ORAL ARGUMENT SCHEDULED FOR MAY 9, 2002

In The

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 01-5241

COMPETITIVE ENTERPRISE INSTITUTE and CONSUMER ALERT,
Appellants,

v.

PAUL H. O'NEILL and BRADLEY A. BUCKLES,
Appellees.

Appeal from the United States District Court for the District of Columbia

---

CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Pursuant to Circuit Rules 26.1 and 28(a)(1) of this Court, the undersigned counsel for Appellants state as follows:

A) Parties and amici: Appellants Competitive Enterprise Institute (CEI) and Consumer Alert (CA), and Appellees Paul H. O'Neill (and his predecessors) in his capacity as Secretary of the Treasury and Bradley A. Buckles (and his predecessors) in his capacity as Director of the Bureau of Alcohol, Tobacco and Firearms (ATF) are the only parties who have appeared before the district court. There are no other parties, intervenors or amici.

CEI and CA are both incorporated in the District of Columbia as nonprofit organizations. CEI is engaged in analysis and education on regulatory issues of public interest. It has no formal parents, subsidiaries or affiliates, but it does conduct a separately-named program entitled the Center For Private Conservation. CA is a membership organization involved in regulatory issues that affect consumer choice. It has no formal parents, subsidiaries or affiliates, but is informally affiliated with two ad hoc organizations, the National Consumer Coalition and International Consumers for a Civil Society. No publicly-held company has a 10 percent or more interest in either CEI or CA.

B) Rulings Under Review: The ruling at issue is the June 18, 2001 Memorandum and Order, issued by Judge Thomas P. Jackson of the United States District Court for the District of Columbia. JA__. There is no official citation to this Memorandum and Order.

C) Related Cases: There are no related cases in this or any other court.

DATED: January 2, 2002

SAM KAZMAN
BEN LIEBERMAN
Competitive Enterprise Institute
1001 Connecticut Ave. N.W., Suite 1250
Washington, DC 20036
Telephone: (202) 331-1010

Counsel for Appellants

TABLE OF CONTENTS

TABLE OF AUTHORITIES CITED

CASES

* Authorities upon which we chiefly rely are marked with asterisks

STATUTES AND REGULATIONS

MISCELLANEOUS

GLOSSARY

ATF: Bureau of Alcohol, Tobacco, and Firearms

AR: Administrative Record

CA: Consumer Alert

CEI: Competitive Enterprise Institute

CHD: Coronary Heart Disease

CSAP: Department of Health and Human Services, Center for Substance Abuse Prevention

FAAA: Federal Alcohol Administration Act

FDA: Food and Drug Administration

JA: Joint Appendix

NIAAA: National Institute on Alcohol Abuse and Alcoholism

NPR: Notice of Proposed Rulemaking

ORAL ARGUMENT SCHEDULED FOR MAY 9, 2002

In The

IN THE UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 01-5241

COMPETITIVE ENTERPRISE INSTITUTE and CONSUMER ALERT,
Appellants,

v.

PAUL H. O'NEILL and BRADLEY A. BUCKLES,
Appellees.

Appeal from the United States District Court for the District of Columbia

---

BRIEF FOR APPELLANTS COMPETITIVE ENTERPRISE INSTITUTE AND CONSUMER ALERT

INTRODUCTION

At issue in this case is the validity of a federal agency's ban on any mention of the health benefits of moderate alcohol consumption in alcohol beverage labels or advertisements. These benefits are supported by such a wide body of medical research that they are even mentioned in the federal government's *Dietary Guidelines for Americans.* Nonetheless, for over nine years the federal Bureau of Alcohol, Tobacco, and Firearms (ATF) has effectively banned any reference to these benefits in beverage labels and ads. ATF has enforced its policy despite the fact that it has no empirical evidence that such references would be misleading.

In June 2001, more than two years after cross-motions for summary judgment had been fully briefed, District Court Judge Thomas P. Jackson ruled that the case was unripe because ATF had commenced a new rulemaking on this issue. As is shown below, that ruling is incorrect, and this Court should proceed to examine the legality of ATF's policy under both the First Amendment and the statutes governing ATF.

JURISDICTION

The jurisdiction of the District Court was based on 28 U.S.C. § 1331 (federal question jurisdiction), and 28 U.S.C. §§ 2201-2202 (Declaratory Judgment Act). ATF, a bureau of the United States Treasury, has jurisdiction over alcoholic beverage labeling and advertising content under the Federal Alcohol Administration Act (FAAA), 27 U.S.C. §§ 201 *et al*. This Court has jurisdiction under 28 U.S.C. § 1291. This appeal was filed on July 5, 2001, within 30 days of the June 18, 2001 Memorandum and Order filed by the District Court. That ruling was a final order that disposed of all of the Appellants' claims.

STATEMENT OF ISSUES

1. Whether the present policy of ATF, which bars any mention of the health benefits of moderate alcohol consumption on alcoholic beverage labels and ads, is ripe for judicial review, given the evidence that this policy has blocked, and continues to block, numerous specific attempts by industry members to disseminate such information.

2. Whether this ATF policy violates the First Amendment, given that it rests on no empirical evidence of misleading effect, and given that the agency failed to consider less drastic approaches to regulating such information.

3. Whether this ATF policy violates the FAAA, the agency regulations promulgated thereunder, and the Administrative Procedure Act.

STATEMENT OF THE CASE

A. Procedural Background

Under the FAAA, 27 U.S.C. §§ U.S.C. 201, *et seq*., regulatory authority over alcoholic beverage labeling and advertising rests with ATF. (Addendum, A-1 to A-7). ATF regulations allow "curative and therapeutic claims" on alcoholic beverage labels unless they are false or misleading. 27 C.F.R. §§ 4.39(h), 5.42(b)(8), 7.29(e) (Addendum, A-8 to A-10). Labels must be approved in advance by ATF, with substantial penalties for non-compliance. 27 U.S.C. §§ 205(e) and 207; 27 C.F.R. §§ 4.50, 5.55, 7.41 (Addendum, A-2 to A-5, A-11 to A-13). Alcoholic beverage advertisements are not required to have ATF pre-approval, but they are subject to agency oversight. 27 U.S.C. § 205(f); 27 C.F.R. §§4.64(i), 5.65(d) 7.54(e) (Addendum, A-3 to A-4, A-14 to A-16). However, ATF has advised industry members wishing to make moderate consumption health claims in their ads to utilize the agency's "voluntary advertisement preclearance service" in order to avoid problems. Administrative Record (AR) 2.

ATF first detailed its policy on such health claims in an August 1993 Industry Circular entitled *Health Claims In The Labeling and Advertising Of Alcoholic Beverages.* AR 101-04. In this Circular, ATF acknowledged that it "has received many inquiries regarding the inclusion on wine labels and in wine advertising of statements which make therapeutic or curative claims or which otherwise attribute positive effects to the consumption of wine." AR 101. The agency conceded that there was a growing body of scientific research linking moderate drinking with lower risk of death from

coronary artery disease, and announced its "intention to engage in rulemaking on this subject, so as to develop more concrete guidelines with respect to health claims in the labeling and advertising of alcoholic beverages." AR 101. In the interim, ATF stated that "[p]ending the initiation of rulemaking proceedings, ATF will continue to evaluate health claims made in the labeling and advertising of alcoholic beverages on a case-by-case basis." AR 103. However, the Industry Circular proceeded to discourage such case-by-case attempts at obtaining approval, declaring that such statements are "considered to be misleading unless they are properly qualified, present all sides of the issue, and outline the categories of individuals for whom any positive effects would be outweighed by numerous negative health effects." AR 104. The agency noted that its requirements probably made such claims impossible; in its words, "ATF considers it extremely unlikely that such a balanced claim would fit on a normal alcoholic beverage label." AR 104.

