

life in men than heart disease, and both are linked to alcohol use. In women, breast cancer and motor vehicle accidents each account for more potential years of life lost before age 75 than heart disease. (May 23, 2000; San Francisco, CA, pages 53–54).

Dr. Criqui also stressed the importance of evaluating the patterns of consumption among drinkers. He said that in the United States, about 80% of men and 70% of women drink alcohol, with 50% of drinkers reporting temporary problems with alcohol. (*Id.* at page 55). About 10% of men and 5% of women are alcoholics. Furthermore, Dr. Criqui stated that “half of all the alcohol consumed in the United States is consumed by the 10% of men and the 5% of women who are alcohol-dependent.” (*Id.* at page 57).

Other medical professionals stressed the health benefits associated with moderate drinking for persons who do not belong in the categories of individuals for whom alcohol consumption is contraindicated. Dr. Curtis Ellison, a Professor of Medicine, testified that “science clearly indicates that moderate drinkers have much lower risk of coronary heart disease and ischemic stroke. Because these are the number one and number three causes of death, it is not surprising that moderate drinkers will live longer in the United States.” (April 26, 2000; Washington, DC, page 109). Dr. Ellison suggested that “if I am withholding from a patient information that may reduce that individual’s risk of a heart attack by 30 or 40 percent and do not tell him about it, I am doing him a disservice.” (*Id.* at page 110).

B. Decision

The evidence presented by the medical experts, as well as the studies presented with some of the comments, indicate that there are differences of opinion as to how the relative risks and benefits of alcohol consumption should be weighed. The evidence reflects a broad consensus that heavy levels of alcohol consumption pose serious health risks. The record also reflects that there is a broad consensus that certain categories of people should not consume any alcohol. With regard to those individuals for whom alcohol consumption is not contraindicated, there was some difference among the experts as to how to weigh the relative risks and benefits of moderate consumption, with some experts stressing the protection against cardiovascular disease, and other experts stressing the increased risk of injury and certain cancers.

Because TTB is not an expert on public health issues, we (and our predecessors) have generally deferred to the findings of the Department of Health and Human Services, including NIAAA, FDA, CSAP, and the Surgeon General, on issues related to the effects on health of alcohol consumption. In the case at hand, TTB finds that the evidence in the rulemaking record supports the findings of NIAAA’s 1999 “Alcohol Alert” and the 2000 Dietary Guidelines published by USDA and HHS. The main points of these findings can be summarized as follows:

- Alcohol beverages are harmful when consumed in excess, and some people should not drink at all. Excess alcohol alters judgment and can lead to dependency and many other serious problems. Heavy levels of alcohol consumption cause social and psychological problems, cirrhosis of the liver, inflammation of the pancreas, and damage to the brain and heart.
- Taking more than one drink per day for women or two drinks per day for men can raise the risk for motor vehicle accidents, other injuries, high blood pressure, stroke, violence, suicide, and certain types of cancer. Even one drink per day can slightly raise the risk of breast cancer.
- Alcohol consumption during pregnancy increases the risk of birth defects.
- Certain individuals should not drink any alcohol; for these individuals, even moderate levels of alcohol consumption may cause health risks. Included in this category are children and adolescents; individuals of any age who cannot restrict their drinking to moderate levels; women who may become pregnant or who are pregnant; individuals who plan to drive, operate machinery, or take part in other activities that require attention, skill, or coordination; and individuals taking prescription or over-the-counter medications that can interact with alcohol.
- Moderate levels of alcohol consumption are associated with a reduced risk of coronary artery disease for certain individuals, but causation has not been conclusively established.
- To the extent that moderate consumption is linked to a lowered risk for coronary heart disease, the link appears mainly among men over 45 and women over age 55. Moderate consumption provides little, if any, health benefit for younger people.
- The effects on health of alcohol consumption vary from individual to individual, depending on the individual’s health profile and history, as well as the levels of consumption.

Risk of alcohol abuse increases when drinking starts at an early age. Some studies suggest that older people may become more sensitive to the effects of alcohol as they age.

Based on the above, it is TTB’s conclusion that the medical data still supports ATF’s longstanding (and now our) position that notwithstanding the data linking moderate alcohol consumption to a reduced risk of heart disease in some individuals, there are significant health risks associated with all levels of alcohol consumption. The medical data submitted by the commenters, as well as the testimony presented by experts at the public hearings, suggest that there is a link between moderate alcohol consumption and a reduced risk of heart disease in certain individuals; however, causation has not been conclusively established. The risk/benefit ratio varies with the individual’s own health profile and the level of consumption. For example, moderate alcohol consumption confers few, if any, benefits on people at low risk for heart disease. The evidence also establishes that there are serious risks associated with higher levels of alcohol consumption, and that even moderate consumption poses health risks for certain individuals. Finally, there are certain categories of individuals for whom any level of alcohol consumption is not recommended.

XV. Are Health Claims and Health-Related Statements in the Labeling and Advertising of Alcohol Beverages Inherently Misleading?

A. Comments in Opposition to the Use of Health Claims and/or Health-Related Statements

Approximately 120 comments opposed the use of health claims and/or health-related statements (including directional statements) in the labeling and advertising of alcohol beverages. Many of these commenters, including the American Medical Association, the American Cancer Society, and the Center for Science in the Public Interest, commented in support of a complete ban on the use of such statements in the labeling or advertising of beverage alcohol. The primary arguments made by these commenters are summarized below.

1. It Has Not Been Proven That Moderate Alcohol Consumption Lowers the Risk of Heart Disease

NCADD commented that the evidence for the alleged health benefits of alcohol consumption was “far from concrete,” noting that the 1999 NIAAA report concludes that while there is “an