ATTACHEMENT A

COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE AND CONSUMER ALERT ON THE BUREAU OF ALCOHOL, TOBACCO AND FIREARMS' PROPOSED RULE REGARDING HEALTH CLAIMS IN THE LABELING AND ADVERTISING OF ALCOHOL BEVERAGES

64 Federal Register 57,413 (October 25, 1999)

SUMMARY

ATF's notice of proposed rulemaking seeks to prohibit what it deems misleading statements about the health benefits of alcohol consumption from appearing on alcoholic beverage labels and advertisements, but would in fact serve to suppress entirely truthful and non-misleading speech. The cardiovascular and overall health benefits associated with moderate alcohol consumption are amply supported by the medical evidence, and summary statements of these benefits are protected by the First Amendment. ATF's notice of proposed rulemaking should be withdrawn.

INTRODUCTION

The Competitive Enterprise Institute (CEI) is a pro-market public interest group dedicated to advancing the principles of free markets and limited government. Consumer Alert (CA) is a free-market consumer advocacy group. Both organizations have a longstanding interest in the free flow of information between producers and consumers of alcoholic beverages. In 1995, CEI filed a petition for rulemaking with the Bureau of Alcohol, Tobacco and Firearms (ATF) regarding the use of health claims on alcoholic beverage labels and advertisements. Attachment 1. Despite a substantial body of evidence that moderate consumption reduces cardiovascular risk and overall mortality, and mounting legal precedent that such communications are protected by the First Amendment, the agency had in place a policy that effectively stopped all industry attempts to put health information on labels or ads.

Prior to our petition, industry had never been given any guidance by ATF to distinguish acceptable from unacceptable health claims language, other than a 1993 Industry Circular implying that all health claims are presumptively misleading and will be heavily scrutinized. Several industry attempts to communicate with consumers about the health benefits of moderate consumption were thwarted by ATF, in some instances by threats of administrative action against industry members. For this reason, CEI petitioned the agency to provide industry with an effective means for obtaining health claim approvals. CEI hoped that the rulemaking would result in several approved statements, such as the suggested "there is significant evidence that

moderate consumption of alcoholic beverages may reduce the risk of heart disease," or any variations acceptable to the agency.

After a year and a half of agency inaction in responding to our petition, CEI, along with CA, filed suit in 1996 challenging ATF's policy. *Competitive Enterprise Institute v. Robert E. Rubin, Civil Action No. 96-2476 (D.D.C., filed October 29, 1996)(CEI v. Rubin).*[1] Only after the suit was filed did ATF deny our petition for rulemaking. *CEI v. Rubin*, as amended, challenges the denial of our petition as well as the legality of ATF's ongoing policy, and is still pending.

Although ATF is finally engaging in a rulemaking on its health claims policy, CEI and CA are disappointed that, rather than opening the door to truthful statements about the health benefits associated with moderate consumption, the proposed rule is designed to shut that door, and essentially codify ATF's de facto ban on health information.

As will be discussed below, we believe this rulemaking should result in a policy allowing a wide range of accurate summary statements about moderate drinking and health to appear on alcoholic beverage labels and ads. Any other outcome would contradict the evidence as well as the First Amendment. For this reason, ATF's proposed change to its rules should not be promulgated.

I
ATF'S PROPOSED RULE WOULD RESTRICT TRUTHFUL AND NON-MISLEADING INFORMATION

ATF proposes to prohibit as misleading "any statement that makes a substantive claim regarding health benefits associated with the consumption of alcohol beverages unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects." 64 Fed. Reg. 57,413. This would include any statement referring to the cardiovascular and overall health benefits associated with moderate alcohol consumption. ATF then concedes, as it first did in its 1993 Industry Circular, that its proposed requirements amount to a de facto ban, because "it would be extremely unlikely that any such balanced claim would fit on a normal alcohol beverage label." 64 Fed. Reg. 57,415. This was the agency's rationale for rejecting the suggested health statement in CEI's petition for rulemaking, as well as several others submitted by industry members over the past decade. However, ATF's proposed requirements are completely unsupported by the evidence concerning health claims and their effect on consumers.