As a result of this policy, ATF has not approved any substantive health claims regarding moderate consumption. In 1998, then-Secretary of the Treasury Robert E. Rubin noted that "[t]his is a difficult standard to satisfy and no label has met it to date." AR 637. This statement was repeated by ATF's Assistant Director for Alcohol and Tobacco, who added that "ATF has no plans to change its strict policy with respect to substantive health claims. . . ." AR 716.

Despite its promise in the 1993 Circular to begin rulemaking on this issue, ATF did not do so until late 1999. On May 9, 1995, Appellant CEI filed a rulemaking petition with ATF, calling on the agency to approve a set of short moderate consumption health claims, which could be used by anyone wishing to make such claims in labels or ads. AR

143-60. As one possibility, CEI suggested the statement "there is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of heart disease". AR 146. The consumer organization Consumer Alert (CA) subsequently notified ATF of its support for this approach as a means of providing useful information to its members and the public. AR 174-75.

ATF did not respond to the CEI petition for well over a year. On October 29, 1996, Appellants CEI and CA filed suit in the court below. Count I alleged that ATF's policy restricting health information violated the First Amendment rights of listeners to protected commercial speech. Count II alleged a violation of the FAAA, the Treasury Regulations issued thereunder, and the APA. Count III alleged that ATF had failed to timely respond to CEI's petition for rulemaking.

On January 13, 1997, just before the January 17th deadline for responding to the Complaint, ATF denied CEI's petition. AR 361-74. Focusing on CEI's suggested health claim, ATF stated that the claim was not properly balanced and that no industry member had sought to use the specific language suggested by CEI. Consequently, CEI and CA filed an Amended Complaint on February 14, 1997, with a new Count III challenging ATF's denial. JA __.

ATF moved to dismiss Counts I and II for lack of standing, and for summary judgment on Count III. CEI and CA moved for summary judgment on Count III.

On May 27, 1998, the District Court issued a Memorandum and Order, concluding that CA could represent its members on the basis of "listener standing"; that is, their interest in receiving the information that ATF was restricting. Sl. op. at 2, *citing Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S.

748, 757 (1976). The court granted ATF summary judgment on Count III, holding that its denial of the rulemaking petition was a lawful exercise of agency discretion. The court denied Plaintiffs' motions. *Id.* at 3.

Both parties subsequently filed cross-motions for summary judgment on the validity of ATF's policy. CEI and CA also moved for reconsideration of the rulemaking issue. Briefing on these motions was completed in April 1999. Docket sheet, JA __.

Two months before that, in February 1999, ATF had made one change in its longstanding ban—it approved two claims that stated the following:

- "The proud people who made this wine encourage you to consult your family doctor about the health effects of wine consumption."
- "To learn the health effects of wine consumption, send for the Federal Government's Dietary Guidelines for Americans, Center for Nutrition Policy Promotion, USDA, 1120 20th Street. NW, Washington DC 20036 or visit its website."

AR 934-35. ATF characterized these claims as "directional", since they merely directed consumers to a source of information. AR 685. The claims themselves did not convey any substantive health information about wine consumption, and did not even use the term "health benefits." For this reason, ATF viewed them as meeting its "factual standards as not being false or misleading . . . ." AR 935.

As explained at pages 13-14 below, these directional claims were based on applications that had been filed with the agency several years earlier but never cleared; at ATF's request, the applicants had substituted the phrase "health effects" for the "health benefits" language of their original applications.

B. ATF's Current Rulemaking

On October 25, 1999, ATF finally initiated the rulemaking that it had promised in its 1993 Circular. ATF, *Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages: Notice of Proposed Rulemaking* (NPR), 64 FR 57,413. ATF did not outline any new policy; rather, it proposed to only "revise the current regulations to reflect our current policy. . . ." 64 FR 57,416 col. 1. The NPR also noted the possibility that, because of their risks, alcoholic beverages "may not be entitled to any health-related statement." 64 FR 57,414 col. 2. In a December 9, 1999 press release announcing public hearings, ATF also declared that, for the time being, it would cease approving even the directional statements that it had stated were non-misleading 10 months earlier:

> "Due to the adverse consequences of alcohol abuse, ATF is concerned about any risk of misperception resulting from the two approved statements. Because ATF is seeking public comments on this very issue, ATF will suspend action on any new applications for label approval bearing similar 'directional' health-related statements pending the completion of the rulemaking proceedings." JA ___.

On June 14, 2001, the District Court held a hearing at which ATF counsel stated: "The agency anticipates that it will have a rule, if it decides to finalize a rule—I can't swear that it will do that, but that's the plan—within a year." Transcript (Tr.) 3. On that basis, ATF requested that the case be dismissed as unripe. Tr. 4. The court, declining to reach the First Amendment merits, ruled accordingly and held the action to be prudentially unripe. Memorandum and Order, June 18, 2001, sl. op. 4-5.

STATEMENT OF FACTS

A. The Medical Evidence On Moderate Alcohol Consumption and Health

Over the past twenty-five years, a substantial body of published research has concluded that moderate consumption of alcoholic beverages (an average of one to two drinks per day) reduces the risk of cardiovascular disease. As long ago as 1992, a *New England Journal of Medicine* review of research on the major means of preventing myocardial infarction noted that "there is a substantial body of observational epidemiologic evidence to suggest that moderate consumption of alcohol reduces the risk of heart disease." AR 812. Various studies had found reductions in heart attack risk of 30-54 percent for both men and women, as compared to nondrinkers. This reduction in heart attack risk was independent of the type of alcohol consumed, and was possibly related to alcohol's effect on HDL cholesterol levels and on blood clotting. *Id.* Among the studies surveyed in this review were the following:

- a 1988 study in *The New England Journal of Medicine*, of over 87,000 female nurses, which found a 40 percent reduction in coronary heart disease risk as compared to nondrinkers. The study concluded that "the net effect of moderate alcohol intake might therefore be expected to be beneficial . . . ." AR 420.

- a 1991 *Lancet* study of more than 50,000 men which, after adjusting for numerous coronary risk factors, concluded that moderate alcohol consumption "was consistently associated with a reduced risk of fatal and non-fatal myocardial infarction" as compared to both nondrinkers and heavy drinkers. AR 804.

Since that time, the evidence for this effect of moderate consumption has continued to mount:

- a 1995 research monograph published by the Royal College of Physicians, which states that "low to moderate drinking, variously defined, is associated with a lower risk of CHD [coronary heart disease] than in non-drinkers." AR 841.

- a 1996 research monograph published by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), which states that "[m]odern epidemiological studies have shown that moderate alcohol consumption reduces the risk of coronary artery disease (CAD)," and that "consumption of alcohol, in small to moderate amounts, protects against the development of coronary heart disease (CHD)." AR 381, 391.

- a 1997 *New England Journal of Medicine* study of 490,000 men and women, the largest one to date, which found that "the rates of death from all cardiovascular diseases combined were 30 to 40 percent lower among men . . . and women . . . reporting at least one drink daily than among nondrinkers." AR 823.

