June 26, 2019

The Hon. Steven Mnuchin
Secretary of the Treasury
Department of the Treasury
1500 Pennsylvania Ave., NW
Washington, DC 20220

RE: TTB Notice 176, "Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages"

Dear Secretary Mnuchin:

The undersigned consumer and public health groups appreciate the opportunity to submit comments on the above-referenced Nov. 26, 2018 notice of the Alcohol and Tobacco Tax and Trade Bureau (TTB). As some of our groups explained in an earlier letter, any effort to "modernize" alcohol labeling should include requirements for basic information—serving size, calories, nutrient levels, ingredients, and allergen information—that consumers have come to take for granted in products that do not contain alcohol.[1] We write separately here to urge TTB to provide for a cancer warning on all alcoholic beverages.

The Alcoholic Beverage Labeling Act (ABLA) of 1988 requires that a specific health warning statement appear on the labels of all containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States. The ABLA further directs TTB, "in consultation with the Surgeon General," to update the health warning statement if "available scientific information would justify a change in, addition to, or deletion of the statement."[2] Specifically, the ABLA provides that TTB "shall promptly report such information to the Congress together with specific recommendations for such amendments to this subchapter as the Secretary determines to be appropriate and in the public interest." *Id.*

The available scientific information shows that consuming "even one drink per day"[3] of alcohol increases cancer risk. A "modernized" label for alcoholic beverages should therefore carry a warning that reflects this scientific understanding. In conjunction with this rulemaking, TTB should recommend to Congress that the ABLA health warning statement be amended to include the following statement: **GOVERNMENT WARNING: According to the Surgeon General, consumption of alcoholic beverages can cause cancer, including breast and colon cancers.**

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[1] Letter from Consumer Federation of America, Center for Science in the Public Interest and National Consumers League to Secretary Mnuchin re TTB Notice 176, ""Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages" (Feb. 22, 2019), *available at*: https://consumerfed.org/testimonial/consumer-advocates-plead-for-modernization-of-alcohol-labeling-to-include-basic-nutrition-facts/

[2] 27 U.S.C. § 217

[3] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, p.6-11. Washington, DC: HHS, November 2016, ["Surgeon General's Report"], https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf.

The other elements of the existing warning statement—i.e. "Women should not drink alcoholic beverages during pregnancy because of the risk of birth defects," and "Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems"—should continue to appear, as the available scientific evidence indicates a continuing need for those messages.[4] Rather than appearing together, however, the three warning statements should rotate on alcohol labels, a feature that research on tobacco and other warning labels shows to more effectively capture consumer attention.[5] That body of research also indicates that TTB should act on its authority to determine the placement and size of the warning statement by requiring it to be more prominent and conspicuous.[6] In doing so, TTB would increase consumer awareness, and bring alcohol labeling into greater consistency with other hazardous products like tobacco.[7]

The Consensus on Alcohol and Cancer

The proposed warning statement has the potential to greatly improve public health. According to the National Cancer Institute, "there is a strong scientific consensus that alcohol drinking can cause several types of cancer."[8] Yet most consumers remain unaware of this link. A 2017 telephone survey of 1,004 U.S. adults found that just 39% of respondents knew that alcohol increases cancer risk. The results of that survey, conducted every two years by the American Institute for Cancer Research, indicate that public awareness has actually decreased from 2001, when 42 percent of respondents identified alcohol as a cancer risk.[9] Several other studies, discussed further below, indicate that most U.S. consumers do not associate alcohol consumption with increased cancer risk.

The available scientific information, however, leaves little doubt that alcohol use significantly contributes to the burden of cancer illnesses. The World Health Organization documented the link between alcohol and a variety of cancers in 1987.[10] Since then, the scientific consensus that even moderate alcohol consumption can cause cancer has grown. Of particular relevance to the TTB, the

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[4] *See, e.g.,* May PA, Chambers CD, Kalberg WO, et al. Prevalence of Fetal Alcohol Spectrum Disorders in 4 US Communities. JAMA. 2018;319(5):474–482. doi:10.1001/jama.2017.21896; (deriving "estimated prevalence of fetal alcohol spectrum disorders across 4 sites in the United States" that were "consistent with mounting evidence that harmful fetal alcohol exposure is common in the United States today."); Surgeon General's Report, *supra* note 3 ("In 2014, 9,967 people were killed in motor vehicle crashes while driving under the influence of alcohol, representing nearly one third (31 percent) of all traffic-related fatalities in the United States.").

