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The Power of Positive Drinking: Are Alcoholic Beverage Health Claims Constitutionally Protected?

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I. INTRODUCTION

It seems almost too good to be true that moderate consumption of alcoholic beverages substantially reduces one's risk of contracting heart disease, but a wealth of published studies have shown it to be an accurate statement. Today, few medical experts dispute that light drinkers, on average, have significantly lower rates of cardiovascular disease and live longer than both abstainers and heavy drinkers. Given that heart disease is the leading cause of death in both adult men and women, the potential benefits for a well-informed public are substantial.

Predictably, many alcoholic beverages industry members would like to put "heart healthy" messages on product labels and advertisements; however, the federal government has blocked nearly every such attempt. The Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), which has authority over alcoholic beverage labels and advertisements, asserts that any health-related claim would be misleading unless it detailed the risks of heavier drinking and explained every category of individual unlikely to benefit. The agency admits that a statement meeting its standard would almost certainly be too wordy for practical use in labeling or advertising, but insists its policy is not a ban and does not violate the First Amendment.

Recent commercial speech case law casts doubt, however, on the constitutionality of so broad a restriction. The legal precedent strongly suggests that there is a First Amendment right for producers to use, and consumers to read, accurate summary statements about moderate drinking and health on alcoholic beverage labels and advertisements.

II. THE MEDICAL EVIDENCE ON MODERATE DRINKING AND HEALTH

Over the past twenty-five years, a substantial body of published research has concluded that moderate consumption of alcoholic beverages (usually defined as one to two drinks per day) reduces the risk of cardiovascular disease. In 1992, a *New England Journal of Medicine* review of research on the major means of preventing myocardial infarction noted, "there is a substantial body of observational epidemiologic evidence to suggest that moderate consumption of alcohol reduces the risk of heart disease."¹ Various studies found reductions in heart attack risk of thirty to fifty-four percent for both men and women. Among the studies 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 forty percent reduction in coronary heart disease risk as compared to

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The Competitive Enterprise Institute's (CEI's) 1996 lawsuit challenging the federal government's policy regarding alcoholic beverage health claims was dismissed, without prejudice, on procedural grounds. *See* CEI v. O'Neill, No. 96-2476 (D.D.C. June 18, 2001), *appeal dismissed*, CEI v. O'Neill, No. 01-5241, 2002 WL 1359478 (D.C. Cir. May 10, 2002).

¹ JoAnn E. Manson et al., *The Primary Prevention of Myocardial Infarction*, 326 *NEW ENG. J. MED.* 1406, 1412 (1992).

nondrinkers, and concluded that “the net effect of moderate alcohol intake might therefore be expected to be beneficial”², and

- a 1991 *Lancet* study of more than 50,000 men, which, after adjusting for numerous 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.³

Since that time, the evidence for the benefits of moderate consumption has continued to mount.

- A 1995 research monograph published by the Royal College of Physicians states that “low to moderate drinking, variously defined, is associated with a lower risk of CHD [coronary heart disease] than in non-drinkers.”⁴
- A 1996 research monograph published by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) states that “consumption of alcohol, in small to moderate amounts, protects against the development of coronary heart disease (CHD).”⁵
- A 1997 *New England Journal of Medicine* study of 490,000 men and women 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.”⁶
- A 2003 *New England Journal of Medicine* study of 38,000 men concluded that “[a]mong men, consumption of alcohol at least three to four days per week was inversely associated with the risk of myocardial infarction.”⁷

The health effects of moderate alcohol consumption are now accepted so widely that they are mentioned routinely in cardiology textbooks. For example, *Heart Disease: A Textbook of Cardiovascular Medicine* states that “overt coronary heart disease has been shown to be inversely related to moderate alcohol consumption”⁸

Heart disease accounts for approximately one in three deaths; thus the potential benefits of reducing cardiovascular risk are substantial.⁹ While there are health risks associated with alcohol consumption, these risks are relatively small for most adults compared to the cardiovascular risks. Indeed, cardiovascular disease account for forty-five percent and thirty-seven percent of all deaths among men and women, respectively, while all alcohol-related deaths (largely from excessive drinking) accounts for only seven percent and fifteen percent of deaths.¹⁰ By examining the effects of moderate consumption not only on heart disease, but also on overall mortality, numerous studies have found that the benefits outweigh the risks—that is, moderate consumption increases average 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.”¹¹

² Meir J. Stampfer et al., *A Prospective Study of Moderate Alcohol Consumption and the Risk of Coronary Disease and Stroke in Women*, 319 *NEW ENG. J. MED.* 267, 270 (1988).