The health benefits of moderate alcohol consumption are now so widely accepted that they are routinely mentioned in cardiology textbooks. For example, *Heart Disease: A Textbook of Cardiovascular Medicine* (by Eugene Braunwald, 4th ed., 1992) states that "overt coronary heart disease has been shown to be inversely related to moderate alcohol consumption . . . ." AR 149. The textbook *The Heart* (by J.W. Hurst and R.C. Schlant, 7th ed., 1990) states that "a growing body of literature supports the inverse association between moderate alcohol consumption and coronary heart disease." AR 150.

A former government epidemiologist, in his review of the research for CEI, described this evidence as follows:

> "The combination of epidemiological studies with current understanding of the biological basis of the beneficial effects of moderate alcohol consumption presents a convincing picture. The prestige of the researchers—some of whom are among the most respected epidemiologists and statisticians in the world—who have demonstrated the beneficial effects of low-level consumption of alcohol and the publication of their results in highly respected journals underlines the credibility of the reported beneficial effects of moderate alcohol consumption." AR 773.

Heart disease accounts for approximately one in three deaths; thus the potential benefits of reducing cardiovascular risk are substantial. AR 806. While there are health risks associated with alcohol consumption, these risks are relatively small for most adults as compared to the cardiovascular risks. Indeed, cardiovascular disease accounts for 45

percent and 37 percent of all deaths among men and women, respectively, while all alcohol-related deaths (largely from excessive drinking) account for only 7 percent and 15 percent of deaths. AR 823. By examining the effects of moderate consumption not only on heart disease but on overall mortality as well, numerous studies have found that, on balance, its benefits outweigh its risks—that is, moderate consumption not only reduces the risk of heart disease, but also increases overall longevity:

- a 1992 *Annals of Internal Medicine* study found that "[l]ighter drinkers have a lower mortality risk than either abstainers or heavier drinkers, due substantially to a lower risk for death from coronary heart disease." AR 424.

- a 1994 *British Medical Journal* study concluded that "[f]or most causes of death studied, the mortality was higher in non-drinkers than in light drinkers . . . ." AR 797.

- the 1997 *New England Journal of Medicine* study (page 9 above), found that "those who consumed up to one or two drinks of alcohol daily had lower overall mortality rates than nondrinkers." AR 824.

The possibility that some factor other than moderate consumption is responsible for these health benefits has been excluded by researchers. For example, the 1991 *Lancet* study (page 8, above) concluded that "[t]he magnitude of the association, consistency with results from other studies, and plausible biological mechanisms strongly suggest that the inverse association between moderate alcohol intake and risk of coronary disease is causal." AR 805. In particular, the hypothesis that the higher mortality of nondrinkers is due to seriously ill persons who gave up drinking (the "sick quitter" syndrome) has been disproved. A 1990 study of over 275,000 subjects, published in *Epidemiology*, concluded that "[t]hese data indicate an apparent protective effect of moderate alcohol intake on CHD mortality that cannot be attributed to the inclusion of subjects with CHD or related diseases into the nondrinker category." AR 407.

Although women suffer heart disease at lower rates than men, the overall mortality benefit from moderate alcohol consumption has been found to apply to them as well. For example, the 1997 *New England Journal of Medicine* study noted that "[t]he rates of death from all causes were lowest among both men and women who reported one drink daily . . . ." AR 823.

Reflecting this view, the magazine *Consumer Reports* has stated:

> "For most women, the risk of heart disease is far greater than that of breast cancer. So if you weigh just those two effects, alcohol's apparent beneficial effect on the heart outweighs the possible risk increase [of breast cancer]." AR 189.

Most importantly, the federal government itself has acknowledged the health benefits of moderate alcohol consumption. In 1995 the government issued a new edition of its *Dietary Guidelines for Americans*, which stated: "Current evidence suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals." AR 441. The guidelines, published by the Departments of Agriculture and Health and Human Services, constitute the government's foremost public statement on nutritional policy.[1]

B. The History of Health Claims Submitted to ATF

In 1991 the national news program *60 Minutes* broadcast a story on the health benefits of moderate wine consumption. This led a number of wineries to seek ATF approval for publicizing this information through their product labels and ads. Virtually

[1] The *Guidelines* are published every five years under 7 U.S.C. § 5341, which states that they "shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program." The most recent edition of the *Guidelines* continues to recognize the health benefits of moderate consumption, though it adds an age qualification: "Drinking in moderation may lower risk for coronary heart disease, mainly among men over age 45 and women over age 55." USDA and HHS, *Dietary Guidelines for Americans, 2000*, at 36 (5th ed. 2000).

all of these attempts were rejected as misleading, or were never acted upon by the agency. The following examples from ATF documents are an incomplete listing of such attempts; indeed ATF has conceded that its record may not contain all such submissions. Libertucci Decl. To AR, para. 32 (Oct. 6, 1998).

1. *1992: The Leeward Winery Newsletter*

In a 1992 newsletter, Leeward Winery discussed the *60 Minutes* segment, noting the "possible beneficial aspects of moderate wine consumption on a person's health," and the fact that "more than two dozen epidemiological studies have reported that individuals who consume moderate amounts of alcohol have significantly lower rates of heart disease." AR 3. Characterizing the newsletter as advertising, ATF threatened to revoke Leeward Winery's federal permit, essentially putting it out of business, unless it immediately ceased distributing it. AR 1. The winery complied under objection. AR 8. In a 1998 affidavit, Leeward Winery reiterated its interest in communicating this information. Brigham Aff., Nov. 11, 1998, JA __.

2. *1992: The Coalition For Truth And Balance Advertising Claim*

In 1992, the Coalition for Truth and Balance, a group of twelve California wineries, submitted to ATF for preclearance a 600-word statement on alcohol and health, entitled *Wine and Heart Disease–Behind the French Paradox,* for use in advertising. AR 37-38. In 1993, ATF submitted a revised version of this statement for review by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), which found it to be "consistent with the current state of knowledge on this subject." AR 86. Nonetheless. ATF never acted on the submission, which remains pending to this day. In 1997, the

Coalition informed ATF that it was still interested in having the statement precleared. Lieberman Aff., Dec. 3, 1998, Attachment 1, JA __.

3. *1993-1994: Health Claims Reviewed Under the Industry Circular*

A number of health claims submitted shortly before or after ATF's issuance of its Circular were rejected by the agency. In 1993, the agency turned down a wine ad which stated: "Having reviewed modern research on the benefits of modest wine consumption, we believe that our wine, when enjoyed with wholesome food, will promote health and enhance the pleasure of life." Lieberman Aff., Dec. 3, 1998, Attachment 2-1, JA __. ATF also rejected an ad that stated: "Recent studies suggests (sic) that [redacted brand] wine may reduce the risk of heart disease," and "Try [redacted brand] with a healthy meal." *Id.*, Attachment 3-2 (undated), JA ___.

In 1994, ATF rejected a wine ad that stated that "[s]everal medical authorities say that a glass or two of wine enjoyed daily is not only a pleasant experience but can be beneficial to an adult's health." AR 138. Another 1994 label submission containing the phrase "health giving" was similarly blocked. AR 140-41.

