1</sup> **Note:** Several terms are used for beverages containing an alcohol content greater than 7% of volume: alcohol beverages, alcoholic beverages and beverage alcohol. For purposes of this report the term alcohol beverages will be used.

<sup>2</sup> [<http://www.niaaa.nih.gov/databases/consum01.tx.htr>]

In 2000, about 62% of all individuals surveyed reported being drinkers, including 68% of men and 56% of women.<sup>3</sup> By level of alcohol consumed as self-estimated and reported by current drinkers, 71% reported light and 22% reported moderate consumption. In 2000, 7% of individuals aged 18 years and over described themselves as heavy alcohol users, defined as five or more drinks on at least one occasion in the past month. Among current drinkers, about 32% of individuals in this age group reported consuming five or more drinks on at least one occasion in the past year, including 43% of men and 19% of women. This level of alcohol consumption was most common among young adults 18-24 years of age.

## Health Effects of Alcohol Consumption

Considerable attention has been paid to the issue of the health effects of alcohol consumption. Excessive alcohol consumption can have widespread deleterious effects throughout the body, with consequences that include neuropsychological and reproductive abnormalities and increased susceptibility to infection. The adverse consequences of alcohol abuse may vary considerably depending on such factors as the amount consumed, gender, age, and nutritional status of the individual. The contribution of excessive alcohol intake to liver damage, heart and cardiovascular disease, high blood pressure and stroke, mental impairment, interference with normal endocrine function, and dysregulation of immune defenses have been well-documented.<sup>4</sup> Chronic liver disease and cirrhosis, which are frequently associated with alcohol abuse, ranked as the tenth leading cause of death in 1997.<sup>5</sup> Particular concern focuses on early drinking which seems to increase lifetime risk of alcoholism.<sup>6</sup> An estimated 14 million adults either abuse or are physically dependent on alcohol.<sup>7</sup> The effects of excessive drinking are the primary basis for opposition to allowing health benefit statements on alcohol beverages (described below).

However, increasing attention has focused on epidemiologic data that suggests potential health benefits may result from moderate alcohol consumption. A decade ago, numerous media reports introduced the American public to what was termed the “French Paradox.”<sup>8</sup> The reports described how the French population, while consuming a higher fat diet, smoking more and exercising less than Americans,

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<sup>3</sup> U.S. Dept of Health and Human Services. Centers for Disease Control and Prevention. Health, United States, 2002 with Chartbook on Trends in the Health of Americans. DHHS Pub. No. (PHS) 2002-1232. July 2002.

<sup>4</sup> U.S. Dept. of Health and Human Services. Public Health Service, National Institutes of Health. National Institute on Alcohol Abuse and Alcoholism. *Ninth Special Report to the U.S. Congress on Alcohol and Health*. From the Secretary of Health and Human Services. June 1997.

<sup>5</sup> U.S. Dept. of Health and Human Services. Healthy People 2010. Final Report. Washington, D.C. November, 2000.

<sup>6</sup> Squires, S. *Early Drinking Said to Increase Alcoholism Risk*. Washington Post. January 20, 1998. Health Section. p. 8.

<sup>7</sup> [<http://www.niaaa.nih.gov/faq/q-a.htm>]

<sup>8</sup> Kazman, S. *Here's to Honesty in Liquor Labels*. Wall St. Journal. February 18, 1999. p. A22.

experienced only half as many heart attacks as the U.S. population. The difference in cardiovascular disease was suggested to result from moderate alcohol consumption, especially red wine, by the French. As defined in the scientific literature, moderate alcohol consumption consists of 1-2 drinks a day and is believed to be beneficial in reducing the risk of coronary artery disease (CAD). A recent published report from the Harvard School of Public Health indicates that two drinks a day will reduce the risk of heart attack in individuals by at least 25%.<sup>9</sup> Research and debate continue on several possible metabolic pathways that may be affected by moderate alcohol consumption, which may result in reducing the risk of CAD. The implications of epidemiological and experimental findings may hold valuable information for clinical practice and public health policies in the future.

While moderate drinking may reduce the risk of CAD in some individuals, other population subgroups, such as pregnant women and individuals who are operating motor vehicles or heavy machinery, are advised to avoid drinking alcohol beverages. Individuals with a family history of alcoholism need to exercise caution in their decision to drink. Currently, the epidemiological studies have suggested that moderate drinking is associated with improved cardiovascular health.<sup>10</sup> Certain individuals who are at high risk of CAD, especially men over 45, postmenopausal women and smokers, may benefit from the cardioprotective effects of alcohol beverages more than persons at low risk. Further study is needed to verify whether the relationship is supported by additional research scrutiny.

