GAO

Report to the Chairman, Committee on Governmental Affairs, U.S. Senate

June 1989

ALCOHOL WARNING LABELS

Current Rules May Allow Health Warnings to Go Unnoticed

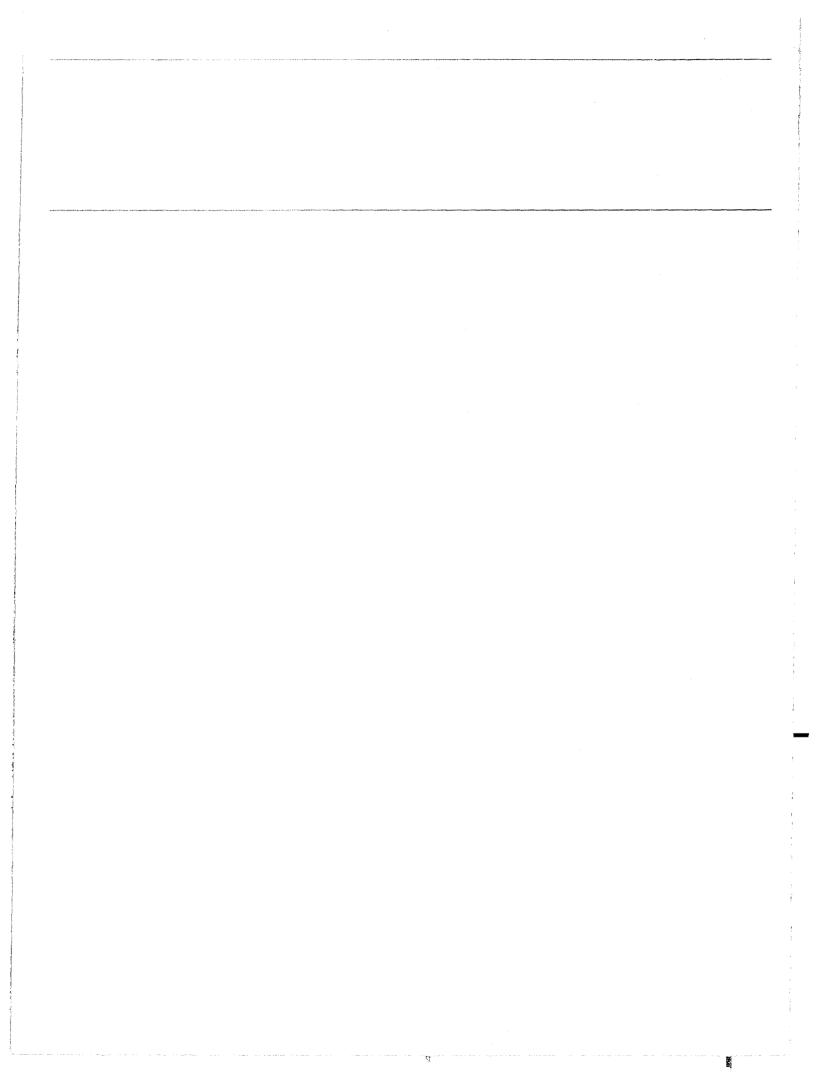




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United States General Accounting Office Washington, D.C. 20548

Human Resources Division

B-235788

June 14, 1989

The Honorable John Glenn Chairman, Committee on Governmental Affairs United States Senate

Dear Mr. Chairman:

This report responds to your request that we review the Bureau of Alcohol, Tobacco and Firearms' (BATF) implementation of the Alcoholic Beverage Labeling Act of 1988 (title VIII of P.L. 100-690). Enacted in November 1988, the act amended the Federal Alcohol Administration Act by requiring that alcoholic beverage containers carry warning labels.¹

You raised concern that BATF's temporary rules for implementing the act would allow the industry to sidestep the Congress' intent to inform the public about the health hazards that may result from alcohol abuse or consumption by applying labels that are small and difficult to read. In response to these issues, we reviewed BATF's development of the temporary rules, the public's response to these rules, and BATF's plans for monitoring industry compliance.