4. *1995-Present: The Wine Institute and Laurel Glen Winery Label Claims*

While CEI's rulemaking petition was pending (as was ATF's far earlier Industry Circular promise to conduct its own rulemaking), two more wine industry entities submitted wine labels with health claims. In May 1995, Laurel Glen Winery submitted a label containing the statement "The proud people who made this wine encourage you to consult with your family doctor about the health benefits and risks of moderate wine consumption." AR 161. In May 1996, the Wine Institute, on behalf of its members, submitted the statement "To learn the health benefits of moderate wine consumption,

write for the federal government's Dietary Guidelines for Americans: National Health Information Center, P.O. Box 1133, Washington, DC 20013." AR 241-42.

Although routine label submissions are usually processed in several weeks, ATF did not respond to these submissions for several years. Hinman Aff. para. 2, May 7, 1997, JA__. Finally, in February of 1999, ATF approved two altered versions of the submissions, in which the phrase "health benefits" was replaced by "health effects" and the reference to "moderate" was dropped. AR 934-35. These approvals came after several years of consideration by ATF; during that time, a study conducted by the Department of Health and Human Services (described at pages 16-18 below) found these claims to be non-misleading. AR 555-624.

The approved statements were as follows:

- "The proud people who made this wine encourage you to consult your family doctor about the health effects of wine consumption." AR 909.
- "To learn the health effects of wine consumption, send for the federal government's Dietary Guidelines for Americans, Center for Nutrition Policy and Promotion, USDA, 1120 20th Street. NW, Washington DC 20036 or visit its web site: http:/www.usda.gov/fcs/cnpp.htm." AR 903.

The record strongly suggests that the changes in text were made at ATF's request; Laurel Glenn made its changes after a "meeting" and "discussion" with ATF officials. AR 447.

At ATF's request, the Wine Institute withdrew all earlier versions of its health claim. AR 954. Laurel Glen, however, did not; one of its earlier submissions, utilizing the evidently prohibited phrase "health benefits and risks of moderate wine consumption," is still pending. AR 161, 935A.

Despite their lack of substantive content, even the approved directional claims were strongly criticized by Senators Robert Byrd (D-WV) and Strom Thurmond (R-SC).

AR 479-80, 635-36. Both questioned whether ATF "is the appropriate agency to have jurisdiction over alcohol labeling." *Id.* Senator Thurmond added that he was "considering introducing legislation that transfers alcohol labeling authority from the BATF to the Food and Drug Administration." AR 635-36. The Senator added a handwritten request that ATF's Director give this "serious matter" his "personal attention." AR 636.

Treasury Secretary Robert E. Rubin responded with letters emphasizing that "ATF has never approved an alcohol beverage label containing a substantive claim that alcohol consumption results in health benefits." AR 637-40. He also pointed out that ATF found that the two approved directional claims "do not mislead consumers." AR 638, 640.

Senator Thurmond wrote back, stating that he was "greatly disappointed" with ATF's plans, and ending with the warning that "[i]f you will not reconsider this decision, then I will seek legislative action to remedy the situation." AR 641.

Despite the Treasury Secretary's strong defense of the approved directional claims, in December, 1999, ATF announced that it would not permit any more such claims until its current rulemaking is completed. *See* page 7, above.[2]

[2] In response to a Freedom of Information Act request, ATF stated it had documents indicating the withdrawal of 10 label applications under this new ban. CEI Motion re Newly Obtained Documents (Dec. 14, 2000), Attachment, JA ___ . However, ATF also noted that "contacts with applicants on this matter were handled through informal telephone conversations." *Id.,* JA ___. Hence, the actual number of withdrawals under this ban may well have been far greater. (On the other hand, the number of labels bearing directional claims that had been approved under ATF's short-lived prior policy was reportedly nearly 100. *Id.,* JA___.)

The blocked health claims described above, beginning with the 1992 Leeward Winery newsletter, represent only a fraction of the potential speech that has been restricted by ATF's policy. There is evidence that many industry members were dissuaded from even bothering to file applications, given the futility of such efforts. ATF itself noted, in its 1993 Circular, that it had received "many inquiries" regarding moderate consumption health claims. AR 101. Moreover, a number of wine and beer makers submitted affidavits describing their frustration at being unable to publicize the health benefits of their products, and their decisions not to file applications which had no chance of success. Brigham Aff. (Nov. 11, 1998); MacIver Aff. (June 23,1997); Paski Aff. (April 9, 1999); JA ___, ___, ___.

C. ATF's Evidence On The Allegedly Misleading Effect of Health Claims

Since 1988, the federal government has required all alcoholic beverage labels to include the following:

> "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." 27 U.S.C. § 215 (Addendum A-6).

In its 1993 Circular, ATF suggested that "a health benefit claim would be misleading unless it was further qualified by information regarding the adverse effects of alcohol consumption," and that information inconsistent with the government health warning "may result in label information which is misleading and confusing to the consumer. . . ." AR 102.

After Laurel Glen and the Wine Institute submitted their original applications, ATF sponsored a study, conducted by Center for Substance Abuse Prevention (CSAP) of the Department of Health and Human Services, to test the consumer impact of their

proposed labels.[3] Released in January of 1998, this study, *The Effect of Wine Labels on Public Perception*, concluded that "neither of the two labels . . . would likely induce wine drinkers to alter their drinking pattern, quantitatively or otherwise." AR 557. It found that those exposed to the health statements still had a "[g]eneral understanding: there are risks of alcoholism, and certain conditions would counterindicate wine drinking." AR 623. As CSAP's Director subsequently noted, "[r]egarding the issue of two 'contradictory' labels on a single bottle of wine . . . nothing in the proposed labels appeared to diminish focus group participant perceptions about the risks of drinking." AR 653-54. As for ATF's concerns about pregnant women, the Director stated that "the population studied overwhelmingly understands that drinking is counter-indicated during pregnancy." AR 654.

Then-ATF Director John Magaw conceded that the CSAP study

> "did not provide evidence that the proposed wine labels would tend to encourage the consumption of wine for health reasons. Furthermore, the survey provided no evidence that the labeling statements would mislead consumers as to the overall health consequences of alcohol consumption." AR 643.

The CSAP study is the only study in the administrative record that attempts to empirically assess the actual consumer impact of alcoholic beverage health claims.

The CSAP study also found that "[m]any would like more information about health and wine." AR 623. However, current sources of information are apparently inadequate. A 1995 CEI survey found that most people did not know about the health benefits of moderate alcohol consumption. AR 190-94. Only 41.7 % of those surveyed knew of those benefits. AR 191. Moreover, of those who did know, most mistakenly

[3] In the CSAP study, the Wine Institute's phrase "health benefits" was replaced by the phrase "health effects". AR 556.

believed that the benefits apply only to wine, rather than to alcohol in general. AR 192.

These results should not be surprising; indeed, this Court has noted that, although it is possible to discuss product health claims in articles and books, "those channels of communication reach consumers less effectively than does a claim made directly on the label because they impose higher search costs on consumers." *Pearson v. Shalala*, 164 F.3d 650, 658 n.7 (D.C. Cir. 1999) (internal citations omitted).

SUMMARY OF THE ARGUMENT

Since at least 1992 and continuing up to the present day, ATF has enforced a policy of suppressing virtually all moderate consumption health information on alcoholic beverage labels and ads. ATF currently bans even the directional claims that it itself found non-misleading and approved in 1999. Nonetheless, on the basis of ATF's tentative claim that it would conclude a rulemaking first promised in 1993, the District Court ruled that this action was prudentially unripe.