A. The Medical Evidence Supports General Statements That Moderate Drinking is Beneficial For Adults.

[1] ATF has compiled an extensive administrative record in this case. The administrative record is also highly relevant to this notice of proposed rulemaking, and is therefore incorporated by reference into these comments.

There is a substantial body of evidence, far more than cited in the notice of proposed rulemaking, demonstrating that moderate consumption of alcoholic beverages confers significant cardiovascular and other health benefits and reduces overall mortality for the adult population. The attached summary of the evidence (with references), conducted for CEI and CA by Dr. Michael Gough in 1998, is particularly useful in light of the fact that ATF does not present an overview of net health effects associated with moderate drinking. Attachment 2. Additional studies, including some published subsequent to Dr. Gough's comments, are also attached. Attachment 3. Instead of accurately summarizing this evidence, ATF devotes much of its time to identifying every conceivable category of individual who is not likely to benefit from moderate drinking. This includes adults too young to be at significant risk for cardiovascular disease, pregnant women, and recovering alcoholics. After identifying these and other groups, the agency essentially concludes that any summary of the effects of moderate drinking would be misleading unless accompanied by a lengthy discussion of each exception. In other words, the agency deems accurate summaries impossible.

ATF's review of the literature is highly misleading. In truth, the published research, including the studies selectively quoted by ATF, nearly unanimously concludes that moderate drinking reduces cardiovascular risk and overall mortality for the adult population. Regarding those not likely to obtain these net benefits, Dr. Gough concludes that "with the exception of these groups, who comprise a minority of the population, there does not appear to be a group of adults that does not benefit from moderate alcohol consumption." Attachment 2, p. 17. Among the studies relied upon by Dr. Gough are:

- a 1991 Lancet study stating that "moderate alcohol consumption reduces the risk of coronary artery disease."

- a 1992 New England Journal of Medicine review article on the major means of preventing myocardial infarction, which states that "there is a substantial body of observational epidemiologic evidence to suggest that moderate consumption of alcohol reduces the risk of heart disease."

- a 1997 New England Journal of Medicine study concluding the "those who consumed up to one or two drinks of alcohol daily had lower overall mortality rates than nondrinkers."

- A 1994 British Medical Journal study concluding that "for most causes of death studied, the mortality was higher in non-drinkers than in light drinkers…

Indeed, virtually every scientific study in the medical literature supports the general thrust of the information the agency would prohibit – that moderate consumption of alcoholic beverages reduces cardiovascular risk and overall mortality. ATF's studied preoccupation with the exceptions to the general rule does not negate the truth of that rule.

In addition to overstating the proportion of the adult population that would not derive net benefits for moderate drinking, ATF has also overstated the degree of risk to such persons who do drink moderately. This is particularly true of the largest category of exceptions, adults too young to be at substantial risk of cardiovascular disease (especially younger women, whose cardiovascular risk is less than that for men). For example, ATF quotes one article claiming "an increase in all-cause mortality even in young women who are light drinkers … compared with abstainers." 64 Fed. Reg. 57,414. However the underlying research paper on which this claim is based, a 1995 New England Journal of Medicine study entitled "Alcohol Consumption and Mortality Among Women," merely found a statistically insignificant mortality increase among such women aged 34-39. Attachment 4, p. 1,247. More importantly, this same study found statistically significant reductions in overall mortality among light and moderate drinking women aged 34-59, concluding that "these findings indicate that for women as a group light-to-moderate alcohol consumption confers a significant overall survival advantage." Attachment 4, p. 1,250. This conclusion is nearly identical to scores of others from studies of moderate drinking's net effects on adult men and women, but is precisely the kind of statement the agency now seeks to prohibit.

For these reasons, Dr. Gough states that "the available evidence contradicts ATF's statement that 'there is no significant scientific evidence to support an unqualified conclusion that moderate alcohol consumption has net health benefits for all or even most individuals.'" Attachment 2. p. 19.