Background

Concern about alcohol abuse has been increasing. According to the Department of Health and Human Services (HHS), the economic costs for alcoholism and alcohol related problems in 1983 were estimated to total \$117 billion, with health care costs accounting for \$15 billion. Alcohol abuse in the United States accounts for a considerable number of deaths—100,000 in 1980. Alcohol use creates problems for an estimated 18 million persons 18 years old or older. These problems include alcohol dependence symptoms, such as loss of control over drinking, or negative personal consequences, such as problems with health, work, or marital and family relationships.²

¹Shortly after Prohibition was repealed, the Congress passed the Federal Alcohol Administration Act, which was signed into law August 29, 1935. Since enactment, the act has been administered by the Department of the Treasury. In 1972, Treasury's newly created Bureau of Alcohol, Tobacco and Firearms became responsible for administering the act.

²HHS, Sixth Special Report to the U.S. Congress on Alcohol and Health from the Secretary of Health and Human Services, National Institute on Alcohol Abuse and Alcoholism, Rockville, MD, January 1987, pp. xvi, 6, and 21.

Alcohol is associated with a wide variety of diseases and disorders. In 1983, cirrhosis of the liver, an alcohol related disease, was the ninth leading cause of death in the United States. Other alcohol related diseases include those of the nervous, gastrointestinal and respiratory systems. Nearly one-half of all accidental deaths, suicides, and homicides are alcohol related. Nearly one-half of convicted prison inmates were under the influence of alcohol when they committed the crime.³

Also of great concern are the health effects of maternal drinking on the developing fetus. Fetal alcohol syndrome includes neurological, behavioral, skeletal, and developmental disorders, including mental retardation. While severe developmental and behavioral symptoms occur in children born to chronic alcoholics and heavy drinkers, lower levels of drinking may have some measurable effect on the fetus.⁴ Fetal Alcohol Syndrome afflicts fully 5,000 babies every year and another 50,000 suffer milder forms of alcohol related birth defects.⁵

The alcoholic beverage industry currently spends considerable funds on advertising—more than \$1.2 billion in 1984.6 Despite health concerns associated with alcohol consumption, there is no legislative requirement to place health warning statements on alcoholic beverage advertising. For two decades, the Congress and federal agencies have considered warning labels on alcoholic beverage containers as a method of informing the public of the health hazards of alcohol consumption.7 Advocates of warning labels consider them an important part of an educational effort to inform the public of health risks associated with alcohol consumption. Others believe that warning labels will not alter the behavior of persons who abuse alcohol and, therefore, impose a cost and burden that is unjustified.

In June 1987, HHS transmitted to the Congress a review of the research literature on the effects of health warning labels that was done under

³HHS, pp. xvi, and 5.

⁴HHS, p. 5.

⁵Statement of Kenneth L. Jones, M.D., American Academy of Pediatrics, before the Subcommittee on the Consumer, Senate Committee on Commerce, Science and Transportation, August 10, 1988.

⁶Statement of Michael F. Jacobson, Executive Director, Center for Science in the Public Interest, before the Subcommittee on Telecommunications, Consumer Protection, and Finance of the Committee on Energy and Commerce, House of Representatives, May 21, 1985.