## Government Guidance on Alcohol

Over the years, the use of alcohol beverages has been addressed in at least two government-sponsored initiatives: dietary guidance and health objectives. The fifth edition of the Dietary Guidelines for Americans released by the U.S. Departments of Agriculture (USDA) and HHS stated in its tenth “rule” that: “If you drink alcoholic beverages, do so in moderation.”<sup>11</sup> This wording or similar language has appeared in each edition of the Dietary Guidelines since the first one in 1980. The accompanying text for this “rule” has expanded over time and outlines the hazards of excessive intake of alcohol. The text reports that current research suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals. Moderation is defined as no more than one drink per day for women and two drinks per day for men. A single drink would amount to 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of 80-proof distilled spirits. The increased health risks from higher intakes are also provided: high blood pressure, stroke, heart disease, certain cancers, accidents, violence, suicides, birth defects, and overall mortality. The problems from excessive consumption are reviewed: cirrhosis of the

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<sup>9</sup> Rimm, E. et al. *Moderate Alcohol Intake and Lower Risk of Coronary Heart Disease: Meta-analysis of Effects on Lipids and Hemostatic Factors*. *British Medical Journal*. v. 319 December 11, 1999. p.1523-1528.

<sup>10</sup> Zakhari, S. and E. Gordis. *Moderate Drinking and Cardiovascular Health*. *Proceedings Assoc. Amer. Physicians*. v. 111, no. 2. March/April 1999. p. 148-158.

<sup>11</sup> U.S. Dept. of Agriculture. Dept. of Health and Human Services. *Nutrition and Your Health: Dietary Guidelines for Americans*. Washington, D.C. Fifth Edition., 2000.

liver, inflammation of the pancreas, damage to brain and heart, and malnutrition. The text identifies individuals who should not drink: children and adolescents; anyone who consumes more than moderate amounts; pregnant women; individuals on prescription and over-the-counter drugs; and individuals driving or undertaking activities that require skill or attention.

In the final report submitted by the Dietary Guidelines scientific advisory committee, the alcohol guideline was unchanged.<sup>12</sup> However, the accompanying text draft was revised to place greater emphasis on excessive consumption of alcohol and updating statements based on current scientific evidence. It provides information on moderate drinking, which was comparable to the text in the previous edition. While the text does mention the potential benefit of lowering coronary heart disease risk in men over 45 and women over 55, it continues to identify the subgroups of individuals who should not drink at all. The sixth edition is anticipated in 2005 and preliminary activities in its preparation are currently underway.

The final version of Healthy People 2010 Objectives was released by HHS in November, 2000.<sup>13</sup> These objectives, published about every decade since 1979, are a 10-year plan for improving the nation's public health. The recent document identified 10 leading indicators of health status, one of which is substance abuse (alcohol and drugs). The specific alcohol objectives seek to decrease the proportion of adolescents using alcohol, and to reduce the proportion of adults engaging in binge drinking. The text reviews the health and social impact of alcohol use and abuse. It reports that the trends in alcohol abuse by adolescents ages 12-17 remained at a level of about 20% from 1992-1997, with 8% reporting binge drinking and 3% considered to be heavy drinkers (five or more drinks on the same occasion on each of 5 or more days in the past month). For adults, binge drinking has remained at about 16% since 1988, with the highest current rate at 32 % among adults aged 18-25 years.

## **Current Regulatory Jurisdiction**

The Department of the Treasury and its BATF was responsible for the regulation of alcohol beverages, until it was renamed the Alcohol and Tobacco Tax and Trade Bureau (TTB), following the creation of the Department of Homeland Security. The Bureau regulates the qualification and operations of domestic distilleries, wineries and breweries, as well as importers and wholesalers in the alcohol beverage industry. The TTB National Laboratory Center is the primary tester of new alcohol products prior to their marketplace introduction, as well as the facility that determines whether any product currently on the market poses a health hazard to consumers.

TTB conducts a full range of regulatory functions within the alcohol beverage industry. Under the provisions of the Federal Alcohol Administration Act of 1935 (FAAA) as amended, the Bureau is authorized to fully regulate the industry and to provide consumer protection. In addition to collecting the alcohol beverage excise

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<sup>12</sup> U.S. Dept. of Agriculture. Dept. of Health and Human Services. *Report of the Dietary Guidelines Advisory Committee*. Final Report. Released February 18, 2000. 129 p.