As is shown below, that ruling incorrectly relies on pre-enforcement case law. It totally ignores the fact that ATF's ban has been repeatedly imposed on numerous attempts to communicate information concerning moderate alcohol consumption. For this reason, ATF's policy is fully ripe for review.

Rather than simply remand this case, this Court should itself proceed to adjudicate the validity of ATF's policy. The health benefits of moderate consumption are so well established that they are recognized in the federal government's *Dietary Guidelines for Americans.* ATF's prohibition on any mention of those benefits in labels and ads rests on pure paternalism. Its alleged concern over misleading effect has absolutely no empirical

support, and its failure to consider less stringent regulation is contrary to the commercial speech rulings of both this Court and the United States Supreme Court.

ARGUMENT

I

ATF'S BAN ON HEALTH CLAIMS, WHICH HAS BEEN IN EFFECT FOR NEARLY A DECADE, IS RIPE FOR REVIEW NOTWITHSTANDING THE AGENCY'S CURRENT RULEMAKING

The District Court ruled that this case was "not prudentially ripe" because ATF has a new rulemaking underway on the health claims issue which it tentatively plans to complete by June, 2002. Sl. op. 3; *see also* Tr. 3. In the court's view, a ruling on the merits at this point could be a waste of judicial resources and a premature entanglement "in abstract disagreements". *Id., quoting National Treasury Employees Union v. United States (NTEU),* 101 F.3d 1423, 1431 (D.C. Cir. 1996) (internal citations omitted). The court acknowledged that ATF had a "current 'de facto ban'", but characterized it as "not fit for judicial decision". Sl. op. 3. It also expressed uncertainty as to possible remedies, stating "it is not clear what real relief the Court could provide to the plaintiffs." *Id.* Finally, it found that withholding action pending the rulemaking would not impose a "substantial" hardship on the plaintiffs. Sl. op. 4.

The court's ruling might be justified if ATF were only now beginning to formulate, for the first time, a ban on health claims. If that were the case, there might be legitimate questions regarding just what form that ban would take, and whether any potential speakers would ever be affected by it.

But ATF already has such a ban in place. It has been in force since 1992, and the record shows that it has blocked numerous attempts to communicate information. If ATF

had not undertaken its current rulemaking, its ban would certainly be ripe for review. ATF should not be allowed to somehow make it unripe by belatedly commencing a drawn out rulemaking, especially given its past rulemaking delays on this issue. For these reasons, this Court should overrule the decision below on the basis of its own *de novo* review. *Brown v. Plaut*, 131 F.3d 163, 167 (D.C. Cir. 1997).

A. The District Court Erroneously Relied On Pre-Enforcement Case Law To Avoid Ruling On A Speech Ban That Has Long Been In Force

In ruling that this action was unripe, the District Court relied primarily on the Supreme Court's ruling in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), a case which, like the instant, involves label regulations. The District Court stated:

> "[p]rudentially, the ripeness doctrine exists to prevent the courts from wasting our resources by prematurely entangling ourselves in abstract disagreements, and, where, . . . , other branches of government are involved, to protect the other branches from judicial interference until their decisions are formalized and their 'effects felt in a concrete way by the challenging parties.'"

Sl. op. 3, *quoting NTEU*, 101 F.3d at 1431, which itself quotes *Abbott*, 387 U.S. at 148-49.

Abbott, however, dealt only with pre-enforcement review. In this Court's words, *Abbott* established "the two-part test" for "analyzing the ripeness of pre-enforcement agency action . . . ." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 434 (D.C. Cir. 1986).

But the instant case is in no sense a pre-enforcement challenge. It deals with a policy that has been in place since 1993 and has been enforced repeatedly. As described at pages 3-4 above, that policy was clearly set out in ATF's 1993 Industry Circular. It has been applied time and again to block numerous ads and labels, and to dissuade many potential industry speakers from even attempting to apply to ATF. *See* pages 11-16, above.

Far from being a speculative future issue, the impact of this policy has been real, undeniable, and even touted by government officers. The Secretary of the Treasury called it "a difficult standard to satisfy [that] no label has met . . . to date", and ATF's Assistant Director characterized it as "strict". AR 637, 716.

In such circumstances, courts have dismissed agency claims of unripeness that were premised on the existence of ongoing, or future, administrative proceedings. In *Time Warner Entertainment Co. v. FCC*, 93 F.3d 957 (D.C. Cir. 1996), for example, this Court rejected the claim that a case was unripe due to the prospect of "further FCC rulemaking". *Id.* at 974. In the court's view, "the challenged policy is . . . sufficiently fleshed out to allow the court to see the concrete effects and implications of its decision." *Id., quoting Chamber of Commerce v. Reich*, 57 F.3d 1099, 1100 (D.C. Cir. 1995); *see also Rio Grande Pipeline Co. v. FERC*, 178 F.3d 533, 540-41 (rejecting agency claim of unripeness due to forthcoming rate pronouncements, when policy had "crystallized to its final form"). ATF may perhaps change its policy in the future, but "[t]he fact that a law may be altered in the future has nothing to do with whether it is subject to judicial review at the moment." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000).

The past and continuing impact of ATF's policy makes the District Court's reliance on *NTEU* and *Renne v. Geary*, 510 U.S. 312 (1991) misplaced. Sl. op. 3-4. In *NTEU*, this Court rejected as unripe a challenge to a line-item veto law that had not yet taken effect. 101 F.3d at 1431. In fact, this Court expressly distinguished *NTEU* from other cases where "the allegedly unlawful and injurious act had already occurred by the time suit was brought." *Id.* at 1430. Similarly, in *Renne*, a post–election challenge to restrictions on candidate endorsements was rejected, in part because the record failed to

indicate any specific instances of restricted speech. 510 U.S. at 321. Here, in contrast, there are numerous specific health claims blocked by ATF, and its policy of speech suppression is in effect to this day.[4]

B. Contrary To Its Ruling, The District Court Could Have Provided Effective Relief Through Either A Declaratory Judgment Or An Injunction

In ruling for ATF, the District Court noted that "it is not clear what real relief the Court could provide to the plaintiffs." Sl. op. 3. But the court had before it a sizable number of health claims that ATF had blocked, together with evidence from several potential speakers of continuing interest in making such claims. The court declined to either order the approval of those claims, or to issue a declaratory judgment on the validity of their disapproval. While the court's ruling says relatively little about its reasons for rejecting such relief, the transcript of the June 14, 2001 hearing sheds more light on its reasoning. For example, CEI counsel expressly requested the court to rule on the validity of "the ten specific instances of ad campaigns squelched by ATF", and to order the agency to "withdraw any statements it made stopping those campaigns." Tr. 13-14. The court declined, stating: "I am not sure that they are valid under First Amendment jurisprudence." *Id.*

But this judicial uncertainty goes to *the merits* of the case, not to its ripeness.