 $^{^7}$ A review of the legislative and executive agency efforts, from 1977 through 1986, to implement warning labels is presented in appendix I.

contract for the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The findings of that review were that health warning labels can have an impact upon consumer behavior, particularly in combination with other educational efforts, provided the labels are correctly designed. However, the study did not address the specific wording, size, or location of a warning label.⁸

A BATF study, requested by a member of the Senate, was completed in 1988. This study reported that 80 percent of the persons surveyed wanted warning labels on alcoholic beverages and that the public believes warning labels could benefit all consumers of alcohol, especially youth and pregnant women.⁹ 10

In February 1988, Senator Strom Thurmond introduced a bill, S.2047, to require a health warning on the labels of all alcoholic beverage containers. In April 1988, Representative John Conyers, Jr. introduced a companion bill, H.R. 4441. The resulting legislation was enacted as the Alcoholic Beverage Labeling Act of 1988, which required a health warning statement on all alcoholic beverage containers by November 1989. Also, the act required the Secretary of the Treasury to determine the location for and size of the warning statement within 90 days after enactment.

On February 16, 1989, BATF issued temporary rules that also served as the notice for proposed rulemaking, and interested persons were invited to comment on those rules. Alcoholic beverage producers were required to use the temporary rules in designing labels containing the health warning statement until final regulations are issued.

Objectives and Methodology

Due to concerns surrounding BATF's implementation of the health warning label for alcoholic beverages, the Chairman of the Senate Governmental Affairs Committee requested that we

review BATF's development of the temporary rules.

⁸HHS, Review of the Research Literature on the Effects of Health Warning Labels, A Report to the United States Congress, Washington, DC, June 1987.

⁹BATF, Final Report of Findings of Research Study of the Public Opinion Concerning Warning Labels on Containers of Alcoholic Beverages, Washington, DC, December 1988.

¹⁰Since the effects of alcohol-specific health warning labels have not yet been investigated, NIAAA recently issued a request for applications to study the impact of warning labels on the knowledge, attitudes, behavior, and alcohol related morbidity and mortality of relevant American populations.

- determine if visibility of the warning label might be impaired yet still be in compliance with the rules,
- · analyze public responses to the temporary rules, and
- review BATF's plans for monitoring industry compliance with the rules.

During our review, we interviewed officials of BATF, NIAAA, the Surgeon General's office, and non-profit consumer organizations, such as the Center for Science in the Public Interest and the National Council on Alcoholism. We also reviewed pertinent legislation and regulations, as well as hhs and BATF studies on alcohol warning labels. At BATF we analyzed a statistically valid sample of comments relative to the proposed rules. The sample included comments from the alcoholic beverage industry.

As agreed with your office, we did not obtain formal agency comments, however, we discussed our findings with BATF officials and incorporated their comments where appropriate. Our work was performed during April and May 1989, in accordance with generally accepted government auditing standards.

BATF Development of Temporary Rules

The Alcoholic Beverage Labeling Act of 1988 requires a health warning label on all containers of alcoholic beverages bottled on or after November 18, 1989, which is 1 year after enactment of the legislation. As prescribed by the law, the label states

"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."

The law also requires the Secretary of the Treasury to consult and coordinate the "health awareness efforts" of the labeling requirements with the Surgeon General of the United States. In a January 31, 1989, letter to the Secretary, the Surgeon General expressed his personal interest and support for the Secretary's efforts to implement alcohol warning labels. The Surgeon General transmitted the 1987 HHS report on the effects of health warning labels with the letter to assist Treasury in developing its regulations.

The law requires the label to be located in a conspicuous and prominent place on the container and appear on a contrasting background. The law states, however, that the Secretary of the Treasury shall determine the placement and size of the warning label. The report of the Senate Committee on Commerce, Science, and Transportation on S.2047 stated that the Committee anticipated that Treasury may consider current labeling regulations in formulating its rules.

In developing its temporary rules to implement the Alcoholic Beverage Labeling Act of 1988, BATF officials stated that the agency considered the Committee's report on S.2047. The temporary rules specify that

- the warning shall be stated on the brand label or separate front label, or on a back or side label, separate and apart from all other information;
- the label shall be so designed that the statement is readily legible under ordinary conditions and the statement will be on a contrasting background;
- the statement shall be in printing, type, or script and (1) for containers
 holding more than 237 milliliters (8 fluid ounces), the size of the letters
 shall be no smaller than 2 millimeters and (2) for containers holding 237
 milliliters or less, the size of the letters shall be no smaller than 1 millimeter; and
- the labels shall be firmly affixed to the container so they cannot be removed without thorough application of water or other solvent.