<sup>13</sup> U.S. Dept. of Health and Human Services. *Healthy People 2010*. Final Report. Washington, D.C. November, 2000.

taxes and preventing any unlawful practices in the alcohol beverage industry, TTB is charged with protecting consumers by preventing false or misleading claims on beverage labels and in advertising. To ensure alcohol beverage labels do not contain misleading information and do adhere to regulatory mandates, the Bureau examines all label applications for premarket approval. TTB enforces the *Government Health Warning Statement* requirements (see below), prohibits health or exaggerated quality claims, monitors industry advertising, and conducts investigations of suspected label fraud. *Certificates of Label Approval* are issued by the Bureau for every alcohol beverage offered for sale in interstate commerce in the United States. The agency is responsible for all malt liquor products and all wine and distilled spirits that contain more than 7% of alcohol by volume.

In contrast, the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition is responsible for regulating the safety and labeling of other beverages and most food products. FDA regulates these products under the provisions of the Food, Drug and Cosmetic Act of 1938, as amended (FDCA). The agency does not review food product labels prior to marketing, but conducts post market compliance checks on food labels. It is responsible for the regulation of a few food products that contain small amounts of alcohol (less than 7% of volume), such as fruit juices and candies. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service is responsible for the regulation of meat and poultry products. USDA's jurisdiction is authorized by the Meat Inspection Act of 1907 and the Poultry Products Inspection Act of 1957. The Department reviews all meat and poultry product labels prior to marketing. Finally, the Federal Trade Commission is responsible for the regulation of the advertising of food products.

## **Memorandum of Understanding<sup>14</sup>**

Since 1987, FDA and TTB have worked under a memorandum of understanding (MOU) that clarifies and delineates the enforcement responsibilities of each agency for alcohol beverages considered to be adulterated (unsafe) under FDCA. The MOU facilitates communication and exchange between the agencies; confirms TTB policy on the labeling of ingredients and substances in alcohol beverages that pose a public health problem; and clarifies and coordinates the responsibilities of each agency concerning the identification, testing and recall of adulterated alcohol beverages. The Bureau is charged with the administration and enforcement of the FAAA, which it implements through the issuance of permits and procedures that require the prior approval of all labels. TTB is responsible for the promulgation and enforcement of regulations with respect to labeling of distilled spirits, wine and malt beverages. When FDA determines that the presence of an ingredient in food products, including alcohol beverages, poses a recognized public health problem and must be identified on the product label, TTB is responsible for promulgating labeling regulations for alcohol beverages consistent with its health policy for these products. The agencies consult on a regular basis concerning the propriety of promulgating regulations concerning the labeling of other ingredients and substances for alcohol beverages.

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<sup>14</sup> U.S. Food and Drug Administration. Compliance Policy Guides. Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms. Guide 7155g.04. FDA-225-88-2000. November 20, 1987. 8 p.



## Alcohol Beverages: Labeling, Claims and Warning Requirements

The labeling requirements for alcohol beverages include several different elements, depending on the product.<sup>15</sup> Wine bottle labels are required to contain brand name; class, type or other designation; blends; manufacturers/distributors' name and address; net contents, and when present, FD&C yellow no. 5 coloring, saccharin warning statement, and sulfites declaration. Distilled spirits bottles are to list the following mandatory statements: responsible advertiser; class and type; alcohol content; percentage of neutral spirits and name of the commodity from which the product is distilled. Labeling requirements for malt beverages include brand name; class; name and address, net contents, and when present, FD&C yellow no. 5 coloring, declaration of sulfites, saccharin and aspartame warnings. TTB reviews all product labels and certifies their approval prior to marketing.

All alcohol beverages bottled or imported for sale in the United States are required to carry a warning label mandated by the Alcohol Beverage Labeling Act of 1988. Since its November 18, 1989 effective date, the following statements are required to appear on the labels:

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.(2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

In November 1999, the Center for Science in the Public Interest, along with a coalition of public health, consumer, safety and child-protection organizations and four Members of Congress, petitioned TTB to improve the legibility, clarity and noticeability of the congressionally mandated health warnings required on alcohol beverage labels.<sup>16</sup> In December 1999, TTB sent letters to FDA, FTC, the National Institute on Alcohol Abuse and Alcoholism, and the Surgeon General requesting review and comment on CSPI's petition. While comments were received on the petition, no final decision on how to proceed has yet been announced, despite a signal from the agency that it would be forthcoming.<sup>17</sup>

In February 1999, after several years' debate over the wine industry's request, TTB approved the use of health messages on wine labels.<sup>18</sup> The new label statements were based on the information in the Dietary Guidelines for Americans that address alcohol beverage consumption. Either of these two messages were allowed:

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<sup>15</sup> Code of Federal Regulations. Section 27. Ch 1. Parts 4.30, 5.31, 7.1.

<sup>16</sup> CSPI et al. Petition to improve the legibility, clarity and noticeability of health warnings required by the Alcoholic Beverage Labeling Act of 1988. Submitted to BATF. November 17, 1999. 6 p.