³ Eric B. Rimm et al., *Prospective Study of Alcohol Consumption and Risk of Coronary Artery Disease in Men*, 338 *LANCET* 464, 467 (1991).

⁴ ROYAL COLLEGE OF PHYSICIANS, *ALCOHOL AND THE HEART IN PERSPECTIVE: SENSIBLE LIMITS REAFFIRMED* 14 (1995).

⁵ NAT’L INST. ON ALCOHOL ABUSE AND ALCOHOLISM, *ALCOHOL AND THE CARDIOVASCULAR SYSTEM* 16 (1996).

⁶ Michael J. Thun et al., *Alcohol Consumption and Mortality Among Middle-Aged and Elderly U.S. Adults*, 337 *NEW ENG. J. MED.* 1705, 1711 (1997).

⁷ Kenneth J. Mukamal et al., *Roles of Drinking Pattern and Type of Alcohol Consumed in Coronary Heart Disease in Men*, 348 *NEW ENG. J. MED.* 109 (2003).

⁸ EUGENE BRUNWALD, *HEART DISEASE: A TEXTBOOK OF CARDIOVASCULAR MEDICINE* 1154 (4th ed. 1992).

⁹ Manson et al., *supra* note 1, at 1406.

¹⁰ Thun et al., *supra* note 6, at 1711.

¹¹ Arthur L. Klatsky, *Alcohol and Mortality*, 117 *ANNALS INTERNAL MED.* 646 (1992).

- A 1994 *British Medical Journal* study concluded that “[f]or most causes of death studied, mortality was higher in non-drinkers than in light drinkers”¹²
- A 1997 *New England Journal of Medicine* study found that “those who consumed up to one or two drinks of alcohol daily had lower overall mortality rates than nondrinkers.”¹³

Researchers have excluded the possibility that some factor other than moderate consumption is responsible for these health effects. For example, the 1991 *Lancet* study 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.”¹⁴ In particular, the hypothesis that the higher mortality of nondrinkers is due to seriously ill persons who gave up drinking (the so-called 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.”¹⁵

Although women suffer heart disease at lower rates than men, the overall mortality benefits from moderate alcohol consumption apply to them as well. For example, a 1995 *New England Journal of Medicine* study concluded “these findings indicate that for women as a group light-to-moderate alcohol consumption confers a significant overall survival advantage.”¹⁶

The Departments of Agriculture (USDA) and Health and Human Services (DHHS) now recognize the health benefits of moderate drinking. Since 1995, USDA and DHHS have acknowledged these benefits in their *Dietary Guidelines for Americans*, which state that “[c]urrent evidence suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals.”¹⁷ The most recent version has retained this message but modified the wording to “[d]rinking in moderation may lower the risk for coronary heart disease, mainly among men over age 45 and women over age 55.”¹⁸ Both versions also contained a discussion of the risks of drinking. The *Dietary Guidelines* were established under the National Nutrition Monitoring and Related Research Act of 1990, and “shall be promoted by each Federal agency in carrying out any federal food, nutrition, or health program.”¹⁹

III. THE PROPOSED PRODUCT HEALTH MESSAGES

In 1991, the national news program *60 Minutes* ran a segment about the health benefits of moderate wine consumption. Afterwards, a number of wineries sought approval to publicize this information through product labels and advertisements. Among the substantive statements submitted for approval on product labels and advertisements since that time are:

¹² Richard Doll et al., *Mortality in Relation to Consumption of Alcohol: 13 Years' Observations on Male British Doctors*, 309 BRIT. MED. J. 911, 915 (1994).