B. The Evidence Demonstrates That Health Claims Do Not Mislead The Public

There is another reason that ATF's overemphasis on the minority of adults who would not benefit from moderate drinking fails as justification for banning health claims - the individuals who comprise these categories know who they are and are unlikely to be misled. Indeed, completely absent from ATF's purely speculative assertion that health statements would have a misleading effect is any mention of the only evidence the agency has obtained regarding the consumer response to health statements. A 1998 study (excerpts attached), conducted for ATF by the federal government's Center for Substance Abuse Prevention (CSAP), evaluated the consumer response to the following two short statements on wine labels:

- to learn the health effects of moderate wine consumption, send for the Federal Government's "Dietary Guidelines for Americans."

- 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.

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Attachment 5, p. 1-2. The CSAP study's central conclusion is that "neither of the two labels … would likely induce wine drinkers to alter their drinking pattern, quantitatively or otherwise." Attachment 5, p. 3. With regard to concerns about alcoholism and the existence of certain categories of individuals who should not drink, the study concluded that, even among those exposed to the health claims, there still is a "[g]eneral understanding: there are risks of

alcoholism, and certain conditions would counter indicate wine drinking." Attachment 5, p. 4. In fact, in a response to an ATF attempt to exaggerate the risk of health claims to pregnant women, the Director of CSAP stated in a letter that "the population studied overwhelmingly understands that drinking is
counter-indicated during pregnancy." Attachment 6.

C. Other Federal Agencies Have Approved Summary Health Statements Without The Extensive Qualifications Required By This Proposed Rule.

In its notice of proposed rulemaking, ATF defers to the expertise, and potential jurisdiction, of the Food and Drug Administration and Federal Trade Commission. 64 Fed. Reg. 57,415. However, ATF's proposed restrictions flatly contradict the practice of both FDA and FTC regarding summaries of nutritional research on product labels and ads.

Under the National Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353, FDA has conducted a series of rulemakings to approve more than 20 health claims, including several linking saturated fat and cholesterol and coronary heart disease, fiber-containing foods and coronary heart disease, calcium and osteoporosis, and sodium and hypertension. 21 CFR §§ 101.72-81.

For example, FDA has established the following "safe harbor" statements for appropriate food labels:

- "While many factors affects heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease." 21 CFR § 101.75(e)(1)

- "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors." 21 CFR §101.74(e)(1).

Similarly, FTC has allowed health claims in advertisements, including several statements that mention the link between high fiber foods and reduced risk for certain cancers.

In terms of both their generality and their lack of warnings for special groups of people, these approved claims are similar to CEI's suggested claim, yet under ATF's proposed approach they would all be supposedly misleading. For example, during FDA's rulemaking on the saturated fat claim (the first claim quoted above), the agency received comments that "questioned the applicability of a claim linking diets low in saturated fat and cholesterol to reduced risk of heart disease in the general U.S. population." FDA, *Final Rule – Health Claims: Dietary Saturated Fat and Cholesterol and Coronary Heart Disease*, 58 Fed. Reg. 2,739, 2,745 (1993). FDA agreed that "the beneficial effects … are highly variable among individuals," but it nonetheless allowed the claims because there is "strong scientific agreement that the majority of persons in the U.S. will benefit…." *Id.* at 2,745-46. FDA expressly refused to require that this

health claim use the phrase "some persons, but not all," characterizing it as "too conservative." *Id.* at 2,746. The agency took a similar approach in its low-sodium rulemaking, where it stated that despite the fact "that not all persons may be sensitive to salt," the "word 'some' may erroneously lead consumers to believe that only a small percentage of the population will benefit…." FDA, *Final Rule – Health Claims: Sodium and Hypertension*, 58 Fed. Reg. 2,820, 2,825 (1993). FDA pointed out that "the use of 'may' or 'might' …conveys the meaning that not all individuals respond to sodium restriction with lower blood pressure levels." 58 Fed. Reg. 2,825-26.