[5] *See, e.g.,* Hammond. "Health warning messages on tobacco products: a review," *Tobacco Control* 2011;20:327-337, *available at*: https://tobaccocontrol.bmj.com/content/20/5/327

[6] *See* 27 U.S.C. § 215(b) ("The statement required by subsection (a) of this section shall be located in a conspicuous and prominent place on the container of such beverage, as determined by the Secretary, shall be in type of a size determined by the Secretary, and shall appear on a contrasting background.").

[7] *See* 15 U.S.C. § 1333(a)(2)(providing that warning statements on tobacco "shall comprise the top 50 percent of the front and rear panels of the package.").

[8] National Cancer Institute, "Alcohol and Cancer Risk," https://www.cancer.gov/about-cancer/causes-prevention/risk/alcohol/alcohol-fact-sheet

[9] American Institute for Cancer Research, "Survey: Fewer than half of Americans recognize alcohol, processed meats, other controllable factors affect cancer risk," Feb. 1, 2017, *available at*: http://www.aicr.org/press/press-releases/2017/Fewer-than-half-of-Americans-recognize-alcohol-processed-meats-affect-cancer-risk.html

[10] Ian Austen, "Yukon Government Gives In to Liquor Industry on Warning Label Experiment," *N.Y.Times*, Jan. 6, 2018, https://www.nytimes.com/2018/01/06/world/canada/yukon-liquor-alcohol-warnings.html

consensus on alcohol and cancer includes the Surgeon General, whose recent report, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, concludes that "[e]ven one drink per day may increase the risk of breast cancer" and that higher levels of alcohol consumption are associated with "cancers of the oral cavity, esophagus, larynx, pharynx, liver, colon, and rectum."[11]

The Surgeon General's findings are consistent with those of other public health authorities. The American Society of Clinical Oncology (ASCO) noted in a 2017 statement on alcohol and cancer that "the relationship between drinking alcohol and cancer risk has been evaluated extensively in epidemiologic case-control and cohort studies" and that "[e]ven modest use of alcohol may increase cancer risk."[12] According to the World Health Organization's International Agency for Research on Cancer (IARC), "Alcohol consumption causes cancers of the oral cavity, pharynx, larynx, oesophagus, colorectum, liver (hepatocellular carcinoma) and female breast."[13] The National Toxicology Program of the U.S. Department of Health and Human Services similarly lists consumption of alcoholic beverages as a known human carcinogen in its Report on Carcinogens. And the American Institute for Cancer Research states on its website that "there is strong evidence that consuming alcoholic drinks increases the risk of mouth, pharynx and larynx cancers, oesophageal cancer (squamous cell carcinoma), [and] breast cancer (pre and postmenopause)."[14]

Cancers associated with alcohol consumption affect nearly 90,000 Americans each year. Researchers estimate that, in the U.S., alcohol consumption represents the third largest contributor to cancer cases in women (behind smoking and obesity) and the fourth largest contributor to cancer in men (behind smoking, obesity, and UV radiation).[15] In 2014, alcohol consumption was associated with an estimated 6.4%--50,110--of all cancer cases in women, and 4.8%--37,410--of all cancer cases in men. According to the researchers, "the largest burden by far was for female breast cancer (39,060 cases)."[16]

How Alcohol Causes Cancer

The above estimates, and the more general conclusion that alcohol causes cancer, are based on both epidemiological studies of human populations and animal studies. These studies make clear that all types of alcoholic beverages—beer, wine, and spirits—cause cancer.[17] Alcohol can cause cancer in a variety of ways but acetaldehyde, which the body produces when metabolizing alcohol

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[11] Surgeon General's Report, *supra* note 3, at p.6-11.
[12] LoConte et al. "Alcohol and Cancer: A Statement of the American Society of Clinical Oncology," Journal of Clinical Oncology 2018 36:1, 83-93, https://ascopubs.org/doi/full/10.1200/JCO.2017.76.1155 ["ASCO Statement"]
[13] International Agency for Research on Cancer. Monograph Volume 100E (2012), Consumption of Alcoholic Beverages, *available at*: https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-17/ ("IARC Statement")
[14] World Cancer Research Fund/American Institute for Cancer Research, "Alcoholic drinks and the risk of cancer," https://www.wcrf.org/dietandcancer/exposures/alcoholic-drinks
[15] Islami et at. "Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States." *CA: A Cancer Journal for Clinicians*. 2018 Jan;68(1):31-54. https://doi.org/10.3322/caac.21440
[16] *Id.* at 40.
[17] ASCO Statement, *supra* note 12, at 84 (noting "that the associations between alcohol drinking and cancer risk have been observed consistently regardless of the specific type of alcoholic beverage.").

