

upheld as long as the disclaimers are "reasonably related to the State's interest in preventing deception" and do not constitute an undue burden on the advertiser. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651–53 (1985).

TTB recognizes that under the commercial speech doctrine, there is a preference for disclosure over suppression. See e.g., *Zauderer and Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In *Pearson*, the Court of Appeals for the D.C. Circuit required the Food and Drug Administration to consider appropriate disclaimers for health claims on dietary supplement labels. The Court noted that "the government's interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied—at least ordinarily—by inclusion of a prominent disclaimer setting forth those adverse effects." 164 F.3d at 659.

Consistent with the Supreme Court cases cited above, as well as the DC Circuit's ruling in the *Pearson* case, the final rule requires any industry member who wishes to make an explicit or implicit health claim on a label or in an advertisement to make a more complete disclosure of the adverse effects on health caused by alcohol consumption. The final rule does not impose any additional requirements on industry members who do not wish to make such claims. However, given the very serious health risks associated with alcohol consumption, TTB believes that the use of health claims without such qualifications and disclaimers would be misleading to consumers.

The final rule is completely consistent with the preference expressed by the courts for disclosure over suppression in the commercial speech arena. The Supreme Court has held that more speech, not less, is the preferred means of ensuring that consumers have sufficient information to make informed choices in the commercial arena. *In re R.M.J.*, 455 U.S. at 203. The final rule does not "ban" any type of speech regarding health claims or health-related statements in the labeling or advertising of alcohol beverages. Instead, the rule simply requires disclaimers for specific health claims and health-related directional statements.

CEI and CA suggested that there is no need for disclaimers in connection with health claims in the labeling or advertising of alcohol beverages. They point to the fact that the Government warning statement required on alcohol beverage containers already advises consumers that "Consumption of alcoholic beverages impairs your ability

to drive a car or operate machinery, and may cause health problems." CEI and CA further suggest that consumers are well aware of the health risks associated with alcohol abuse, and there is no need to remind them of such risks.

TTB does not agree with this comment. The administrative record contains overwhelming evidence of the serious health risks associated with alcohol consumption. These risks are not merely hypothetical; they are well documented. Among other things, the comments established that over 8 million American adults are alcoholics; alcohol is a known human carcinogen; and alcohol contributes to the deaths of more than 100,000 Americans each year. Furthermore, alcohol abuse has devastating effects on innocent third parties. In 1998, 15,935 people were killed in alcohol-related traffic crashes, and an estimated 850,000 were injured. Mothers Against Drunk Driving commented that the NIH estimated that the overall societal costs of alcohol abuse and alcoholism in 1995 (\$167 billion) were more than 50 percent higher than the costs to society of illegal drug use (\$110 billion). The health risks associated with alcohol consumption are not simply hypothetical; on the contrary, they present a serious public health problem in this country. Accordingly, the record supports a conclusion that a health claim that does not include information about these serious health risks would tend to mislead consumers about the health consequences of alcohol consumption.

TTB also disagrees with the suggestion by CEI and CA that health-related statements presented a necessary "balance" to the warning presented by the mandatory Government warning statement. The warning statement was intended by Congress to present a clear and nonconfusing reminder of the health hazards associated with consumption or abuse of alcohol beverages. See 27 U.S.C. 213. The use of health claims or other health-related statements without qualification or disclosure of adverse effects to "balance" the mandatory warning statement not only undermines the intent of the ABLA; it also tends to confuse consumers about the very real health risks associated with alcohol consumption.

The administrative record contains significant evidence that truthful statements about certain health benefits associated with moderate consumption of alcohol beverages for certain individuals will tend to mislead consumers unless such statements are truthful and adequately substantiated by scientific or medical evidence;

sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately disclose the health risks associated with both moderate and heavier levels of alcohol consumption; and outline the categories of individuals for whom any levels of alcohol consumption may cause health risks. Most consumers are unable to conduct or verify health research for themselves to determine whether a health claim is valid as to their own alcohol consumption, and are ill equipped to interpret the medical data, evaluate the potential benefits, or identify and weigh the other medical factors that may bear upon their individual decision to use alcohol for therapeutic reasons. See *In re R.M.J.*, 455 U.S. at 202 (the public's comparative lack of knowledge regarding the product being advertised is an important factor in determining whether speech is misleading). A requirement for disclaimers of this nature in such a situation is clearly directly related to the Government's interest in ensuring that consumers are not misled by health statements on alcohol beverage labels.

Some commenters suggested that the types of disclaimers and qualifications required by the proposed regulations would overly burden industry members who wish to make health claims about alcohol consumption, making such requirements unconstitutional. CEI and CA suggested that "summary" health claims for alcohol consumption are just as truthful as other short health claims allowed by FDA for diets low in saturated fat and cholesterol, as well as diets low in sodium. Other commenters suggested that because an alcohol beverage label is not large enough to include the volume of information necessary in order to give consumers a complete picture of the effects on health of alcohol consumption, such statements should be banned completely from alcohol beverage labels.

TTB agrees that the regulations make it difficult to present a substantive health claim (for example, one involving cardiovascular benefits associated with moderate alcohol consumption) on an alcohol beverage label, because of the level of qualification and explanation that would be necessary to set forth the risks associated with such consumption. TTB would also note that there seems to be an overwhelming lack of interest on the part of the alcohol beverage industry in using such health claims on alcohol beverage labels. The comments from major trade associations representing wineries, importers, brewers, and distillers did not indicate a concrete