In contrast, ATF insists that the existence of exceptions to the general rule that moderate consumption reduces cardiovascular risk and overall mortality renders all summary health statements misleading, and therefore unallowable. Further unlike FDA and FTC, ATF shows absolutely no concern about requiring qualifying language that serves to misleadingly overstate these exceptions.

Measured by any standard – the strength of scientific support, the percentage of the population for whom the claim applies, the extent of the expected health benefit, the degree to which any exceptions are obvious and well-known – the health claims ATF seeks to prohibit are as justified, if not more so, than numerous health claims currently appearing on many product labels and advertisements. Under ATF's approach, none of these claims would have ever seen the light of day.

In sum, there is no basis for ATF's assertion that summaries of the net health benefits associated with moderate drinking are false or misleading, neither in terms of their scientific support nor in terms of the effect they have on consumers.[2]

II ATF'S PROPOSED RULE VIOLATES THE FIRST AMENDMENT

Despite the obvious First Amendment concerns raised by ATF' proposal to severely restrict speech, the agency devotes only one paragraph to First Amendment issues, citing two cases in support of its assertion that its proposed rule is Constitutional. 57 Fed. Reg. 57,416. Ironically, in both cases the Supreme Court struck down as unconstitutional government restrictions on speech, and in the most recent one the Court upheld the First Amendment rights of alcoholic beverage advertisers. *44 Liquormart v. Rhode Island*, 517 U.S. 484 (1996). These and other Supreme Court cases have spawned many other successful challenges to federal and state restrictions on advertising and labeling, including some involving product health

2 Furthermore, any statement regarding the net health benefits of moderate drinking on an alcoholic beverages label would share space with the federally mandated statement: "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. 213 *et seq.* (1988). Thus ATF's insistence that summaries of benefits be "balanced" is already satisfied by a summary statement of the risks that appears on every alcohol product label.

statements. Indeed, virtually every argument made by ATF in support of its proposed speech limitations has repeatedly failed Constitutional scrutiny.[3]

A. ATF Has Not Met Its Burden In Justifying A Restriction On Commercial

Speech.

The First Amendment applies to so-called commercial speech, protecting the labeling and advertising rights of both the speaker and the listener consumer. *See, Virginia State Bd. Of Pharmacy v. Virginia Consumer Council*, 425 U.S. 748 (1976) (drug price advertising); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977) (attorney advertising); *Central Hudson Gas v. Public Service Comm'n of N.Y.*, 447 U.S. 557 (1980)(utility promotional advertising); *In Re RMJ*, 455 U.S. 191 (1982)(attorney advertising); *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626 (1985)(attorney advertising); *Peel v. Attorney Reg. & Disciplinary Com'n*, 496 U.S. 91 (1990)(attorney advertising); *Edenfield v. Fane*, 507 U.S. 761 (1993)(accountant in-person solicitations); *Ibanez v. Fla. Dept. of Bus. & Pro. Regulation*, 512 U.S. 136 (1994)(accountant advertising); Rubin *v. Coors*, 514 U.S. 476 (1995)(percent alcohol content on beer cans and labels). The state can place limited restrictions on commercial speech, but only if certain conditions are met. "It is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Edenfield v. Fane*, 507 U.S 761, 770 (1993)(internal quotations and citation omitted). Furthermore, "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 in fact alleviate them to a material degree." *Edenfield*, at 770-771. For example, in *Rubin v. Coors*, ATF tried to justify its ban on percent alcohol content information on beer cans and labels by speculating that the restriction was necessary to prevent brewers from competing on the basis of alcoholic strength. The Supreme Court unanimously rejected as inadequate ATF's "anecdotal evidence and educated guesses to suggest that competition on the basis of alcohol content is occurring," and that the "ban has constrained strength wars that otherwise burst out of control." *Id.* 514 U.S., at 490.

Here, ATF has similarly failed to meet its burden. Rather than present evidence refuting the general assertion that moderate consumption reduces cardiovascular risk and overall mortality, the agency (albeit in a selective and misleading manner) cites medical evidence that actually supports this conclusion. In addition, the CSAP study, rather that confirming ATF's speculation that health claims would have misleading effects on consumers, demonstrates the precise opposite to be the case.