(ethanol), plays a predominant role.[18] Acetaldehyde is mutagenic, carcinogenic, and highly toxic. As the Centers for Disease Control and Prevention website explains:

> When you drink alcohol, your body breaks it down into a chemical called acetaldehyde. Acetaldehyde damages your DNA and prevents your body from repairing the damage. DNA is the cell's "instruction manual" that controls a cell's normal growth and function. When DNA is damaged, a cell can begin growing out of control and create a cancer tumor.[19]

Animal experiments have demonstrated that ingesting ethanol or acetaldehyde increases the incidence of cancerous tumors.[20] Other experiments have shown that certain genetic make-ups result in higher levels of acetaldehyde build-up in the body, amplifying alcohol's carcinogenic effect.[21] As early as 1996, researchers documented that both everyday drinkers and alcoholics with these "high-risk genotypes" are much more likely to develop esophageal cancer.[22] These and other studies make clear that the correlation between cancer incidence and alcohol use reflects a causal relationship.

Cancer and Moderate Drinking

Cancer risk increases with the amount of alcohol consumed, but even small amounts of alcohol have been shown to cause cancer. As noted in the recent Surgeon General's report, "[f]or breast cancer, studies have shown that even moderate drinking may increase the risk."[23] More specifically, researchers have estimated that every 10 grams of ethanol consumed per day results in a 5% increase in premenopausal breast cancer risk, and an almost 10% risk increase for postmenopausal women.[24] Other cancers are implicated as well. Recent studies have revealed that "light" drinking—defined as less than one alcoholic drink (up to 12.5 g ethanol) per day—is associated with an increased risk of cancer of the oral cavity, pharynx, and esophagus.[25] Overall, researchers have estimated that daily consumption of less than a drink-and-a-half per day accounts for 26–35% of alcohol-attributable cancer deaths in the United States each year.[26]

Despite this body of evidence, some public health researchers have argued that the health benefits associated with moderate drinking outweigh the cancer risks, at least for some individuals.[27]

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[18] Poschl et al. "Alcohol and Cancer," *Alcohol and Alcoholism*, Volume 39, Issue 3, May 2004, Pages 155–165, https://doi.org/10.1093/alcalc/agh057

[19] CDC. "Why Does Alcohol Use Raise Cancer Risk?", https://www.cdc.gov/cancer/alcohol/index.htm

[20] ASCO Statement, *supra* note 12, p. 86.

[21] *Id.*

[22] Yokoyama, A., Muramatsu, T., Ohmori, T., Makuuchi, H., Higuchi, S., Matsushita, S., Yoshino, K., Maruyama, K., Nakano, M. and Ishii, H. (1996) Multiple primary oesophageal and concurrent aerodigestive tract cancer and the aldehyde dehydrogenase-2 genotype of Japanese alcoholics. *Cancer* 77:10, https://doi.org/10.1002/(SICI)1097-0142(19960515)77:10<1986::AID-CNCR4>3.0.CO;2-F

[23] Surgeon General's Report, *supra* note 3, at p. 1-12.

[24] ASCO Statement, *supra* note 12, p.85.

[25] Bagnardi et al. "Light alcohol drinking and cancer: a meta-analysis," *Annals of Oncology*, Volume 24, Issue 2, February 2013, Pages 301–308, https://academic.oup.com/annonc/article/24/2/301/223860

[26] Nelson DE, Jarman DW, Rehm J, Greenfield TK, Rey G, Kerr WC, Miller P, Shield KD, Ye Y, Naimi TS. Alcohol-attributable cancer deaths and years of potential life lost in the United States. Am J Public Health. 2013; 103(4):641–648. [PubMed: 23409916]

[27] *See, e.g.,* Rubin E. To drink or not to drink: that is the question. Alcohol Clin Exp Res. https://onlinelibrary.wiley.com/doi/abs/10.1111/acer.12582

Identifying under which circumstances moderate drinking may contribute to better health outcomes goes beyond the scope of this letter. However, no U.S. public health authority currently advises individuals to begin drinking alcohol if they do not already, and recent research suggests that at least some of the benefits attributed to moderate drinking may be overblown. As the CDC has explained:

> Although past studies have indicated that moderate alcohol consumption has protective health benefits (e.g., reducing risk of heart disease), recent studies show this may not be true. While some studies have found improved health outcomes among moderate drinkers, it's impossible to conclude whether these improved outcomes are due to moderate alcohol consumption or other differences in behaviors or genetics between people who drink moderately and people who don't.[28]

In contrast to this uncertainty, the scientific evidence linking alcohol consumption to cancer is well-established, and growing. A cancer warning label would better equip consumers to judge for themselves whether these risks outweigh alcohol's purported health benefits.