<sup>17</sup> Buckles, B.A. Director of BATF. Speech before the American Vintners Association March 20, 2000. Washington, D.C. 3 p.

<sup>18</sup> U.S. Dept. of Treasury. Office of Public Affairs. Treasury News. *Treasury Announces Actions Concerning Labeling of Alcoholic Beverages*. RR-2937. February 5, 1999.

To learn the health effects of wine consumption, send for the Federal Government's *Dietary Guidelines for Americans*; Center for Nutrition Policy and Promotion, USDA 1120 20<sup>th</sup> Street, NW, Washington, D.C. 20036 or visit its Web site - [<http://www.usda.gov/cnpp/>] or

The proud people who made this wine encourage you to consult your family doctor about the health effects of wine consumption.

Under existing law, TTB believed it could only deny such labeling statements if they were false and misleading.<sup>19</sup> The wine labeling health effect statements were approved because they met the Bureau's factual standards of not being false or misleading, and no health claim was made. In TTB's view, consumers were simply being directed to several sources of information about the health effects of alcohol consumption.

TTB based its decision in part on a survey of current wine drinkers conducted by the Substance Abuse and Mental Health Service Administration's Center for Substance Abuse Prevention (SAMHSA).<sup>20</sup> The survey findings were obtained through mall interviews and focus groups using three label messages. The results indicated that for most of those surveyed, drinking patterns would not be influenced by any label message tested. The survey also revealed that the word "moderate," when associated with drinking, had virtually no meaning to most individuals surveyed. In addition, wine drinkers indicated that the amount of alcohol which constituted "moderate" was less than they considered to be moderate.

Reaction to the TTB decision to allow the health effects statement to appear on the wine labels varied. Prior to the agency issuing its decision, Surgeon General and Assistant Secretary for Health Dr. Satcher, in a letter to TTB, expressed his concern about allowing the wine label claim.<sup>21</sup> Numerous health and consumer groups also opposed the label, with concerns that ranged from the alcohol abuse issue to questions about the strength of the scientific evidence supporting the health benefits. Members of the 1995 Dietary Guidelines advisory committee indicated that the text submitted to the agencies for that edition of the Guidelines was modified in the final publication and that they had no intention of implying endorsement of alcohol beverage consumption for health benefits.<sup>22</sup> Several bills introduced in Congress were intended to relieve the Bureau of jurisdiction over these products as a result of the proposed rule(see below). On the other side, wine manufacturers who had requested use of the claim were pleased with TTB's decision. Members of the distilled spirits segment of the industry were also considering a request to use similar label messages, since the Dietary Guidelines text is not specific in its wording to

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<sup>19</sup> *Ibid.*

<sup>20</sup> DHHS. Substance Abuse and Mental Health Services Administration Center for Substance Abuse Prevention. *The Effect of Wine Labels on Public Perception*. Main Findings. January 30, 1998. PHD752. 14 p.

<sup>21</sup> Letter to Arthur Libertucci, Asst. Dir. Alcohol and Tobacco, BATF from Dr. David Satcher, Asst. Sec. for health and Surgeon General. January 12, 1999. 3 p.

<sup>22</sup> *Uncle Sam Never Said Drink for Your Health*. Marin Institute, Summer 1996.

wine, but states that current research suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals.<sup>23</sup>

Partially as a result of the negative reaction to the announcement allowing wine labels to carry health-related messages, the Bureau announced in May 1999 that it would initiate rulemaking on this issue.<sup>24</sup> The announcement included the agency's intent to publish a proposed rule for notice and comment within several months, with completion of the final rule on alcohol beverage health statements within 2 years. In the interim, the agency indicated that wine makers would continue to be allowed to use the health statements that it already had approved, with the understanding that the rulemaking might change the type of statement allowed.

TTB proposed the regulation for the health labeling of alcohol beverages in October 1999.<sup>25</sup> The rule would prohibit the appearance on labels or in advertising of any statement that makes a substantive claim regarding health benefits associated with the consumption of alcohol beverages, unless such claims are properly qualified, balanced, sufficiently detailed, and specific. In addition, the claims would have to outline the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects. TTB also proposed to prohibit any advertisements that attribute health benefits to the consumption of alcohol beverages, unless such statements are appropriately qualified in a manner that is not likely to result in either consumer confusion or deception. The Bureau requested comments on the question of whether the negative consequences of alcohol consumption or abuse disqualify, as misleading, these products entirely from entitlement to any health-related statements. It also sought comments on whether health-related statements on alcohol beverage labels and advertising, that directs consumers to information sources, such as the U.S. Dietary Guidelines, are misleading, and whether TTB should continue to approve such statements. The agency stated that the proposed regulation was intended to ensure that labels and advertisements do not contain statements or claims that would tend to mislead consumers about the potential health consequences of alcohol consumption. The closing date for comments was February 22, 2000.