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[3] Its should also be understood that ATF's proposed rule, in violating the First Amendment, also violates the Administrative Procedure Act (APA), §§ 5 U.S.C. 551 *et seq*. In addition, by restricting non-misleading therapeutic or curative claims, ATF's proposed rule violates the Federal Alcohol Administration Act (FAAA), 27 U.S.C. § 205(e) and (f).

Further, ATF's underlying assumption that health statements must be weighed down with extensive detail lest they be deemed misleading has often failed as a rationale for suppression. This is particularly true given ATF's highly paternalistic assumptions regarding easily-deceived consumers, and the agency's admission that its proposed disclosure requirements would serve to restrict the flow of information by making it nearly impossible to say anything at all about alcohol and health on product labels and ads. In *Bates*, the Supreme Court reviewed similar restrictions on attorney advertising, and concluded 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.

Id., 433 U.S. at 374-375. Some accurate information is always preferred to suppression. "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendments presumes that some accurate information is better than no information at all." *Central Hudson*, 447 U.S., at 562. With regard to the assumption that the public is better off if shielded from certain facts, the Court has stated that "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." *44 Liquormart*, 517 U.S. at 503. Disclaimers are preferred to outright suppression, but overly onerous and impractical disclaimer requirements may violate the First Amendment. "We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected speech." *Zauderer*, 471 U.S. at 651. ATF's attempt here to "protect" consumers from summaries of the health benefits of moderate consumption, by means of disclosure requirements so extensive as to make it unlikely that any such information will ever appear on a label or ad, is equally suspect.

Further, restrictions on commercial speech must be narrowly tailored to their end. "[W]e 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." *Central Hudson*, 447 U.S. at 566. Broad restrictions on speech rarely pass muster, especially when more targeted restrictions or non-speech alternatives are not given adequate consideration. In *Rubin v. Coors*, for example, the Court noted several means of combating alcoholic strength wars short of an all out ban on percent alcohol content information. The Court concluded that "the availability of these options, all of which could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights, indicates that [its ban] is more extensive than necessary." *Id.* at 491. Here, ATF is, by its own admission, attempting to effectively ban an entire category of speech, without contemplating more targeted measures. The notice of

proposed rulemaking does not even acknowledge the possibility that health summaries could be worded so as to satisfy ATF's stated concerns, and instead repeats the agency's assertion from its 1993 Industry Circular that any and all statements short enough to be of use are unacceptably misleading.

B. Recent Federal Cases Cast Further Doubt On the Constitutionality of ATF's Proposed Rule.

In addition to *44 Liquormart v. Rhode Island* and *Rubin v. Coors*, the two Supreme Court cases upholding the First Amendment against state attempts to restrict alcoholic beverage labels and advertisements, two recent federal cases dealing with health-related product information call into question the Constitutionality of ATF's proposed rule.

In 1999, an attempt by the Food and Drug Administration to ban certain health statements from dietary supplement labels was held unconstitutional. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *rehearing denied*, 172 F.3d 72 (April 2, 1999). The court rejected as "almost frivolous" the FDA's contention that consumers are easily deceived by product health statements as if they "were asked to buy something while hypnotized." *Id.*, at 655.

In 1998, another FDA rule restricting manufacturer distribution of information regarding so-called off label uses of drugs was struck down as unconstitutional. *Washington Legal Foundation v. Friedman*, 13 F.Supp. 2d 51 (D.D.C. 1998). Again, regarding the government's asserted need to protect recipients of this information, the court concluded that "to endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection … is practically an engraved invitation to have the restriction struck." *Id.*, at 70.

Here, the medical evidence is at least as strong, and ATF's speculation of an easily- misled populace is at least as weak, as in these two cases involving the FDA.

CONCLUSION

ATF's proposed rule is both unsupported by the evidence and in violation of the First Amendment. For these reasons, the proposed rule should be withdrawn.

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