Alcohol Cancer Warnings outside the United States

The linkage between alcohol and cancer has already led to warning labels in several other countries. South Korea's labeling law requires warnings that include the statement: "Alcohol is [a] carcinogen."[29] In Canada, a pilot program in the Yukon required a warning, similar to the one proposed here, that "Alcohol can cause cancer, including breast and colon cancers."[30] In Ireland, a recently enacted law will soon require "a warning that is intended to inform the public of the direct link between alcohol and fatal cancers" on all alcohol product labels and advertisements.[31]

Awareness of the Alcohol-Cancer Link Among U.S. Consumers

Public health authorities identified alcohol as a carcinogen decades ago. Yet the available evidence, while limited, indicates that awareness of the link between alcohol use and cancer remains uncommon among consumers. As mentioned above, the American Institute for Cancer's most

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[28] CDC. "Moderate Drinking" https://www.cdc.gov/alcohol/fact-sheets/moderate-drinking.htm (last visited June __, 2019) *citing* I Chikritzhs T, Fillmore K, Stockwell T. A healthy dose of skepticism: four good reasons to think again about protective effects of alcohol on coronary heart diseaseExternal. *Drug Alcohol Rev* 2009;28:441–4; Andréasson S, Chikritzhs T, Dangardt F, Holder H, Naimi T, Stockwell T. Evidence about health effects of "moderate" alcohol consumption: reasons for skepticism and public health implications.Cdc-pdf[PDF-9.44 MB]External . In: *Alcohol and Society 2014*. Stockholm: IOGT-NTO & Swedish Society of Medicine, 2014; Knott CS, Coombs N, Stamatakis E, Biddulph JP. All cause mortality and the case for age specific alcohol consumption guidelines: pooled analyses of up to 10 population based cohortsExternal. *BMJ* 2015;350:h384; Holmes MV, Dale CE, Zuccolo L, et al. Association between alcohol and cardiovascular disease: Mendelian randomisation analysis based on individual participant data.External *BMJ* 2014;349:g4164; Naimi TS, Brown DW, Brewer RD, et al. Cardiovascular risk factors and confounders among nondrinking and moderate-drinking US adultsExternal. *Am J Prev Med* 2005;28(4):369–73.

[29] International Alliance for Responsible Drinking, Health Warning Labeling Requirements, http://www.iard.org/resources/health-warning-labeling-requirements/ (last visited June __, 2019).

[30] Ian Austen, "Yukon Government Gives In to Liquor Industry on Warning Label Experiment," *N.Y.Times*, Jan. 6, 2018, https://www.nytimes.com/2018/01/06/world/canada/yukon-liquor-alcohol-warnings.html

[31] Public Health (Alcohol) Act 2018, available at: https://www.oireachtas.ie/en/bills/bill/2015/120/

recent (2017) survey shows that just 39% of adults identify alcohol as a cancer risk, and that proportion has actually declined since AICR began conducting the survey in 2001.[32] Unfortunately, the AICR's findings are consistent with other studies on consumer awareness of alcohol's contribution to cancer.

For example, a 1999-2001 survey of 1,120 female college students in the United States found that just 10.1% recognized alcohol as a risk factor for breast cancer.[33] More recently, a survey of 758 undergraduate and graduate students in the southeastern United States found that, while eighty-six percent of participants correctly identified that alcohol leads to an increased risk of liver cancer, awareness of the association between alcohol and head/neck and breast cancers was below fifty percent.[34]

Where researchers have presented respondents with open-ended questions, rather than identifying alcohol as a potential risk factor up front, awareness appears even lower. In a 1999 study asking sixth-grade girls in Wisconsin to list potential causes of cancer, 91% listed smoking, and just 8% listed alcohol.[35] In a 2010 qualitative study of 32 women in North Carolina, none of the respondents identified alcohol as a risk factor for cancer and in an interview one woman made the remark: "I don't really associate alcohol with breast cancer. I don't think there's ever been an alcohol link. Cigarette smoking, yes."[36]

Even among groups with heightened cancer risk, awareness of alcohol's dangers remains low. A 2015 study of 593 survivors of colorectal cancer—a cancer to which alcohol is known to specifically contribute[37]—found that "15% had never heard of recommendations to limit alcohol," and 11% were only "slightly familiar" with those recommendations. The researchers further found that "survivors received less social support for limiting alcohol than for healthy eating and less than half of survivors recalled medical providers discussing alcohol consumption with them."[38]

Surveys in other countries have revealed comparable collective blind spots.[39] Perhaps because of this low awareness, research abroad further suggests that consumers will appreciate and