Subsequently, TTB announced that it would hold public hearings in five cities concerning health claims and other health-related statements on the labeling of alcohol beverages.<sup>26</sup> The public hearings were scheduled to be held in Washington, D.C., San Francisco, Atlanta, Chicago, and Dallas between April and September

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<sup>23</sup> Solomon, J. Distillers consider health-benefit labels. *Wall St. J.* February, 10, 1999. B11

<sup>24</sup> New wine labels to be reexamined. *San Francisco Chron.* Wire Story. May 15, 1999.

<sup>25</sup> U.S. Dept. of Treasury. Bureau of Alcohol, Tobacco and Firearms. Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages. Notice of Proposed Rulemaking. *Federal Register*. v. 64, no.205. October 25, 1999. p.54713-18.

<sup>26</sup> U.S. Dept. of Treasury. Bureau of Alcohol, Tobacco and Firearms. Health Claims Statements in the Labeling and Advertising of Alcohol Beverages. Public Hearing. *Federal Register*. v. 65, no.29. February 28, 2000. p.10434-10436.

2000. The final rule was not to be published until after these meetings were concluded.

On March 3, 2003 the Department of the Treasury published the final rule on health claims and related statements in the labeling and advertising for alcohol beverages.<sup>27</sup> The regulation requires that TTB evaluate health claims on a case-by-case basis to determine if such claims would tend to mislead consumers. It codifies the Bureau's long-standing position that any substantive health benefit claim is considered misleading, unless it is truthful and adequately substantiated by scientific/medical evidence; sufficiently details and qualified with respect to categories of individuals for whom the claim applies; adequately discloses the health risks associated with alcohol consumption and outlines the categories of individuals for whom any level of alcohol consumption may cause health risks. The rule requires that any such claim include appropriate qualifications and disclaimers about health risks associated with alcohol consumption. In addition, health-related directional statements that are not substantive health claims must nonetheless include a disclaimer to clarify that the statement does not advocate the consumption of alcohol beverages for health reasons or some other appropriate disclaimer to avoid misleading consumers. TTB will consult with FDA as needed on the use of specific health claims on labels. If FDA determines that a specific claim is a drug claim that is not in compliance with the requirements of FDCA, TTB will not approve the use of such statements on labels. The rule is scheduled to go into effect on June 2, 2003.

## **Foods: Labeling, Claims and Warning Requirements**

In the early 1990s, FDA and USDA undertook a comprehensive overhaul of food labeling, with primary focus on improving nutrition information and consistency across food labels for consumers. The Nutrition Labeling and Education Act of 1990 (NLEA) provided FDA with the mandate to implement the labeling changes, while USDA agreed to implement similar changes under its existing authority. The new labeling rules required for the first time that labels provide nutrition information and a complete ingredient listing on most foods. In addition, food products were allowed to provide nutrient content and health claims under certain circumstances. The requirements for the labeling, claims and warnings on food products are numerous.<sup>28</sup> For purposes of this report, only those provisions that are comparable to those for alcohol beverages are reviewed. The following discussion generally applies to both labeling on the food products regulated by FDA and the meat and poultry products regulated by USDA.

Food and meat product labels must provide mandatory information on the standard of identity, language requirements, net quantity of contents, name and address of manufacturer, ingredients, manufacturing code, prominence of required statements, and the universal product code. Mandatory wording is required for

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<sup>27</sup> U.S. Dept. of Treasury. Alcohol and Tobacco and Trade Bureau. Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages. Final Rule. *Federal Register*. v. 68, no.41. March 3, 2003. p.10076-10106.

<sup>28</sup> CRS Report 91-146, *Nutrition Labeling and Education Act of 1990: P.L. 101-535*, Donna V. Porter. (archived)

nutrition labeling, grades, information on special dietary use, and when present, a sulfite declaration and warning statements for aspartame, saccharin and FD&C yellow dye #5. Optional information includes dating and certain other symbols.

Provisions of NLEA allowed nutrient content and health claims for foods that were authorized in advance by the government. Nutrient content claims are label statements that provide relative quantitative statements about the presence or absence of a nutrient in the food product. Examples include low fat, reduced salt, high fiber or high calcium. A manufacturer wishing to make a new nutrient content claim must first petition the agency. FDA then must review the petition and propose a regulation for the new claim before it can become a final regulation, after notice and comment rulemaking.