The rules do not require the first two words of the statement "GOVERN-MENT WARNING" be capitalized and in bold print as the words appear in the Alcoholic Beverage Labeling Act.

According to the temporary rules' preamble, in determining the requirements for disclosure of the health warning statement, BATF relied upon current regulations related to the labeling of wine, distilled spirits, and malt beverages. In particular, BATF considered existing labeling requirements for mandatory disclosure of the artificial sweetener saccharin to be appropriate.

The disclosure of saccharin is required under the Federal Alcohol Administration Act which was amended to include the provisions of the Saccharin Study and Labeling Act. Implementing regulations require that a product containing saccharin must bear on its label a health warning statement disclosing the presence of that ingredient. The placement, lettering size and type, and legibility requirements for saccharin labeling are similar to the temporary rules for the alcohol health warning statement. In terms of placement, however, the health warning regulations permit placement on a side label, whereas the saccharin label

requirements do not. However, according to BATF officials, they allow saccharin health warnings to appear on side labels.

Potential for Impairment of Label's Visibility

After the temporary regulations were issued, BATF has approved some labels containing the health warning statement submitted by alcoholic beverage producers. Approval of these labels was based on meeting the criteria of the temporary rules.

BATF provided us copies of 98 labels that it had approved as of early May 1989. In our review of these labels, we noted that the warning statement in 38 percent of the labels was less noticeable because the words "GOVERNMENT WARNING" were not emphasized in bold type. In 40 percent of these cases the statement was placed on the side of the container perpendicular to the product name or logo. In addition, the amount of space devoted to the health warning statement in some cases was limited. Although the letter size in these cases met requirements, letters were closely spaced making the statement both difficult to notice and read. The BATF temporary rules require that statements be "readily legible under ordinary conditions."

We could not determine from the BATF records we reviewed the number of alcoholic beverages with health warning labels that are currently on the market. However, we identified two products from the market with labels containing the warning statement. Both statements were located on the side of the container perpendicular to the product name. On one container the "GOVERNMENT WARNING" was emphasized in bold type making the statement more noticeable and the statement's lettering covered 19 characters per inch. In contrast, the warning statement on the second container was not distinguishable from other information on the container. The words "GOVERNMENT WARNING" were not emphasized in bold type and the lettering was more condensed (about 28 characters per inch). By comparison, the health warning statement on page 4 of this report contains about 18 characters per inch.

Using two approved labels, figures 1 and 2 illustrate some ways the warning statement is being displayed on alcoholic beverage containers. As shown in figure 1, the warning statement can be placed on the side of the label rather than directly on the front and still be in compliance with the temporary rules. Figure 2 is an example of the warning statement on a separate label. These figures demonstrate that the placement of the statement, as well as the space devoted to the statement, will directly

affect the visibility of the warnings. In both figures, the warning statement is printed with about 28 characters per inch.

Comments on BATF Proposed Rules

As stated in the published rules, the temporary health warning statement regulations also serve as the text of the proposed rulemaking for final regulations. The issuance of the proposed rulemaking allows interested persons to comment and, therefore, have input into an agency's final regulations.

According to a BATF official, as of April 24, 1989, BATF had received 12,484 comments on the proposed rules. BATF officials noted that the number of comments on the health warning statement was unusually high compared to other regulations. Those comments were overwhelmingly in favor of the rules as written. Based on our analysis of a random sample of 400 comments, 94 percent, or about 11,700, of the comments favored the proposed rules, whereas about 700 disagreed with them. BATF officials stated that they would review all comments before finalizing the proposed rules.

