

false. A claim that is supported by scientific evidence might still mislead the consumer without appropriate qualification and detail. Any such claim is considered misleading unless it is properly qualified and balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive effects on health would be outweighed by numerous negative effects on health.

II. Health Consequences of Alcohol Consumption

The risks associated with alcohol consumption are well documented. In Notice No. 884, ATF summarized these risks as set forth in an article by Charles H. Hennekens, M.D. as follows:¹

The hazards of heavy alcohol consumption are clear and substantial and have far-reaching health and social consequences. Alcohol is the second leading cause of preventable deaths in the United States as well as most industrialized countries, second only to cigarette smoking. Drinking increases the risk of cancer of the liver, mouth, tongue, and esophagus and has been implicated as a cause of 3 to 5 percent of all cancer deaths. Heavy alcohol consumption is also associated with increased risks of hemorrhagic stroke and cardiomyopathy, and it predisposes to hepatic cirrhosis, the ninth most common cause of death in the United States. In pregnant women, heavy alcohol consumption is associated with fetal alcohol syndrome. Alcohol drinking is also implicated in over 40 percent of all fatal traffic crashes, which are a chief cause of premature deaths in younger people, and it is associated with suicides, industrial accidents, sex crimes, robberies, and murders. It is estimated that 14 million U.S. residents suffer from alcohol abuse and dependence, and 76 million are affected by its presence in a family member. (Citations omitted).

It is true that heavier levels of alcohol consumption cause many of these health risks. It is also true that there are millions of Americans with alcohol dependency problems who find themselves unable or unwilling to control their consumption of alcohol. Given the serious health risks associated with higher levels of alcohol consumption, and given the fact that most medical studies agree that the effects of moderate consumption differ from individual to individual, it was ATF's longstanding, and is now our, position that any claim associating health benefits with moderate alcohol consumption must be carefully evaluated to ensure that it does not mislead the consumer about the various health consequences related to the consumption of alcohol beverages.

Prior to engaging in this rulemaking, ATF recognized that there were several scientific studies establishing a link

between moderate alcohol consumption and a reduced risk of coronary artery disease ("CAD").² However, it was ATF's conclusion that there was not significant scientific evidence to support an unqualified conclusion that moderate alcohol consumption has net health benefits for all or even most individual consumers. Some studies have suggested that only older drinkers will accrue any net health benefits from moderate alcohol consumption.³ This is because younger individuals have such a low risk for coronary artery disease, and are much more likely to be at risk from alcohol consumption, even at lower levels. This difference in risk factors has been explained as follows:⁴

The net outcome of all-cause mortality associated with a certain alcohol consumption level therefore also depends on the drinker's absolute risk of dying from these various causes. Accordingly, older people—who are at high absolute risk of coronary heart disease and ischemic stroke and at low risk for injury, cirrhosis, and other alcohol-related diseases—are most likely to benefit from low levels of alcohol consumption. In contrast, for men and women under age 40, who have relatively low absolute risk of dying from strokes, heart disease, and alcohol-related diseases but a high absolute risk of dying from injury, all-cause mortality will increase even at relatively low alcohol-consumption levels. * * *. Finally, the absolute risk of death from injury or coronary heart disease is lower in young women than in young men, leading to an increase in all-cause mortality even in young women who are light drinkers (less than two drinks every 3 days) compared with abstainers. (Citations omitted).

Overall, the available scientific literature establishes that there may be serious health risks associated with heavy as well as moderate alcohol consumption, depending on the individual.⁵

III. Industry Circular 93-8

On August 2, 1993, ATF published Industry Circular 93-8. The circular generally restated ATF's longstanding position regarding misleading curative and therapeutic claims. ATF explained that claims that set forth only a partial picture, representation, or truth might be as likely to mislead the consumer as those that are actually false. Thus, a statement that attributed health benefits to the moderate consumption of alcohol beverages, even if backed up by medical evidence, might have an overall misleading effect if such statement was not properly qualified, did not give all sides of the issue, and did not outline the categories of individuals for whom any such positive effect would be outweighed by numerous negative effects on health.

ATF also explained that its policy regarding health claims on labels had been reinforced by the 1988 enactment of the Alcoholic Beverage Labeling Act (ABLA), 27 U.S.C. 213 *et seq.* The ABLA contains a declaration of policy and purpose which states that the Congress finds that "the American public should be informed about the health hazards that may result from the consumption or abuse of alcoholic beverages, and has determined that it would be beneficial to provide a clear, nonconfusing reminder of such hazards, and that there is a need for national uniformity in such reminders in order to avoid the promulgation of incorrect or misleading information and to minimize burdens on interstate commerce." 27 U.S.C. 213. As a result of this concern, the ABLA requires that any alcohol beverage container held for sale or distribution in the United States must bear the following statement on the label:

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.

It is clear that one of the purposes of the ABLA was to avoid confusing the American public about the health hazards associated with the consumption of alcohol beverages. In order to effectuate this goal, Congress prescribed specific language that must appear on the labels of alcohol beverage containers. To the extent that the overall message of any health claim is inconsistent with the message of the Government warning statement, then it may result in label information that is confusing and could mislead the consumer, and would thus be prohibited under the FAA Act.

In Industry Circular 93-8, ATF further noted that other Federal agencies, such as the Food and Drug Administration and the Federal Trade Commission, might have jurisdiction over certain aspects of advertising and labeling issues involving health claims. We will address this issue further in section IV ("Role of Other Federal Agencies with Respect to Specific Health Claims and other Health-Related Statements").

ATF also stated that the distribution of advertising materials that included the full text of the April 1992 edition of "Alcohol Alert," a publication of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), would not be in violation of current regulations. This NIAAA publication provides a comprehensive discussion of the health consequences of moderate alcohol consumption. The industry circular