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[32] *See* AICR *supra* note 9.
[33] Peacey et al. "Low levels of breast cancer risk awareness in young women: an international survey," *Eur J Cancer* (2006), https://www.ncbi.nlm.nih.gov/pubmed/16829071?dopt=Abstract
[34] *See* Scheideler, Klein. "Awareness of the Link between Alcohol Consumption and Cancer across the World: A Review."*Cancer Epidemiol Biomarkers* (2018), 429-437. DOI: 10.1158/1055-9965.EPI-17-0645 *citing* Merten JW, Parker A,Williams A, King JL, Largo-Wight E, Osmani M. "Cancer risk factor knowledge among adults." *J Cancer Edu* 2016;32:865–70.
[35] Nichols HB, Trentham-Dietz A, Newcomb PA, Yanke L, Remington PL, Love RR. What causes cancer? Reports from sixth-grade girls. *J Cancer Educ* 2006;21:142–6.
[36] Spector et al. "Breast Cancer Risk Perception and Lifestyle Behaviors among White and Black Women with a Family History" *Cancer Nurs.* 2009 Jul–Aug; 32(4): 299. doi: 10.1097/NCC.0b013e31819deab0, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2814775/
[37] *See* IARC Statement, *supra* note 13.
[38] Hawkins et al. "Awareness of Dietary and Alcohol Guidelines Among Colorectal Cancer Survivors." *American Journal of Preventive Medicine* (2015), https://www.sciencedirect.com/science/article/pii/S0749379715004869
[39] *See, e.g.* Bates el al. "Awareness of alcohol as a risk factor for cancer is associated with public support for alcohol policies." *BMC Public Health* (2018) 18:688, https://doi.org/10.1186/s12889-018-5581-8 (In cross-sectional survey of 2100 adult residents in England "Thirteen per cent of the sample were aware of the alcohol-cancer link unprompted, a further 34% were aware when prompted and 53% were not aware of the link."); *see also* Buykx et al. "Public support for alcohol policies associated with knowledge of cancer risk," *International Journal of Drug Policy*, Vol.26:4,

respond to a cancer warning statement by drinking less. Research shows that sufficiently prominent health warning messages on tobacco packages have motivated smokers to quit or cut down,[40] and surveys of consumers in Australia and the United Kingdom suggest that cancer warning labels could have a similar effect. In particular, an online survey of 1,680 adult drinkers in Australia found that "cancer warning statements have the potential to encourage drinkers to reduce their alcohol consumption."[41] Similarly, a study in the United Kingdom, which involved 1,884 online respondents, found that cancer warnings stimulated respondents' "motivation to drink less."[42]

Finally, studies suggest that, regardless of their impact, consumers want and appreciate information about the link between alcohol consumption and cancer. Participants in a recent focus group study in the Yukon, for example, cited "the consumer's right to know" in expressing support for alcohol warning labels there.[43] And in focus groups associated with the Australian study cited above, "[o]verall, responses to the cancer statements were neutral to favorable, indicating that they are unlikely to encounter high levels of negative reaction from the community if introduced on alcoholic beverages."[44]

Conclusion

The available scientific evidence makes clear that even moderate alcohol consumption increases cancer risk. For the reasons discussed, any effort to "modernize" alcohol labeling should include a report to Congress that recommends amending the health warning statement on alcoholic beverages to include a cancer warning, as provided for under the ABLA.

Thank you for your consideration of these comments.

Sincerely,

American Institute for Cancer Research

American Public Health Association

Breast Cancer Action

Center for Science in the Public Interest

2015, pp. 371-379, https://doi.org/10.1016/j.drugpo.2014.08.006 (In online survey of 2,482 adults in Australia, "Only 47% of participants identified drinking too much alcohol as a risk factor for cancer.")

[40] Hammond D. (2011) Health warning messages on tobacco products: a review. Tob Control 20:327–37. https://tobaccocontrol.bmj.com/content/20/5/327

[41] Pettigrew et al. "The effect of cancer warning statements on alcohol consumption intentions." *Health Educ Res.* (2016); https://www.ncbi.nlm.nih.gov/pubmed/26787351

[42] Blackwell et al. "Informing drinkers: Can current UK alcohol labels be improved?" *Drug Alcohol Depend.* 2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6204577/

[43] Vallance et al. "We Have a Right to Know": Exploring Consumer Opinions on Content, Design and Acceptability of Enhanced Alcohol Labels," *Alcohol and Alcoholism* (2018), https://academic.oup.com/alcalc/article/53/1/20/4160420

[44] Pettigrew et al. "Developing cancer warning statements for alcoholic beverages," (2014), https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/1471-2458-14-786

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U.S. Alcohol Policy Alliance