Agreement With the Proposed Rules

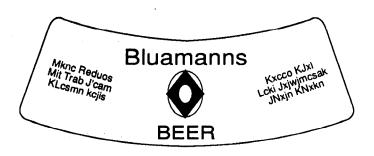
Comments in favor of the proposed rules were received, in large part, from the general public. The alcoholic beverage industry also submitted comments favoring the rules. For example, the Beer Institute, a national trade association for American brewers whose members produce about 90 percent of the beer made in the United States, agreed with BATF's proposed placement of the warning label and the type size requirements. Others agreeing with the proposed rules include

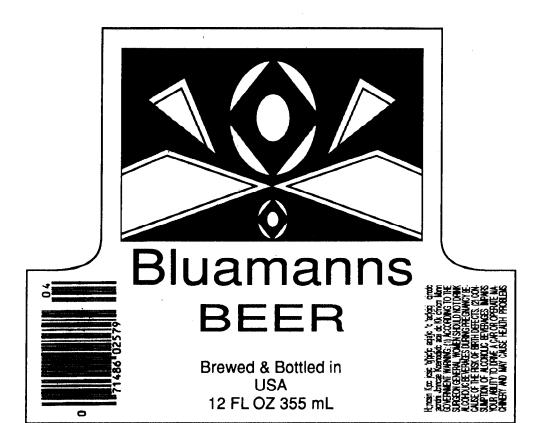
- The Stroh Brewery Company;
- · Grgich Hills Cellar, a small winery;
- Sonoma-Cutrer Vineyards, Inc.; and
- · Sterling Vineyards.

Based on our review of the random sample of comments favoring the proposed rules we noted that 31 percent, or about 3,900, were identical to one of three letters (see appendix II for examples of these letters) and

¹¹Because our estimate is based on a sample it has a sampling error associated with it. The sampling error at the 95 percent confidence level is 3 percentage points. That is, there is only a 5 percent chance that the actual percentage is outside the bounds defined by our estimate plus or minus the sampling error.

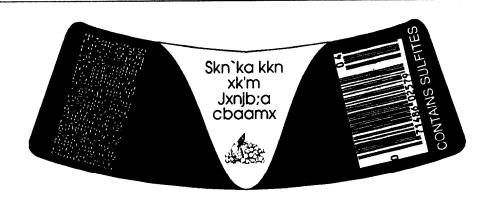
Figure 1





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Figure 2





the comments generally did not specify why the rules were acceptable. ¹² However, many supported the rules by stating that BATF followed the congressional intent of the law.

Disagreement With the Proposed Rules

Those disagreeing with BATF's proposed rules were concerned with the potential for the industry to make the labels less obvious on the container and, therefore, diminish the effectiveness of the warning. Generally, those disapproving of the proposed rules voiced concerns about the placement, size, and typeface used for the warning statement. Also of concern was that the statement was not being set off from other information by a box.

Several organizations commented negatively on the proposed regulations. The Center for Science in the Public Interest, a non-profit citizen organization, and the National Council on Alcoholism, a non-profit organization combating alcoholism, other drug addictions, and related problems, voiced concerns that the proposed rules allow the alcoholic beverage industry to circumvent the spirit of the law at the expense of the public's health.

Other advocates of educating the public about the health hazards of alcohol consumption also disapproved of the proposed rules. These include

- Mothers Against Drunk Driving (MADD),
- · the American Public Health Association,
- · the American Academy of Pediatrics, and
- · the American College of Obstetricians and Gynecologists.

Congressional Response to the Proposed Rules

Three of the 20 members of the Senate Committee on Commerce, Science, and Transportation (which reported on S.2047) submitted formal comments favoring the proposed rules, stating that BATF considered the intent of the Congress in their implementation.

The sponsors of the legislation were not members of the committee and submitted comments to BATF raising concerns about BATF's proposed rules for implementing the legislation. In a February 28, 1989, letter to BATF, the sponsors stated that the rules as proposed violate the intent of the Congress, which was to ensure that such warnings be located in a

 $^{^{12}}$ Sampling error is plus or minus 4 percentage points.

conspicuous and prominent place on alcoholic beverage containers. They stated that the proposed rules have an adverse impact on public and private efforts to educate Americans about alcohol related health and safety risks.