[4] Moreover, courts have generally applied a somewhat lower ripeness standard to First Amendment cases. The criterion is "relaxed somewhat in circumstances . . . where a facial challenge, implicating First Amendment values, is brought." *New Mexicans For Bill Richardson v. Gonzales*, 64 F.3d 1495, 1499 (10th Cir. 1995). "Within the first amendment arena the jurisprudential criteria for constitutional adjudication are sometimes relaxed. . . ." *Martin Tractor Co. v. FEC*, 627 F.2d 375, 380 (D.C. Cir. 1980). The "doctrine of ripeness is more loosely applied in the First Amendment context." *Cheffer v. Reno*, 55 F.3d 1517, 1523 n.12 (11th Cir. 1995). Here, "the possibility that the agency's actions might . . . run afoul of the first amendment demands prompt judicial scrutiny." *Action For Children's Television v. FCC*, 59 F.3d 1249, 1259 (D.C. Cir. 1995), *cert. denied*, 516 U.S. 1072 (1996).

The court similarly refused to rule on the validity of any applications that had been withdrawn under ATF pressure, stating "I can't rule on anything that has been withdrawn." *Id.* The court dismissed the fact that some applicants had expressed a continuing interest in making such health claims: "Then maybe it ought to join as a plaintiff in this case." Tr.14-15. But if the listener standing established in *Virginia Pharmacy*, 425 U.S. at 756-57, requires that potential speakers join as plaintiffs, then the entire concept of such cases is destroyed.

Finally, the court flatly refused to order ATF to take any specific actions on the applications: "I certainly would not tell them what action to take." Tr. 16.

The court's basis for this refusal is unclear, but even if it is accepted, a declaratory judgment could still have provided a remedy. The usefulness of declaratory judgments in First Amendment cases generally, and in commercial speech cases in particular, is clear; the Supreme Court's most recent ruling on alcohol advertising, for example, was in a declaratory judgment action. *44 Liquormart Inc. v. Rhode Island*, 517 U.S. 484 (1996).

Finally, even if the specific health claims blocked in the past by ATF can somehow be viewed as moot, ATF's ongoing policy is still subject to challenge:

> "It is well-established that if a plaintiff challenges both a specific action and the *policy* that underlies that action, the challenge to the policy is not necessarily mooted merely because the challenge to the particular agency action is moot . . . .
>
> . . . .
>
> " . . . this circuit's case law provides that if a plaintiff's specific claim has been mooted, it may nevertheless seek declaratory relief forbidding an agency from imposing a disputed policy in the future, so long as the plaintiff has standing . . . ." *City of Houston v. HUD*, 24 F.3d 1421, 1428-29 (D.C. Cir. 1994).

Given that plaintiffs' standing in this case is not at issue, the court's claim of being unable to provide real relief is simply incorrect.

C. The Public's Interest In Receiving Truthful Information Warrants Judicial Review Of ATF's Current Ban

As its final reason for holding this action unripe, the District Court stated that plaintiffs would suffer no real hardship if the case were delayed:

> "the Court concludes that the hardship to the plaintiffs of withholding court consideration in light of the ATF rulemaking is not substantial. The rulemaking is projected to be completed within one year . . . . None of the plaintiffs is a winemaker actively seeking to use a label concerning 'health benefits.' Plaintiffs are consumer organizations that already have access to [such] information . . . from avenues other than alcoholic beverage labels, and plaintiffs are able to disseminate such information in their own publications or materials." Sl. op. 4.

But this analysis ignores the public interest in the free flow of information. The "right of the public to be informed" is a central element in listener standing jurisprudence. *Illinois Citizens Committee for Broadcasting v. FCC,* 515 F.2d 397, 402 (D.C. Cir. 1975) (internal quotations omitted). As the CEI poll shows (pages 17-18, above), the public is largely uninformed about the benefits of moderate consumption.

As for plaintiffs' alleged ability to obtain alcohol health information by other means, this factor is simply invalid under listener standing case law. In the Supreme Court's words, "we are aware of no general principle that freedom of speech may be abridged when the speaker's listeners could come by his message by some other means . . . ." *Virginia State Bd. of Pharmacy,* 425 U.S. at 757 n.15.

Finally, because this is not a pre-enforcement action, hardship is of dubious relevance. The hardship criterion stems from *Abbott,* which involved pre-enforcement ripeness. As this Court has noted:

> "the 'hardship' prong of the *Abbott Laboratories* test is not an independent requirement divorced from the consideration of the institutional interests of the court and agency. [Citation omitted] Thus, where there are no institutional interests favoring postponement, a petitioner need not satisfy the hardship prong."

Houston, 24 F.3d at 1431 n.9. In the context of this case, the most important criterion, that of the public's right to know, warrants an expeditious rather than delayed adjudication, a point which the District Court itself previously acknowledged: "At this point we're dealing with a constitutional issue . . . . That's a matter which judicially is to be given the highest priority, or certainly a very high priority." Tr. 5.

D. Given Its Past Record Of Delayed Rulemaking, ATF Should Not Be Allowed To Escape Judgment By Its Belated Attempt To Render This Case "Unripe"

The record in this case demonstrates a pattern of regulatory inaction by ATF. Its 1993 Circular promised a rulemaking which never occurred. AR 101. The agency did not act on CEI's rulemaking petition for over year, and finally denied it only days before it needed to answer CEI's Complaint, Count III of which alleged an illegal failure to respond to the petition. *See* page 5, above. ATF's current NPR was published in October, 1999, yet ATF did not move for dismissal on ripeness grounds related to the NPR until over one and one-half years later, at the June, 2001 hearing.[5] Tr. 4.

At that hearing ATF claimed that it needed yet another year to complete its rulemaking, though in April, 2000, ATF had announced that three of the five public hearings scheduled for the rulemaking had been cancelled due to lack of interest. ATF, *NPR: Cancellation and Rescheduling of Public Hearings*, 65 FR 24,158, JA__. *If* ATF in fact completes its rulemaking as promised, its proceeding will have taken two years and eight months to complete, during which time all health claims, substantive or directional, have been barred.

[5] As the docket sheet indicates, when ATF filed its NPR and accompanying press release with the court on December 10, 1999, it did not file any motion related to the NPR. JA__. Nor did ATF file any such motion subsequently.

The rulemaking, however, was first promised by ATF in 1993, and ATF's ban has been in effect since at least 1992. There is no basis for allowing such a protracted process to render this case unripe. Unripe cases may become ripe, but it is unusual for a ripe case to grow unripe. In the instant case, the basis for ATF's late claim of unripeness stems from its own deliberate action of initiating a drawn out rulemaking after years of enforcing its policy.

Courts have taken a dim view of allowing defendants to unilaterally undermine the fitness of their cases. As one court noted with respect to the effect of new events on a pending case, "those problems were completely within the power of the defendants . . . to control, and the outcome of the case should not be affected by the deliberate actions of these parties." *State of South Carolina ex rel. Campbell v. O'Leary*, 865 F.Supp. 300, 305 (D.S.C. 1994), *rev'd on other grounds*, 64 F.3d 892 (4th Cir. 1995). This is particularly true of belated administrative actions initiated after "a history of delay and missed deadlines . . . ." *Environmental Defense Fund v. EPA*, 852 F.2d 1316, 1331 (D.C. Cir. 1988), *cert. denied*, 489 U.S. 1011 (1989).

Finally, it should be emphasized that ATF is *not* proposing to alter its health claim policy; it is simply proposing to *codify* it. In its words, "We are proposing to revise the regulations to reflect our current policy . . . ." NPR, 64 FR 57,416 col 1. Having spent about a decade imposing its ban on speech, ATF should not be able to escape adjudication on the basis of a belated, ongoing proceeding to codify that ban.