¹³ Thun et al., *supra* note 6, at 1712.

¹⁴ Rimm et al., *supra* note 3, at 468.

¹⁵ Paolo Boffeta et al., *Alcohol Drinking and Mortality Among Men Enrolled in an American Cancer Society Prospective Study*, 1 EPIDEMIOLOGY 342 (1990).

¹⁶ Charles S. Fuchs et al., *Alcohol Consumption and Mortality Among Women*, 332 NEW ENG. J. MED. 1245, 1250 (1995).

¹⁷ U.S. DEP'T OF AGRICULTURE & U.S. DEP'T OF HEALTH AND HUMAN SERVS., DIETARY GUIDELINES FOR AMERICANS 40 (4th ed. 1995).

¹⁸ U.S. DEP'T OF AGRICULTURE & U.S. DEP'T OF HEALTH AND HUMAN SERVS., DIETARY GUIDELINES FOR AMERICANS 36 (5th ed. 2000).

¹⁹ 7 U.S.C. § 5341.

- “Several medical authorities say that a glass of wine or two enjoyed daily is not only a pleasant experience but can be beneficial to an adult’s health”;
- “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”;
- “Recent studies suggest that wine may reduce the risk of heart disease”; and
- “There is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of heart disease.”²⁰

The Bureau of Alcohol, Tobacco and Firearms (ATF; now TTB) has not approved any of these statements. The agency even raised objections to the use of heart shape in a Valentine’s Day wine promotion, and threatened to revoke the federal permit of a winery after it discussed the *60 Minutes* segment in its newsletter.²¹

Although the benefits of moderate alcohol consumption have been reported in the general media, there still are a number of people not well informed about them.²² Further, studies have shown that one of the most effective means of communicating a product health message is through labels on, and advertisements of, that product.²³

IV. FEDERAL RESTRICTIONS ON HEALTH CLAIMS

Under the Federal Alcohol Administration Act (FAAA), regulatory authority over alcoholic beverage labeling and advertising rests with TTB.²⁴ TTB regulations allow “curative and therapeutic claims” on alcoholic beverage labels unless they are false or misleading.²⁵ Such labels must be approved in advance by TTB.²⁶ These regulations also allow accurate “curative and therapeutic claims” on alcoholic beverage advertisements.²⁷ Advertisements are not subject to TTB prior approval, but are subject to TTB oversight.

ATF (TTB’s predecessor in implementing the FAAA prior to the reorganization under the Homeland Security Act of 2002), had maintained a strict policy of not approving any substantive health claims. In its 1993 Industry Circular, entitled *Health Claims in the Labeling and Advertising of Alcoholic Beverages*, ATF conceded that “there is currently a growing body of scientific research and other data that seems to provide evidence that lower levels of drinking decrease the risk of death from coronary artery disease.”²⁸ The agency 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.”²⁹ In the interim, the agency stated that it would continue to evaluate health statements on a case-by-case basis, and that any such statements would be rejected as 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.”³⁰ ATF

²⁰ Copies of the applications are on file with the author.

²¹ Copies of the letters are on file with the author.

²² A 1995 poll commissioned by the Competitive Enterprise Institute found that only 42 of those responding were aware of the cardiovascular benefits of moderate drinking.

²³ See Pauline M. Ippolito & Alan D. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, in BUREAU OF ECONOMICS STAFF REPORT, FEDERAL TRADE COMMISSION (Aug. 1989).

²⁴ Federal Alcohol Administration Act, 27 U.S.C. §§ 201 et seq.

²⁵ 27 C.F.R. §§ 4.39(h), 5.42(b)(8), 7.29(e).

²⁶ 27 U.S.C. § 205(e); 27 C.F.R. §§ 4.50, 5.55, 7.41.

²⁷ 27 U.S.C. § 205(f); 27 C.F.R. §§ 4.64(i), 5.65(d), 7.54(e).

²⁸ BUREAU OF ALCOHOL, TOBACCO AND FIREARMS, HEALTH CLAIMS IN THE LABELING AND ADVERTISING OF ALCOHOLIC BEVERAGES 2 (1993).