Health claims are messages that describe the relationship between a nutrient (or other food substance) and a disease or health-condition. These claims are allowed if a regulation authorizing them has been issued by FDA. NLEA created a petition process requiring manufacturers to provide the publicly available scientific evidence that it believes established the basis for the diet and health relationship. The petitioner also must provide information about the claim that will be made and the proposed wording. NLEA requires the agency to conduct a review to determine whether the science supports the existence of the relationship. FDA was directed to authorize a health claim when, based on the totality of the publicly available scientific evidence from well-designed studies, there is significant scientific agreement (SSA) among qualified scientific experts that the claim is supported by the evidence. This review is subject to notice and comment rulemaking. In short, health claim statements in labeling are to be specific, affirmative statements that are accurate, based on the totality of the scientific evidence and able to convince qualified individuals that the food substance, when used in a dietary context, will have the stated impact on a disease or other health-related condition. Health claims are not allowed if a food contains certain components that are present at a level that would represent a health risk. Disqualifying levels were set for total fat, saturated fat, cholesterol, and sodium.

The Food and Drug Administration Modernization Act of 1997 (FDAMA, P.L. 97-105) provided an alternative mechanism for the authorization of health claims, in part because the interested parties recognized the time-consuming, resource-intensive nature of the NLEA-mandated scientific review process. Fast-track options were viewed as possible when the scientific work had already been done elsewhere. FDAMA directed that health and nutrient content claims could be authorized under circumstances where an authoritative statement (AS) had been issued by a scientific body with nutrition research expertise of the federal government or the National Academy of Sciences. The Act identified four criteria for statements to be considered authoritative: the statement has to be currently in effect, concern a relationship (or nutrient level), be published, and can not be a statement of an individual employee of the authoring organization. The manufacturer planning to make the claim must notify the agency that a claim will be made, based on an AS. The notification must contain the exact wording of the claim and the AS supporting it, a description of the determination that the requirements for an AS are satisfied, and a balanced representation of the scientific literature to which the claim refers. The substance that is the subject of the claim must also be safe and lawful and

present at a level in the food that is sufficiently high in an appropriate form to justify the claim. FDA then has 120 days to determine whether the claim meets the agency's criteria, allowing it to be made.

## **Alcohol Beverage Legislation**

Several bills were introduced in the 106<sup>th</sup> Congress that concerned alcohol beverages, of which three bills relate directly to TTB labeling activities. The Alcohol Beverage Labeling Act of 1999 (S. 431) would have amended the Alcohol Beverage Labeling Act of 1988 to grant authority to the Secretary of Health and Human Services for all functions that are exercised currently by the Secretary of the Treasury related to the 1988 Act. Determination of the functions and related resources to be transferred would be made by the Office of Management and Budget. The personnel currently responsible for those functions at the Department of the Treasury would be transferred to HHS. The bill was referred to the Committee on Commerce, Science and Transportation.

A related bill, the Alcohol Abuse, Prevention and Treatment Trust Fund Act of 1999 (S. 432), would have amended the Internal Revenue Code of 1986 to increase the rate of tax on wine and dedicate the resulting increased revenue to programs for the prevention and treatment of alcohol abuse. The current tax rate on wine is considerably below that of beer and distilled spirits. This bill was referred to the Committee on Finance.

A third bill, the Alcoholic Beverage Label Preservation Act of 1999 (S. 433), would have prohibited additional statements and representations related to alcohol beverages and health. The bill would have prohibited any alcohol beverage container from carrying any statement or representation relating to alcohol beverages and health, other than the current Government Warning statements required by the 1988 Act, as outlined above. It was referred to the Committee on Commerce, Science and Transportation.

Two other bills addressed the issue of alcohol shipments. H.R. 2094, the State Responsible Alcohol Access Enforcement Act, would have allowed enforcement of laws prohibiting certain alcohol shipments, and required FTC to conduct a study and determine whether additional authority is needed to regulate the sale, marketing and advertising of alcohol beverages in remote forms of commerce. H.R. 2161, the Alcohol Shipment to Minor Prohibition Act, would have prohibited the shipping of alcohol beverages to minors. Both bills were referred to the Committee on Judiciary. No final action was taken on any bills on alcohol beverages in the 106<sup>th</sup> Congress and no bills that address these issues have been introduced since.

