

provides that any drug that is not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling, or that has not been used to a material extent or for a material time under such conditions, is a "new drug." 21 U.S.C. 321(p). A new drug may not be legally marketed unless FDA has approved a new drug application for such a drug. 21 U.S.C. 331(d) and 355(a). FDA noted that the FFDC Act requires substantial evidence of effectiveness and evidence that the drug is safe for its intended use before FDA will approve a new drug application. 21 U.S.C. 355(d). FDA suggested that this standard differed from the "not misleading" standard proposed by the ATF notice of proposed rulemaking.

FDA advised that ATF should explicitly articulate in its regulations the processes by which it would review claims intended for alcohol beverages. It stated that it was unable to determine, based on the proposed rule, whether the proposed process for a review of health-related statements would be consistent with FDA's statutory and regulatory authorities. Accordingly, FDA urged ATF to clarify the process and criteria it intends to use to substantiate the validity of any health claims or other health-related statements before finalizing the proposed rule.

The former Surgeon General, Dr. David Satcher, also testified in support of adopting standards "consistent with that relied upon by the Food and Drug Administration or for regulated health claims for foods and drugs." (April 25, 2000; Washington, DC, page 77). Accordingly, "[c]laims should be based on significant scientific agreement, and they should be qualified to identify those categories of persons for whom the claims are relevant, as well as to identify those for whom the negative consequences would outweigh any positive effect." (*Id.* at page 78). In response to a question from the panel, Dr. Satcher agreed that there were problems with consumers self-medicating without knowing all the facts, noting that "with alcohol, you also have the added effect that you are dealing with an addictive drug." (*Id.* at page 80). Senator Thurmond also commented that "[a]pplication of the FFDC Act to this issue would appear to prohibit any health-related statements on alcohol beverage labels. It is absurd that the government would prevent whole milk from making health-related claims but allow such claims by alcohol beverages." (Comment 526).

CSAP commented that "[a]lcohol abuse and alcoholism continue to be

among the most vexing public health problems facing the United States. Indeed, alcohol is the nation's number one drug problem among youth." While CSAP did not take a position on any of the issues on which comment was sought, it noted that "[o]ne of the key issues challenging our efforts is the mixed or misleading messages that consumers receive from a variety of sources. The addition of health related information on beverage alcohol labels must be carefully considered in relation to the general public's understanding of alcohol-related health risk." (Comment 430).

CSPI suggested that ATF adopt regulations similar to FDA's regulations under the NLEA, noting that USDA did so on a voluntary basis for health claims on meat and poultry. CSPI stated that under regulations similar to those of FDA, health claims would be prohibited because alcohol consumption increases the risk of other diseases, noting that "[t]o allow health claims for alcohol, America's most devastating drug, while health claims for foods such as whole milk are prohibited, would be indefensible and would make a mockery of the federal government's health-claim regime."

CSPI also noted that if an alcohol beverage label or advertisement claims that alcohol may reduce the risk of disease, the beverage may be regulated as a drug by FDA. CSPI argued that, "aside from its regulatory classification, alcohol is a drug. Depending on a variety of factors such as dose and schedule of use, individual metabolism, personality factors, and situation, alcohol is variously a stimulant and depressant, euphoric and soporific, irritant and anxiety reducer. Alcohol, like other intoxicants, can produce such dependency phenomena as persistent search behavior, withdrawal, relapse, and loss of control."

B. Decision

After giving careful consideration to these comments, and consulting with FDA, TTB does not agree that its health claim regulations should be identical to those of FDA. FDA regulations were promulgated pursuant to a very specific grant of authority by Congress under the NLEA. Because of the differences in statutory authority, as well as the differences in the products regulated under these two statutes, TTB's regulatory scheme for health claim labeling will differ from FDA's regulatory scheme.

However, TTB agrees with the FDA comment in several respects. Most importantly, we agree that it is important to ensure that alcohol

beverage producers do not violate the new drug provisions of the FFDC Act when seeking to use specific health claims on alcohol beverage labels. It would be where the use of that claim would render the product subject to FDA's jurisdiction over drugs. Furthermore, FDA's authority over new drugs has significant public health and safety consequences. TTB does not wish to create any confusion on the part of industry members regarding their obligations to comply with FDA's requirements over drug claims.

In the past, ATF merely advised industry members that they should be aware of the fact that the use of a health claim on an alcohol beverage label may subject the product to FDA's jurisdiction. However, after reviewing the comments on this issue, we met with FDA to discuss a process whereby TTB and FDA could consult on the use of specific health claims on alcohol beverage labels. In this way, FDA would have an opportunity to object to the use of a specific health claim, based on its jurisdiction over drugs, prior to any TTB action.

Accordingly, the final rule now provides that TTB will consult with FDA, as needed, on the use of specific health claims on labels. If FDA determines that a specific health claim is a drug claim that is not in compliance with the requirements of the FFDC Act, TTB will not approve the use of such statement on a label. There is no similar provision in the advertising regulations, since advertisers are not required to obtain prior approval from TTB. We will of course consult with FDA, as appropriate, if the question arises as to whether an advertisement is in violation of the FFDC Act.

XIX. Is the Final Rule Consistent With the First Amendment?

A. Issue

As previously noted, many commenters suggested that the proposed rule did not comply with the protection accorded truthful and non-misleading commercial speech under the First Amendment. CEI and CA argued that ATF is precluded from placing any restrictions on the dissemination of truthful information about health benefits in the labeling and advertising of alcohol beverages. Beer Institute, DISCUS, and NABI suggested that the proposed advertising regulations would restrict protected commercial speech. Mr. Rex Davis, representing the President's Forum of the Beverage Alcohol Industry, testified that he believes the proposed rule violates the First Amendment because it would