²⁹ *Id.* at 1.

³⁰ *Id.* at 4.

concluded that it “considers it extremely unlikely that such a balanced claim would fit on a normal alcoholic beverage label.”³¹

In the nearly ten years since the Industry Circular, ATF (and now TTB) has not approved a substantive health statement for alcoholic beverage labels. In 1998, then-Secretary of the Treasury Robert E. Rubin stated that “[t]his is a difficult standard to satisfy and no label has met it to date.”³²

In 1995 and 1996, two wine industry entities sought approval for the following statements:

- “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.”;
- “To learn the health benefits of moderate wine consumption, write for the federal government’s *Dietary Guidelines for Americans*”³³

ATF refers to these claims as directional because they do not provide substantive health information; instead they direct consumers to third-party sources. After several years of wrangling with ATF over the exact language—at the agency’s insistence, the words “benefits” and “moderate” were removed—the following claims were approved in February 1999:

- “The proud people who made this wine encourage you to consult your family doctor about the health effects of wine consumption.”; and
- “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 website <http://www.usda.gov/fcs/cnpp.htm>.”³⁴

The approvals of these directional claims came at the end of an extensive review by ATF and other agencies. ATF sponsored a survey, conducted by DHHS’ Center for Substance Abuse Prevention (CSAP),³⁵ which tested the consumer impact of the proposed directional statements, including whether they would confuse consumers about the risks of drinking or obfuscate the message in the mandatory health warning statement.³⁶ Released in January 1998, the survey results found that “[n]either of the two labels . . . would likely induce wine drinkers to alter their drinking pattern, quantitatively or otherwise.”³⁷ It found that those exposed to the health-related statements still had a “[g]eneral understanding: there are risks of alcoholism, and certain conditions would counterindicate wine drinking.”³⁸ CSAP’s Director noted subsequently that “[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.”³⁹ In response to concerns regarding the message’s effect on preg-

³¹ *Id.* at 4.

³² Letter on file with the author.

³³ Applications on file with the author.

³⁴ BUREAU OF ALCOHOL, TOBACCO & FIREARMS, DECISION MEMORANDUM: APPROVAL OF TWO HEALTH RELATED STATEMENTS ON WINE LABELS (1999).

³⁵ CENTER FOR SUBSTANCE ABUSE PREVENTION, DEP’T OF HEALTH AND HUMAN SERVS., THE EFFECTS OF WINE LABELS ON PUBLIC PERCEPTION (1998) [hereinafter CSAP SURVEY].

³⁶ The FAAA was amended in 1988 to require a warning statement on all alcoholic beverage containers. 27 U.S.C. § 213 et seq. This statement reads as follows: “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.” At present, this is the only health-related statement allowed to appear on alcoholic beverage labels.

³⁷ CSAP SURVEY, *supra* note 35, at 2.

³⁸ *Id.*

³⁹ Copy of letter on file with author.

nant women, the Director stated that “the population studied overwhelmingly understands that drinking is counter-indicated during pregnancy.”⁴⁰

Even before the 1999 approvals, a number of anti-alcohol organizations and individuals had raised strong objections, most notably two U.S. Senators. Both Senators Robert Byrd (D-WV) and Strom Thurmond (R-SC) threatened to reduce ATF’s jurisdiction over alcoholic beverage labeling and advertising if these statements were allowed.⁴¹ In response, Secretary Rubin assured both Senators that “[b]ased upon ATF’s own analysis of the two labels and upon the results of the CSAP survey, ATF has made a final determination that the labels do not mislead consumers.”⁴² Similarly, the Director of ATF assured the Senators that the CSAP survey “provided no evidence that the labeling statements would mislead consumers as to the overall health consequences of alcohol consumption,” and that “ATF has no legal basis for rejecting these labels.”⁴³

ATF proposed a rule for alcoholic beverage health claims—six years later than first promised in 1993.⁴⁴ In December 1999, ATF announced in a press release that it would no longer approve wine labels containing either of the previously approved statements until the rule was finalized.⁴⁵