II

ATF'S BAN ON MODERATE CONSUMPTION HEALTH CLAIMS VIOLATES THE FIRST AMENDMENT

A. If This Court Overturns The Unripeness Ruling Below, Then Judicial Economy Warrants That It Proceed To Rule On The First Amendment Issue

If this Court were to overturn the ruling below and hold this case ripe for review, it could then either remand the case for adjudication on the merits, or it could undertake that adjudication itself. As discussed below, however, a remand to the lower court would almost certainly result in yet another appeal to this Court. For this reason, and given that the issues at this point are purely legal in nature, this Court itself should rule on the First Amendment claim.

First Amendment jurisprudence makes clear that the burden was on ATF to justify its health claim ban, and that ATF was entitled to only minimal, if any, deference in meeting that burden. The "party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Bolger v. Youngs Drug Products Co.*, 463 U.S. 60, 71 n.20 (1983). Moreover, the "substantial deference due in the administrative context has little relevance when first amendment freedoms are even incidentally at stake." *Century Communications v. FCC*, 835 F.2d 292, 299 (D.C. Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988).

The District Court, however, repeatedly granted ATF overwhelming deference. In its 1998 ruling, the court accepted ATF's view on what constitutes a misleading claim, stating that it "may not substitute its judgment on the issue for that of ATF." 1998 Sl. op. at 3. Similarly, at the June, 2001, hearing, it gave the same rationale when it declined to permit directional claims during the pendency of the rulemaking. The court stated: "That

is substituting my judgment for the agency, and I am not sure that I am prepared to do that." Tr. 27. First Amendment precedent, however, required the court to do exactly that.

For this reason, a remand would very likely lead to yet another appeal by the plaintiffs.[6] This Court noted in a procedurally similar situation:

> "Were we to . . . remand, we would be likely to find the case back before us on appeal for the District Court's disposition on the merits. Since this appeal arose on cross-motions for summary judgment, presenting only issues of law, efficiency suggests that we address the substantive claims at this time."

Block v. Meese, 793 F.2d 1303, 1309 (D.C. Cir. 1986), *cert. denied*, 478 U.S.1021 (1986).

B. The Health Claims At Issue Are Protected Commercial Speech

As the District Court recognized, health-related information on alcoholic beverage labels and ads is commercial speech. Tr. 5. As such, it is protected by the First Amendment under the standard first set out in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of N.Y.*, 447 U.S. 557 (1980):

> "At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest."

Id. at 566.

[6] In the event that ATF were to lose below on the merits, it too would likely appeal. Finally, even if this Court were inclined to view the instant case as prudentially unripe, it is very likely that the codified rule that ATF eventually may issue will be no different than its current policy. *See* page 7, above. In that case, an eventual appeal to this Court would be likely as well.

The *Central Hudson* test has become the standard for testing government restrictions on commercial speech. *See In re R.M.J.*, 455 U.S. 191 (1982); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983); *Zauderer v. Office Of Disciplinary Counsel*, 471 U.S. 626 (1985); *Posadas de Puerto Rico Associates v. Tourism Co. Of Puerto Rico*, 478 U.S. 328 (1986); *Peel v. Attorney Reg. & Disciplinary Comm'n*, 496 U.S. 91 (1990); *Edenfield v. Fane*, 507 U.S. 761 (1993); *Ibanez v. Florida Dept. Of Business and Prof. Reg.*, 512 U.S. 136 (1994); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (ATF restriction on displaying alcohol content on beer cans and labels held unconstitutional); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (state ban on liquor store price advertising held unconstitutional); *Greater New Orleans Broadcasting Ass'n v. U.S.*, 527 U.S. 173 (1999); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

As two Supreme Court decisions make clear, this high standard is not lowered when the commercial speech at issue involves alcohol. *Coors*, 514 U.S. at 482 n.2; *44 Liquormart*, 517 U.S. at 513-14.

In addition to being applied to protect alcoholic beverage labeling and advertising, the *Central Hudson* test has also been applied to strike down restrictions on product health information. In 1998, a Food and Drug Administration (FDA) policy restricting manufacturer distribution of information regarding so-called off label uses of drugs was held unconstitutional. *Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51 (D.D.C. 1998). This decision was subsequently extended to the newly enacted Food and Drug Administration Modernization Act. *Washington Legal Foundation v. Henney*, 56 F.Supp.2d 81 (D.D.C. 1999), *appeal dismissed*, *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). An FDA policy suppressing several health

claims for dietary supplements was also struck down. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). Similarly, ATF's ban on health information on alcoholic beverages and advertisements cannot be justified under the *Central Hudson* test.

Because each of the First Amendment questions raised here presents a question of law, this Court should consider them *de novo*. *Eldred v. Reno*, 239 F.3d 372, 374-75 (D.C. Cir. 2001).

C. ATF Has Failed To Demonstrate That The Banned Speech Is Misleading

The *Central Hudson* test not only details the burden the government must meet in restricting commercial speech, but also makes clear that there is little or no deference afforded an agency's determination that it has met this burden. "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will alleviate them to a material degree." *Edenfield*, 507 U.S., at 770-71. Such speculation or conjecture "does not suffice when the State takes aim at accurate commercial information for paternalistic ends." *44 Liquormart*, 517 U.S. at 507. A government restriction that rests on "anecdotal evidence and educated guesses" does not satisfy this test. *Coors*, 514 U.S. at 490. A justification for banning speech will fail when "[t]he State's arguments amount to little more than unsupported assertions: nowhere does the State cite any evidence or authority of any kind . . . ." *Zauderer*, 471 U.S. at 648. "The absolute prohibition on appellant's speech, in the absence of a finding that his speech was misleading, does not meet these requirements." *In re R.M.J.*, 455 U.S. at 207. "Given the complete absence of any evidence of deception . . . we must reject the contention that petitioners [speech] is actually misleading." *Peel*, 496 U.S. at 106.

The Supreme Court has described this standard as intermediate review, not quite as probing a standard as the strict scrutiny applied to non-commercial speech but far less deferential than rational basis review. *Edenfield*, 507 U.S. at 767-68.

Here, "[t]here is nothing in the record to indicate that the inclusion of this information was misleading." *In re R.M.J.*, 455 U.S. at 206. ATF has banned several health claims (described on pages 11-16 above) as misleading without demonstrating any actual misleading effect. Conspicuously absent from the lengthy administrative record is any such evidence or authority. Quite the contrary, the only relevant evidence in the record, the CSAP study (discussed on pages 16-17) found that the two temporarily-approved claims were *not* misleading. Virtually every concern raised by ATF about moderate consumption health claims – that people would become confused as to the risks of excessive drinking and increase their consumption to dangerous levels, that pregnant women would engage in detrimental drinking behavior, that the intent of the health warning statement would be obfuscated – was refuted by that study. *Id.* Even the Director of ATF conceded that the study "provided no evidence that the labeling statements would mislead consumers as to the overall health consequences of alcohol consumption." AR 643. Nonetheless, ATF subsequently rescinded its approval of these health claims, and did so without any new evidence of misleading effect to counter the CSAP study's findings.[7]

[7] Given its cursory nature, ATF's sudden and unexplained change in policy on these directional claims was an especially egregious violation of administrative law. An "agency changing its course . . . is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

Thus, the record directly contradicts the agency's rationale for rejecting industry's attempts to communicate health information. Clearly, the *Central Hudson* test has not been met.