## **Key Issues Concerning Health Claims on Alcohol Beverages**

The TTB's final regulation for the health labeling of alcohol beverages prohibits the appearance on labels of any statement that makes a substantive claim regarding health benefits associated with the consumption of alcohol beverages, unless such claims are properly qualified, balanced, sufficiently detailed, and specific, along with outlining the categories of individuals for whom any positive health effects would be

outweighed by numerous negative health effects. The final rule also prohibits any advertisements that attribute health benefits to the consumption of alcohol beverages, unless such statement is appropriately qualified in a manner that is not likely to result in either consumer confusion or deception. The agency had sought comments on whether the negative consequences of alcohol consumption or abuse disqualify, as misleading, these products entirely from entitlement to any health-related statements and whether health-related statements on alcohol beverage labels and advertising directing consumers to authoritative sources of information are misleading, warranting termination of their approval. The agency has stated its intention to ensure that labels and advertisements do not contain statements or claims that would tend to mislead consumers about the significant health consequences of alcohol consumption.

**Feasibility.** In the current health claim regulatory environment, it seems possible to interpret TTB's final rule in several ways. The regulation seems to suggest that making such claims is possible, if the manufacturer (or the Bureau) can craft statements that adequately qualify the health messages to convey the level of substantiation and/or provide an authoritative statement to support it. However, the difficulty of establishing such qualifying statements has been demonstrated by FDA's recent experience with health claims when only limited or preliminary scientific evidence on a relationship is available. The challenge arises in determining when the scientific evidence available is "enough" to make any meaningful statement, and then crafting the claim to be truthful and not misleading to consumers. The claim generally needs to be coupled with a disclaimer to provide a context that clarifies the level of evidence supporting the claim. The challenge arises in wording the claim and disclaimer so as not to mislead consumers. The only way to adequately ascertain success in consumer interpretation and understanding is to conduct consumer research on the claim and disclaimer before they appear on the product. The limited space on most packaging further complicates the extent to which adequate information can be provided for consumers' use.

Alternatively, the TTB's rule might be viewed as suggesting an outright prohibition of any health claim for alcohol. This view seems to be supported by the agency's solicitation of comments on whether negative health effects deny any entitlement to health claims, in light of the agency's recognition of (and request for comments on) the negative consequences of alcohol use. One of the bills in the 106<sup>th</sup> Congress would have prohibited these claims on alcohol beverages. However, an outright prohibition might raise first amendment constitutional questions. In 1996, the Competitive Enterprise Institute (CEI) filed suit against TTB to challenge the agency's delay in acting on CEI's petition to issue a rule allowing truthful statements concerning the health benefits of moderate drinking on alcohol beverage labeling and advertisements. The case, which had challenged the constitutionality of TTB's ban on information about the cardiovascular benefits of moderate alcohol consumption on product labels and advertisements, was settled in 1998 by the district court granting the government's motion for summary judgment on CEI's challenge to the denial of its rulemaking petition. In 1999, FDA lost a case before the United States Court of Appeals for the D.C. Circuit in *Pearson v. Shalala*, when the court held unconstitutional under the first amendment FDA rules that prohibited four separate health claims related to dietary supplements. The court decision required that FDA not only allow the claims, but also craft disclaimers to assure that consumers are not

misled by them. Efforts are currently underway at FDA to broaden the use of health claims with disclaimers to the health claims on conventional foods.

If health claims are to be allowed, one option might be to consolidate or locate them together with the required warning labels. Placing the warning statement on the side or back of containers, while the health information statement would likely appear on the front seems to have the potential for consumer confusion. A streamlined statement containing the most pertinent parts of both statements could be developed. For example, a revised consolidated statement might read:

GOVERNMENT WARNING: (1) According to the Surgeon General, pregnant women and anyone operating a car or machinery should not drink; (2) Learn about the health effects of alcohol beverages by consulting your family doctor or sending for the federal government's *Dietary Guidelines for Americans*; Center for Nutrition Policy and Promotion, USDA 1120 20<sup>th</sup> Street, NW, Washington, D.C. 20036 or visit its Web site [<http://www.usda.gov/cnpp/>].

While consolidating the messages, the regulations could continue to require the government warning statement, and allow manufacturers to include the additional statement of health effects on a voluntary basis.

Allowing the current practice of directing consumers to the Dietary Guidelines or physicians for further information on health effects for all alcohol beverage products might be seen as consistent with existing policy for food labeling regarding authoritative statements. However, food labeling regulations prohibit claims on products that contain certain ingredients that are present at harmful levels. A similar policy does not currently exist for the alcohol content of beverages. Furthermore, there is the difficulty of establishing harmful or unsafe levels of alcohol. In addition, identifying physicians as the source of additional information assumes that they are knowledgeable about both negative and potentially positive health effects of alcohol beverages and can advise their patients accordingly.