ATF subsequently sought dismissal of CEI’s pending 1996 legal challenge to its policy, on the grounds that the final rule would resolve all matters without the need for judicial intervention. In 2001, the U.S. District Court for the District of Columbia dismissed the case as prudentially unripe.⁴⁶

In March 2003, TTB finalized its rule, thus codifying its longstanding policy of rejecting any substantive health statement unless it is “sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks.”⁴⁷ TTB insisted that the rule did not categorically ban substantive health information as inherently misleading, but did not provide any examples of statements that would meet its requirements. The agency conceded that “the regulations make it difficult to present a substantive health claim (for example, one involving cardiovascular benefits associated with moderate alcohol consumption) on an alcohol beverage label, because of the level of qualification and explanation that would be necessary to set forth the risks associated with such consumption.”⁴⁸

TTB’s policy toward directional claims is only slightly less restrictive. Under it, the two previously approved directional statements, and others like them, will be rejected as misleading unless accompanied by the disclaimer “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons,” or similar wording.⁴⁹ In effect, a directional statement would have to be followed by a sentence declaring it to be irrelevant.

⁴⁰ Copy of letter on file with author.

⁴¹ Copies of the letters are on file with author.

⁴² Copies of the letters are on file with author.

⁴³ Copies of the letters are on file with author.

⁴⁴ Bureau of Alcohol, Tobacco and Firearms, Dep’t of the Treasury, Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcoholic Beverages, 64 Fed. Reg. 57,413 (Oct. 25, 1999).

⁴⁵ Bureau of Alcohol, Tobacco and Firearms, Dep’t of the Treasury, Press Release, “ATF Announces Public Hearings on Health Claims,” (Dec. 9, 1999).

⁴⁶ *CEI v. O’Neill*, No. 96-2476 (D.D.C. June 18, 2001), *appeal dismissed*, *CEI v. O’Neill*, No. 01-5241, 2002 WL 1359478 (D.C. Cir. May 10, 2002).

⁴⁷ Dep’t of the Treasury, Alcohol and Tobacco Tax and Trade Bureau, Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages, 68 Fed. Reg. 10,075, 10,090 (Mar. 3, 2003).

⁴⁸ *Id.* at 10,100.

⁴⁹ *Id.* at 10,097.

In contrast to its extensive analysis prior to approving the two statements, TTB conceded that it had no empirical evidence to justify its change in position.⁵⁰ Nor did the agency present any evidence that the directional health statements actually had misled or harmed anyone during the period they had been in use. TTB now asserts that, rather than actually asking their doctors about drinking and health (or consulting the *Dietary Guidelines*), consumers will read the message and draw their own incorrect conclusions, and may suffer serious consequences as a result.⁵¹

Under the final rule, none of the substantive or directional health statements previously submitted to TTB would be approved. Given the undesirability of meeting TTB's disclaimer requirements, the likely effect of the rule will be to silence industry use of health information.

V. FIRST AMENDMENT PROTECTIONS FOR COMMERCIAL SPEECH

The Supreme Court has made it clear that alcoholic beverage labeling and advertising is constitutionally-protected commercial speech. In 1995, the Court struck down ATF restrictions on the use of percent alcohol content on beer containers.⁵² One year later, it held unconstitutional a state ban on liquor store price advertising.⁵³ The standard the Supreme Court applied to this speech was first set out in 1980 in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*:

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."⁵⁴

Under this test, TTB's new rule and its policy banning virtually all succinct health messages likely will be struck down on First Amendment grounds.

A. Only Demonstrably Misleading Speech May Be Banned, and Any Restrictions Must Be Narrowly Tailored

Under the *Central Hudson* test, commercial speech may be restricted if it is determined to be misleading, however, "the party seeking to uphold a restriction on commercial speech carries the burden of justifying it."⁵⁵ Furthermore, "[t]his burden is not satisfied by speculation and 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"⁵⁶ Arguments for government suppression that rest on "anecdotal evidence and educated guesses" do not satisfy this test.⁵⁷ A justification for banning speech will fail when "the State's argu-

⁵⁰ *Id.* at 10,096.

