

DEPARTMENT OF THE TREASURY ALCOHOL AND TOBACCO TAX AND TRADE  
BUREAU WASHINGTON, D.C.

Petition for a Report to Congress Supporting )  
a Label on Alcoholic Beverages )  
Warning the Public that Consumption Can ) Docket No. \_\_\_\_\_  
Cause Cancer, Including Breast and Colon )  
Cancers )  
)

CITIZEN PETITION

Submitted by:

Alcohol Justice  
American Institute for Cancer Research  
American Society of Clinical Oncology  
American Public Health Association  
Breast Cancer Prevention Partners  
Consumer Federation of America  
Center for Science in the Public Interest  
The U.S. Alcohol Policy Alliance

October 21, 2020

## INTRODUCTION

Cancers associated with alcohol consumption affect nearly 90,000 Americans each year.<sup>1</sup> Drinking alcohol is the third most important modifiable cancer risk factor, behind smoking and obesity.<sup>2</sup> The U.S. Surgeon General recognizes that “[e]ven one drink per day may increase the risk of breast cancer,” and that alcohol consumption is associated with “cancers of the oral cavity, esophagus, larynx, pharynx, liver, colon, and rectum.”<sup>3</sup> Indeed, current research makes clear that alcohol intake increases risk of cancers of the mouth, pharynx and larynx, esophagus, breast, colorectum, stomach, and liver.<sup>4</sup> Yet low awareness of the link between alcohol use and cancer persists among consumers, with surveys showing that less than half of U.S. consumers identify alcohol as a cancer risk.<sup>5</sup>

The Alcoholic Beverage Labeling Act of 1988 (ABLA) requires that a health statement appear on the labels of all containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States.<sup>6</sup> The current health statement reads:

### 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.<sup>7</sup>

Neither the Treasury Department’s Alcohol and Tobacco Tax and Trade Bureau (TTB), nor TTB’s predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), have updated the content of that health statement, or its appearance, since Congress enacted the ABLA over thirty

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<sup>1</sup> Islami F, Goding Sauer A, Miller KD, Siegel RL, Fedewa SA, Jacobs EJ, McCullough ML, Patel AV, Ma J, Soerjomataram I, Flanders WD, Brawley OW, Gapstur SM, Jemal A. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin.* 2018 Jan;68(1):31-54. doi: 10.3322/caac.21440. Epub 2017 Nov 21. PMID: 29160902.

<sup>2</sup> *Cancer Facts & Figures*, AM. CANCER SOC. 42-49 (2019), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf>; Islami F, Goding Sauer A, Miller KD, et al. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin.* 2018;68: 31-54, 36 (“Alcohol intake was the third largest contributor to all cancer cases among women (6.4%; 50,110 cases) and the fourth largest contributor among men (4.8%; 37,410 cases).”)

<sup>3</sup> *Facing Addiction in America: The Surgeon General’s Report on Alcohol, Drugs, and Health*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (HHS), OFFICE OF THE SURGEON GEN.6-11 (Nov. 2016), <https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf> [“Surgeon General’s Report”].

<sup>4</sup> WCRF/AICR: <https://www.wcrf.org/sites/default/files/Alcoholic-Drinks.pdf>

<sup>5</sup> *2019 AICR Cancer Risk Awareness Survey*, AM. INST. FOR CANCER RESEARCH, <https://www.aicr.org/assets/can-prevent/docs/2019-Survey.pdf>; *2019 Health Information National Trends Survey*, National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services, [https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK\\_Cycle=10&qid=1678](https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=10&qid=1678).

<sup>6</sup> 27 U.S. Code § 215. Labeling requirement. “**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.”

<sup>7</sup> *Id.* at § 215(a).

years ago.

Yet the law directs the TTB, “in consultation with the Surgeon General,” to notify Congress of the need to update the health statement if “available scientific information would justify a change in, addition to, or deletion of the statement.”<sup>8</sup> 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.”<sup>9</sup> In other words, while the ABLA limits TTB’s authority to amend the health warning statement on alcoholic beverages, it requires the agency to “promptly” report to Congress when the need for an amendment arises.