**Agency Jurisdiction.** Currently, TTB has regulatory jurisdiction over all alcohol beverages and FDA regulates other beverages and most foods. Separate agencies can establish separate standards for labeling the products in their jurisdiction so TTB policy does not necessarily have to be consistent with that of FDA. However, different labeling requirements can be potentially confusing to consumers, who might assume that labeling and other regulations are set by a single agency or consistent across government agencies. For example the nutrition information now required on food products is not available to consumers on alcohol beverages, which can add significant caloric intake to the daily diet. Transferring alcohol labeling authority to FDA, as proposed in one of the bills from the 106<sup>th</sup> Congress, would promote consistency, with the assumption that the agency would require comparable rules for all product claim messages. Alternatively, options might include leaving responsibility for the labeling and claims standards to the discretion of TTB; directing the two agencies to work together under the existing MOU to achieve comparable claims requirements; or requiring TTB to adopt the comparable rules to FDA's nutrient composition and claims rules.



Any proposal to transfer authority to FDA raises the issue of the pre-market label approval that is currently required for alcohol beverages. This requirement would be a departure from current FDA policy in that food labels are not pre-approved. Since FDA does not currently have authority to review food labels prior to marketing, continued requirements to do so for alcohol beverages would need to be addressed, since it is tied to other responsibilities that TTB would be likely to retain. Another issue would concern the possibility of using “structure-function” claims on alcohol beverages, if such a transfer in jurisdiction took place. This type of claim, which is currently allowed for foods and supplements, is a truthful, not misleading statement on how a substance affects the structure or function of the body and only requires the manufacturer to notify the agency that the claim will be made. Substantiation of the claim needs to be in the manufacturer’s possession, but the level of scientific support required for a structure-function claim is considerably less than for a health claim. Finally, FTC is responsible for food advertising and has long sought to make advertising as consistent with labeling rules as allowed under its statutory requirements.

**Further Research.** Additional research and/or consensus may be needed before the issue of health claims for alcohol beverages can be fully resolved. Since there are questions as to how well the research supports a claim on the benefits versus the risks of alcohol beverage consumption, legislation could be considered to require either additional research and/or a consensus review to determine the benefits of alcohol consumption. This type of work could generate some type of authoritative statement on the relationship. The bill language could be written to provide that claims would only be allowed if they were made in the same manner and under the same conditions as NLEA and FDAMA claims, including disqualifying levels of substances that present a health risk. Finally, the claim wording might also be required to state the limitation of the benefit, i.e., benefit is only observed when total consumption is limited to 1-2 number of drinks per day (depending on sex and age).

**Consumer Behavior.** Finally, the eternal issue arises as to the impact that warning and health benefit labels have in general on consumer behavior. Consumers are well aware of the food label and nutrition facts panel following the education effort carried out by a public-private partnership after NLEA passage and the final rules were published. Consumer use of the food label, especially the changes to improve it since 1990, have been examined by several researchers. The public-private partnership educational effort was organized to coordinate the efforts of many groups/organizations with limited resources, and its success in reaching consumers with the message has been well documented.<sup>29</sup> Consumers are aware of and report using the nutrition facts panel, ingredient information and claims in their purchases. However, less clear is the long-term impact of this knowledge on eating habits and dietary changes.

Health claim statements on food product labels may, in the end, have very little impact on consumer behavior. Advertising statements and nutrient content flags

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<sup>29</sup> Guthrie, J. B. Derby & A. Levy. *What people know and do not know about nutrition. In: America’s Eating Habits. Changes & Consequences.* U.S. Dept. of Agriculture. Ag. Info. Bull. no.750. April 1999. p. 243.

across the front of packages may have more influence on consumer purchases and indirectly on food consumption than health claims. Similarly, consumers are aware of the alcohol warning labels, but it is unclear whether they have any effect on drinking habits. The SAMHSA survey conducted on the possible addition of health benefit statements to alcohol labels suggests that the additional statements will not influence consumers' drinking habits. The literature on the impact of the alcohol beverage warning labels suggest that over time, knowledge of the label statements increased consumer awareness.<sup>30</sup> However, a recent study on alcohol warning labels conducted by the Center for Science in the Public Interest found that the statements were difficult to notice due to the size, lacked prominence, and readability of the statements, which were serious barriers to their overall effectiveness.<sup>31</sup> Nevertheless, the long term impact of this knowledge on drinking habits is unclear. Awareness and an ability to repeat the messages, whether the statements are warning labels or health messages, does not necessarily translate into behavior change, whether concerned with food or alcohol beverage products.

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<sup>30</sup> Wolfgan, L. *Charting Recent Progress: Advances in Alcohol Research. Alcohol Health & Research World.* v. 21, no.4. September 22, 1997. p. 277

<sup>31</sup> [[http://www.cspinet.org/booze/batf\\_labels2001\\_press.htm](http://www.cspinet.org/booze/batf_labels2001_press.htm)]