⁵¹ *Id.* at 10,096.

⁵² *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

⁵³ *44 Liquormart Inc. v. Rhode Island*, 517 U.S. 484 (1996).

⁵⁴ 446 U.S. 557, 566 (1980).

⁵⁵ *Bolger v. Youngs Drug Prods. Co.*, 463 U.S. 60, 71 n.20 (1983).

⁵⁶ *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993).

⁵⁷ *Coors Brewing Co.*, 514 U.S. at 490.

ments amount to little more than unsupported assertions: nowhere does the State cite any evidence or authority of any kind . . .”⁵⁸ Moreover, the Court has stated that “[t]he absolute prohibition on appellant’s speech, in the absence of a finding that his speech was misleading, does not meet these requirements,”⁵⁹ and “[g]iven the complete absence of any evidence of deception . . . we must reject the contention that petitioner’s [speech] is actually misleading.”⁶⁰

The final steps of the *Central Hudson* test require that restrictions on speech directly serve a substantial state interest, and be no more extensive than necessary.⁶¹ These steps “basically involve a consideration of the ‘fit’ between the legislature’s ends and the means chosen to accomplish those ends.”⁶² “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.”⁶³ “[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.”⁶⁴ 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 sweeping speech restrictions repeatedly have failed these steps.⁶⁵

Using this substantial weight of Supreme Court precedent, entities under Food and Drug Administration (FDA) jurisdiction have challenged successfully the constitutionality of restrictions on product health information.⁶⁶ There is no reason to believe wineries regulated by TTB would not fare as well.

B. TTB’s Speech Restrictions Fail the *Central Hudson* Test

With regard to substantive health claims, TTB offers nothing more than speculation and conjecture that such claims, absent the now-required lengthy qualifications, are misleading. Although the agency declined to state that all substantive health claims are inherently misleading and can be categorically banned,⁶⁷ in practice there is no real distinction between the rule and all-out suppression. Given the space limitations of labeling and advertising, no substantive health statements meeting TTB’s standards could ever see the light of day.

Governmental assertions that a message is misleadingly incomplete without lengthy explanations have been 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.”⁶⁸ In rejecting a state ban on lawyer advertisements considered insufficiently comprehensive to properly inform prospective clients, the Supreme Court stated that:

⁵⁸ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 648 (1985).

⁵⁹ *In re R.M.J.*, 455 U.S. 191, 207 (1982).

⁶⁰ *Peel v. Attorney Reg. & Disciplinary Comm’n*, 496 U.S. 91, 106 (1990).

⁶¹ *Central Hudson*, 447 U.S. at 566.

⁶² *Coors Brewing Co.*, 514 U.S. at 486 (quoting *Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 341 (1986)).

⁶³ *In re R.M.J.*, 455 U.S. at 203.

⁶⁴ *Zauderer*, 471 U.S. at 646.

⁶⁵ *Coors Brewing Co.*, 514 U.S. at 485-87; *44 Liquormart*, 517 U.S. at 505-07.

⁶⁶ *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) (FDA policy restricting manufacturer distribution of information regarding unapproved uses of drugs held unconstitutional); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (FDA rule banning several health claims for dietary supplements struck down under the First Amendment).

⁶⁷ 68 Fed. Reg. at 10,090.

⁶⁸ *Central Hudson*, 557 U.S. at 562.

[I]t 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.⁶⁹

Although demonstrably misleading speech may require clarifying disclaimers, those disclaimers must be “no broader than reasonably necessary to prevent the deception.”⁷⁰

It also is worth noting that the risks of alcohol consumption for which TTB now demands exhaustive explanation are listed in the *Restatement (Second) of Torts* as an example of a product risk “generally known and recognized” for which a seller’s duty to warn is excused.⁷¹

TTB’s *de facto* ban on substantive health information absent prohibitively lengthy qualifications does not pass constitutional muster. TTB has not demonstrated any misleading effect necessitating such disclaimers. A governmental “concern about the possibility of deception in hypothetical cases is not sufficient to rebut the constitutional assumption favoring disclosure over concealment.”⁷² Even if disclaimers are necessary, TTB’s requirements for them are far too unreasonable under the *Central Hudson* test.