In response, the Director of BATF stated that based on the Senate Committee report on the alcoholic beverage labeling bill, the proposed rules follow BATF's current labeling requirements. He also stated that the rules are subject to change until final regulations are issued.

Similar to others disapproving of BATF's proposed rules, the sponsors had four concerns with the proposed rules. Their first objection was that only two categories of alcoholic beverage containers were considered, believing that the type size of 2 millimeters would be completely ineffective on containers of 30 ounces or more. Another concern was allowing the warnings to appear anywhere on the container. They believe the warning message would be most effective on the front label of the container and oriented in the same direction as the product's name or logo. They also suggested that the Secretary of the Treasury select one easily readable typeface so there will be uniformity in the appearance of the label from one container to another. Additionally, they believe that the warning should be highlighted with an outlining box, have a white background, and be in a larger boldface than that proposed.

Monitoring Compliance With Labeling Requirements

BATF must certify that all alcoholic beverage labels meet BATF labeling requirements. However, BATF does not require the producer to resubmit a previously approved label for recertification unless the addition of the health warning statement removes or changes the placement of already approved information. As of early May 1989, BATF had received and approved 98 requests for label certification after the producer added the health warning statement to its previously approved label. A BATF official stated that, although not required, most major alcoholic beverage producers have asked BATF to comment on the appropriateness of their labels containing the health warning statement.

According to a BATF official, BATF's Product Compliance Branch reviews between 60,000 and 70,000 labels annually for certification. This official said that some labels submitted either for certification or informally for comment were rejected because BATF determined that the warning statement did not meet the criteria established by the temporary rules. The official stated that with the volume of label certification requests BATF

receives it does not keep records of the reasons labels have been rejected.

To assess compliance with the health warning statement requirement, BATF officials indicated that they will use BATF's market-sampling program to monitor compliance with mandatory labeling requirements. This program involves a review of products (based on a sample drawn in a specific market) to check for compliance with BATF requirements.

Conclusions

Because of the medical, social, and economic problems caused by alcohol abuse, the Congress, federal officials, and health professionals see a need to educate the public about the wide-ranging health consequences associated with alcohol consumption. They believe health warning labels can be a significant part of these educational efforts.

The Alcoholic Beverage Labeling Act of 1988 requires a warning label to be located in a conspicuous and prominent place on alcoholic beverage containers. Concerns have been raised by members of the Congress, health professional organizations, and consumer groups, however, as to the potential effectiveness of the warning statement as specified by BATF's temporary rules regarding its size, placement, and typeface.

BATF's temporary rules provide alcoholic beverage producers wide latitude on how the warning statement is displayed. As a result, based on our review of 98 labels approved by BATF as of May 1989, the warning statement on some labels was not readily noticeable or easy to read. We believe BATF could do more to assure that the warning statement is readily legible and conspicuously and prominently placed. These efforts can be aided by providing detailed guidance regarding the display of the statement and ensuring that the words "GOVERNMENT WARNING" be displayed in the same bold type as those words appear in the Alcoholic Beverage Labeling Act of 1988. The readability of the warning statement could also be enhanced by setting a specific standard for the number of letters that can be used in a designated amount of space; for example, the number of letters per inch.

Recommendation to the Secretary of the Treasury

To help assure that the warning statement is legible, conspicuous, and prominent, the Secretary of the Treasury should direct BATF to specify in its final regulations (1) that the words "GOVERNMENT WARNING" be capitalized and in bold type, and (2) the minimum space and lettering requirements for the warning statement. Moreover, the final regulations

should provide detailed criteria to ensure that the statement is prominently displayed to better inform consumers of the warning.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 20 days from its issue date. At that time, copies will be sent to the cognizant congressional committees and subcommittees; the Secretary of the Treasury; the Secretary of Health and Human Services; and the Director, Office of Management and Budget, and we will make copies available to others upon request. Major contributors to this report are listed in appendix III.