1. ATF's Requirement of Impracticably Extensive Counterspeech Is Unconstitutional

In its 1993 Industry Circular, ATF stated that all health claims would be "considered misleading unless they are properly qualified, present all sides of the issue, and outline the categories of individuals for whom any positive effects would be outweighed by numerous negative health effects." AR 104. ATF further stated that it "considers it extremely unlikely that such a balanced claim would fit on a normal alcoholic beverage label." AR 104. This assertion has been borne out by the agency's record of not allowing (with the exception of the temporary approval of the two directional claims) any health related information on a label. However, requirements of detailed completeness in otherwise accurate advertising and labeling have been explicitly rejected as a justification for suppression. "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all." *Central Hudson*, 557 U.S. at 562.

In rejecting a state ban on lawyer advertisements considered insufficiently comprehensive to properly inform prospective clients, the Supreme Court stated that:

> "it seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision. The alternative – the prohibition of advertising – serves only to restrict the information that flows to consumers. Moreover, the argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public.

> In any event, we view as dubious any justification that is based on the benefits of public ignorance."

Bates v. State Bar Of Arizona, 433 U.S. 350, 374-375 (1977). ATF's argument for completeness is further undercut by the existence of the mandatory warning statement, which already provides consumers with information regarding the risks of alcohol abuse. *See* page 16, above.

2. ATF's Policy Rests On Paternalistic Assumptions That Have Repeatedly Been Invalidated As Rationales For Suppression

Notwithstanding the total absence of evidence of misleading effect (*see* 16-17, above), ATF still insists that health claims must contain lengthy, unnecessary, and obvious disclaimers that render them too long to use. Of course, any communication can be branded misleading if one speculates, as ATF has, that the audience is quite easily misled. However, such paternalistic assumptions are particularly disfavored as rationales for suppression. The Supreme Court has held that:

> "Precisely because bans against truthful, non-misleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. [Citation omitted] The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products."

44 Liquormart, 517 U.S. at 503. Here, ATF seeks to keep all alcohol consumers in the dark about the proven benefits of moderate consumption based on the speculative assertion that the public cannot handle the truth. In *Pearson*, this Court similarly rejected that assumption:

> "health claims [FDA argues] are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were

> asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous."

Pearson, 164 F.3d at 655. Here, ATF has used precisely the same paternalistic argument that failed in *Pearson*.

D. ATF's Extensive Restrictions Are Not Narrowly Tailored To Serve a Substantial State Interest.

ATF has refused to consider using succinct disclaimers, as suggested by CEI in its rulemaking petition, as an alternative to its ban. AR 146-47. Instead, the agency has adopted a policy that effectively bans all moderate consumption health information.

However, the *Central Hudson* test requires that restrictions on speech directly serve a legitimate state interest, and be no more extensive than necessary. 447 U.S. at 556. While the promotion of responsible drinking habits among the general public has been accepted as a legitimate state interest, attempts to serve that interest through broad speech restrictions have repeatedly failed these last two steps of the test. *Coors*, 514 U.S. at 485-87; *44 Liquormart*, 517 U.S. at 505-07. These steps "basically involve a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." *Coors*, 514 U.S. at 486 (quoting *Posadas*, 478 U.S. at 341). Under the intermediate standard of review, the fit must be tighter than that required under rational basis review. *Edenfield*, 507 U.S. at 768. Here, however, ATF has totally failed to demonstrate any fit between its total and indefinite ban on all health information on labels and advertisements and the interests it claims to be serving.

A commercial speech "restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Central Hudson*, 447 U.S. at 564. Here, there is

no evidence that ATF's ban on health information on labels and advertisements has done anything to deter irresponsible or harmful drinking. The only evidence in the administrative record of the effects of health claims on drinking behavior demonstrates that such claims do not mislead persons into making detrimental choices regarding alcohol. *See* pages 16-17, above. Thus, restricting access to this information has not been shown to advance any legitimate public health interest. Quite the contrary, given the evidence that moderate drinking substantially reduces the risk of cardiovascular disease, a leading cause of death in the U.S. (AR 806, 823), these claims "convey truthful information relevant to important social issues," making "the First Amendment interest served by such speech paramount." *Bolger*, 463 U.S. at 69.

Even if a restriction on speech serves a legitimate purpose, the restriction must be as narrow as possible. "States may not place an absolute prohibition on certain types of information . . . if the information also may be presented in a way that is not deceptive." *In re R.M.J.*, 455 U.S. at 203. "[T]he free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Zauderer*, 471 U.S. at 646. ATF cannot prevent the use of truthful and non-misleading health claims in its quest to bar false and misleading ones. But here, ATF's blanket ban does exactly that.

In finding the most reasonable means-end fit, there is a clear preference for allowing speech with reasonable disclaimers (where shown to be necessary to cure potential misleadingness), rather than outright suppression. In *Pearson*, this Court noted that "when government chooses a policy of suppression over disclosure – at least where

there is no showing that disclosure would not suffice to cure misleadingness – government disregards a far less restrictive means." 164 F.3d at 658 (internal quotations omitted). However, such disclaimers "may be no broader than reasonably necessary to prevent the deception." *In re R.M.J.*, 455 U.S. at 203. Here, not only has ATF rejected health information with no showing that reasonable disclaimers could not cure potential misleadingness, but has actually blocked the two directional health claims that it concedes are not misleading and thus should not require disclaimers at all.

The only disclaimers acceptable to ATF are, by its admission, impractically long and unlikely to ever be used. AR 104. Such a policy is a de facto ban on health information, even though "the general thrust of federal alcohol policy appears to favor greater disclosure of information, rather then less." *Coors*, 514 U.S., at 484.

E. By Banning Truthful Speech That Is Constitutionally Protected, ATF's Policy Also Violates The FAAA And The APA

The FAA and ATF's implementing regulations permit "curative and therapeutic claims" that are truthful and nonmisleading. 27 U.S.C. §§ 205(e) and (f) (Addendum A2 to A4); 27 C.F.R. §§ 4.39(h), 4.64(i), 5.42(b)(8), 5.65(d), 7.29(e), and 7.54(e) (Addendum A-8 to A-10, A-14 to A-16). If the moderate consumption health claims described above are not misleading under First Amendment case law, then they are valid under the FAAA as well. For this reason, ATF's attempts to ban them under its regulations are arbitrary and capricious, "contrary to constitutional right" and "in excess of statutory authority" under the APA, 5 U.S.C. § 706(2) (A), (B), and (C). Moreover, since the FAAA evidently does contemplate the possibility that truthful claims of some sort could fit on labels, ATF's attempt to permit only claims that cannot fit runs counter to this statutory scheme.

CONCLUSION

The benefits of moderate alcohol consumption are so well established that they are discussed in the federal *Dietary Guidelines.* Since 1992, however, ATF has enforced a policy that effectively bans all references to these benefits in alcohol beverage labels and ads. ATF has failed in its attempts to show that such claims would have any misleading effect on the public.

For the reasons set forth above, this Court should overrule the District Court and hold this action ripe for review. It should proceed to rule that ATF's policy violates the First Amendment, and that each of the blocked labels and ads described above are in fact valid and should be approved by the agency.

DATED: January 2, 2002

SAM KAZMAN
BEN LIEBERMAN
Competitive Enterprise Institute
1001 Connecticut Ave. N.W.
Suite 1250
Washington, D.C. 20036
Telephone: (202) 331-1010

Counsel for Appellants