This petition requests that TTB report to Congress that available scientific information, accrued over more than three decades, shows that alcohol causes cancer. It asks that TTB recommend that Congress amend the current health disclosure to state as follows:

**WARNING: According to the Surgeon General, consumption of alcoholic beverages can cause cancer, including breast and colon cancers.**

The petition further requests that TTB report to Congress the available scientific evidence in support of rotating health disclosures, as opposed to a single static warning. As described below, studies show that rotating disclosures on products are more effective than static ones, because consumers are more likely to notice information that appears to be new or different.<sup>10</sup>

Such changes have the potential to save lives by ensuring that consumers have a more accurate understanding of the link between alcohol and cancer, which will empower them to better protect their health.

## **CITIZEN’S PETITION**

### **ACTION REQUESTED**

Pursuant to 27 C.F.R. § 70.701, petitioners request that the TTB, in consultation with the Surgeon General, issue a report to Congress, as provided for under 27 U.S.C. § 217, recommending an amendment to the ABLA that provides for a warning to consumers of the cancer risk associated with alcohol consumption. The report to Congress should include a comprehensive review of the scientific data on the link between alcohol and cancer, should request authority to issue a regulation amending 27 C.F.R. § 16.20-22. Based on the petitioners’ review of this data, we believe the following amendment is justified:

#### **§ 16.21 Mandatory label information.**

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<sup>8</sup> 27 U.S.C. § 217 (2012).

<sup>9</sup> *Id.*

<sup>10</sup> *See, e.g.,* Lucy Popova, *Sugar-Sweetened Beverage Warning Labels: Lessons from the Tobacco Industry*, 10 J. CAL. DENTAL ASS’N. 633, 633 (2016) (“Large pictorial rotating warnings are particularly effective.”); David Hammond, *Health Warning Messages on Tobacco Products: A Review*, 20 TOBACCO CONTROL 327, 334 (2011), <https://tobaccocontrol.bmj.com/content/tobaccocontrol/20/5/327.full.pdf>.

(a) There shall be stated on the brand label or separate front label, or on a back or side label, separate and apart from all other information, one of the following required statements:

- (1) GOVERNMENT WARNING: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.
- (2) GOVERNMENT WARNING: Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery and may cause health problems.
- (3) GOVERNMENT WARNING: According to the Surgeon General, consumption of alcoholic beverages can cause cancer, including breast and colon cancers.

(b) The warning statements required for alcoholic beverages in paragraph (a) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of alcoholic beverage sold in bottles, cans, or other product packaging and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the beverage manufacturer, importer, distributor, or retailer to, and approved by, the Alcohol and Tobacco Tax and Trade Bureau.

## **ABOUT THE PETITIONERS**

Alcohol Justice is a national alcohol industry watchdog that uses evidence-based research to support alcohol prevention and advocacy.

The American Public Health Association (APHA) champions the health of all people and all communities, strengthens the profession of public health, shares the latest research and information, promotes best practices and advocates for evidence-based public health policies. APHA is the only organization that combines a nearly 150-year perspective, a broad-based member community and the ability to influence federal policy to improve the public's health.

The American Institute for Cancer Research (AICR) helps the public understand the relationship between lifestyle, nutrition and cancer risk. AICR works to prevent cancer through innovative research, community programs and impactful public health initiatives.

The American Society of Clinical Oncology (ASCO) represents more than 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practice for the prevention, diagnosis, and treatment of cancer are available to all Americans.

Breast Cancer Prevention Partners (BCPP) is a national organization focused solely on preventing breast cancer by reducing exposure to chemicals and radiation linked to the disease. BCPP works with advocates and decision-makers to encourage research and policy initiatives to better understand and reduce exposures to toxic environmental chemicals that contribute to increased rates of breast cancer and other diseases.

Consumer Federation of America is an association of over 250 non-profit consumer

organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions, and food safety organizations.

The Center for Science in the Public Interest (CSPI) is a consumer advocacy organization whose twin missions are to conduct innovative research and advocacy programs in health and nutrition and to provide consumers with current, useful information about their health and well-being. Since 1971, CSPI has served as an independent and effective food industry watchdog and public health advocate.