Sincerely yours,

Janet L. Shikles

Director of National and Public Health Issues

Janet J. Shikles

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Legislative and Executive Agency Efforts to Implement Alcohol Health Warning Statement (1977-86)

In 1977, the Commissioner of the Food and Drug Administration urged the Bureau of Alcohol, Tobacco and Firearms (BATF) to require a warning label regarding the risks of alcohol use during pregnancy. In January 1978, BATF issued an advance notice of proposed rulemaking requiring such a label, and subsequently postponed a decision on whether to order the label pending further study and alcoholic beverage industry education campaigns.

In 1979, legislation required the Secretaries of the Departments of Health, Education and Welfare (now the Department of Health and Human Services) and the Treasury to report to the Congress on (1) the extent and nature of birth defects and other health hazards associated with alcohol consumption and (2) what actions should be taken by the federal government with respect to informing the general public about these health hazards.

That report dated November 1980, recommended actions to be taken by the federal government, the alcoholic beverage industry, and private organizations to inform the public about health hazards associated with alcohol consumption. HHS and Treasury agreed that the problems of alcoholism and other alcohol related health hazards are an extremely significant public health problem. However, both departments concluded that it would be premature to recommend health warning labels. Since no scientific studies addressed the effectiveness of alcohol-specific warning labels, they concluded it was unclear that the risks associated with alcohol could be effectively communicated through labeling.

Unsuccessful attempts to legislate alcohol warning labels occurred in 1981, 1983, and 1985 with bills introduced in the Congress. In May 1986, a bill was adopted by the Senate Committee on Health and Human Resources to amend the Public Health Service Act to require that beer, wine, and distilled spirits have one of five specified rotating health warning labels. Instead of supporting the bill, hhs concluded that the Public Health Service (Phs) should study the alcohol warning label issue. In response, the National Institute on Alcohol Abuse and Alcoholism contracted for a review of research literature on the effects of health warning labels on products such as tobacco, food, and drugs, that pose a health risk.

In October 1986, soon after NIAAA initiated its contract review in September 1986, Public Law 99-570 was signed into law. The law expressed the sense of the Senate that PHS should (1) review available knowledge

Appendix I Legislative and Executive Agency Efforts to Implement Alcohol Health Warning Statement (1977-86)

and conduct studies on the potential educational impact of alcohol warning labels, (2) report to the Congress concerning the impact and potential benefits of health warning labels, and (3) make recommendations for specific warning label language.

Examples of the Three Similar Letters Comprising 31 Percent of Comments on BATF's Temporary Regulations

Example 1

"Dear Sir:

"As a consumer, I wish to advise you that I am in favor of the regulations as published by your agency which implement the Alcoholic Beverage Labeling Act of 1988.

Sincerely yours,"

Example 2

"Dear Sir:

"I was glad to see that BATF came up with temporary regulations to implement the Alcoholic Beverage Labeling Act of 1988.

"In my opinion, your agency should implement the regulations as they are now. They accomplish what Congress intended when it wrote the law—that warning labels be on bottles and cans of beer, wine and liquor.

"Again, let's keep the BATF regulations on warning labels the way they are.

Sincerely,"

Example 3

"Dear Sir:

"As a consumer, I am pleased to see that the BATF has proposed temporary regulations regarding the implementation of the Alcoholic Beverage Labeling Act of 1988.

"I am in favor of these regulations as your agency has proposed them. They adhere to what the Congress intended when it wrote the law—that warning labels be on bottles and cans of beer, wine and liquor.

"Again, I am in favor of the BATF regulations on warning labels as published.

Sincerely yours,"

Major Contributors to This Report

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