TTB’s already-high burden in justifying its restrictions on health-related information is made higher still in the case of the previously-approved directional claims. “[A]n 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.”⁷³

TTB has not met its burden in demonstrating that directional statements, without the newly-mandated disclaimer, can be banned as misleading, nor has the agency justified its reversal of course on the two previously-approved claims. TTB cannot point to anything misleading about a message encouraging people to seek health information from their physicians or to read the *Dietary Guidelines*. Instead, the agency offers speculation and conjecture that such statements “could be interpreted as encouraging the consumption of alcohol for health reasons.”⁷⁴ TTB has no evidence to support this assertion, nor does it explain why it would be misleading for those consumers who indeed would benefit from moderate drinking to draw such a conclusion.

TTB has offered no study that counters the findings of the CSAP survey and demonstrates a misleading effect. The agency has not refuted the prior conclusions by the Secretary of the Treasury, the Director of ATF, or the Director of CSAP that the approved directional claims are not misleading and legally cannot be banned. Nor has TTB presented any evidence that the directional claims had actually misled anyone during the time in 1999 when they were in use.

The agency admits that it has no consumer data beyond the CSAP study, thus it concedes that it “must rely upon the secondary data that is available to us, including the opinions of medical and public health experts in the field of alcohol and health.”⁷⁵ This

⁶⁹ *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-75 (1977).

⁷⁰ *In re R.M.J.*, 455 U.S. at 203.

⁷¹ RESTATEMENT (SECOND) OF TORTS § 402A cmt. j.; see Erik Bierbauer, *Liquid Honesty: The First Amendment Right to Market the Health Benefits of Moderate Alcohol Consumption*, 74 N.Y.U. L. REV. 1057, 1097 (1999).

⁷² *Peel*, 496 U.S. at 111.

⁷³ *Motor Vehicle Mfr’s Ass’n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

⁷⁴ 68 Fed. Reg. at 10,096.

⁷⁵ *Id.*

includes a former U.S. Surgeon General as well as “many of the foremost public health experts in the nation.”⁷⁶ But none of these experts presented any evidence to support their conclusions. Further, most of these individuals are physicians and public health officials, thus their expertise is not directly relevant here. Directional claims contain no medical information to evaluate, and physicians and public health officials are not experts on the public perceptions of advertising claims.

Given the complete lack of evidence supporting TTBB’s assertion that substantive or directional moderate consumption health claims are misleading, the agency’s action apparently rests on the paternalistic assumption that the public needs to be protected from this information. The final rule posits that alcoholic beverage health statements on labels or advertisements have “the potential to mislead consumers as to the very serious health consequences associated with alcohol abuse and consumption.”⁷⁷ Of course, an agency always can find speech misleading by assuming that the recipients are misled easily. With regard to alcoholic beverage advertising, 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.⁷⁸

“It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.”⁷⁹ In its most recent commercial speech decision, the Supreme Court reiterated, “[W]e have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information.”⁸⁰ In holding unconstitutional an FDA policy limiting the distribution of information on so-called off-label uses of drugs, a federal district court stated 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”⁸¹

VI. CONCLUSION

TTBB’s recent final rule codifies an agency policy that has served as a *de facto* ban on succinct references to the health benefits of moderate alcohol consumption on product labels and advertisements. This policy violates the Constitution. The agency has not demonstrated, to the satisfaction of First Amendment commercial speech scrutiny, that such health statements are misleading absent the now-mandated disclaimers. Further, the disclaimer requirements are unreasonable, and would serve to keep virtually all such health information off product labels and advertisements, to the detriment of both producers and consumers.

⁷⁶ *Id.*

⁷⁷ *Id.* at 10,089.

⁷⁸ 44 *Liquormart*, 517 U.S. at 503.

⁷⁹ *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976).

⁸⁰ *Thompson v. Western States Medical Center*, 535 U.S. 357, 374 (2002).

⁸¹ *WLF v. Friedman*, 13 F. Supp. 2d at 70.