The U.S. Alcohol Policy Alliance (USAPA) is a nonprofit, nonpartisan organization translating alcohol policy research into public health practice. The Alliance is committed to ensuring that local and statewide organizations engaging in alcohol policy initiatives have access to the science, resources and technical assistance, including support for organizing efforts, required to engage in informed decisions and actions in translating alcohol policy research into public health practice.

## **FACTUAL BASIS**

Petitioners submit this petition because available scientific information demonstrates that consumption of alcoholic beverages carries a significant, recognized, and avoidable cancer risk. Amending the health warning statement on alcoholic beverages to carry a cancer warning will help consumers to make informed choices regarding their health. For purposes of this petition, the term “alcoholic beverages” refers to “any beverage in liquid form which contains not less than one-half of one percent of alcohol by volume and is intended for human consumption,”<sup>11</sup> and the term “alcohol” refers to ethanol or ethyl alcohol.

### *There Is Scientific Consensus that Alcohol Consumption is Linked to Cancer*

According to the National Cancer Institute, “there is a strong scientific consensus that alcohol drinking can cause several types of cancer.”<sup>12</sup> Of particular relevance to the TTB, this 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*, warns of the risks of cancer in connection to alcohol consumption and references findings that “[e]ven one drink per day may increase the risk of breast cancer.”<sup>13</sup>

Yet most consumers remain unaware of the connection between alcohol and cancer.<sup>14</sup> This discrepancy between scientific knowledge and general public awareness suggests that a cancer

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<sup>11</sup> 27 U.S.C. § 214(1) (2012).

<sup>12</sup> *Alcohol and Cancer Risk*, NAT’L CANCER INST., <https://www.cancer.gov/about-cancer/causes-prevention/risk/alcohol/alcohol-fact-sheet> (last visited Feb. 4, 2020).

<sup>13</sup> Surgeon General’s Report, *supra* note 2, at 6-11.

<sup>14</sup> 2019 AICR Cancer Risk Awareness Survey, AM. INST. FOR CANCER RESEARCH, <https://www.aicr.org/assets/can-prevent/docs/2019-Survey.pdf>; 2019 Health Information National Trends Survey, National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services, [https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK\\_Cycle=10&qid=1678](https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=10&qid=1678).

warning statement could significantly improve public health.

There is enormous potential for public health gains given the prevalence of alcohol consumption in the United States. Survey data from 2002 to 2016 have consistently indicated that more than half of the population aged 12 or older reports drinking alcohol within the last 30 days.<sup>15</sup> The data also indicate that excessive drinking, which is associated with the greatest cancer risk,<sup>16</sup> increased over the last decade.<sup>17</sup> In 2015, 22 percent of men and 10 percent of women reported consuming more than 7 drinks per week, and 11 percent of men and 5 percent of women reported consuming more than 14 drinks per week.<sup>18</sup> In 2018, 26.45 percent of people aged 18 or older reported that they engaged in binge drinking in the past month (defined as five or more alcohol drinks for males and four or more alcohol drinks for females on the same occasion, i.e. at the same time or within a couple hours of each other), and 6.6 percent reported that they engaged in heavy alcohol use in the past month (defined as binge drinking on five or more days per month).<sup>19</sup>

The high level of alcohol consumption in the United States contributes to tens of thousands of cancer cases each year. American Cancer Society researchers estimate that, in 2014, alcohol consumption was associated with an estimated 6.4 percent of all cancer cases in women, or 50,110 cases, and 4.8 percent of all cancer cases in men, or 37,410 cases.<sup>20</sup> Data from the Institute for Health Metrics and Evaluation's Global Health Data Exchange estimate that in 2017, 10,387 U.S. deaths from colon and rectum cancer and 7,434 U.S. deaths from breast cancer were attributable to alcohol use.<sup>21</sup>

The ACS researchers note that “the largest burden by far was for female breast cancer (39,060 cases),” and point out that, in the United States, 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).<sup>22</sup> Such estimates are based upon a substantial body of convincing evidence that links alcohol to cancer. The World Health Organization's International Agency for Research on Cancer (IARC) documented the link between alcohol and a variety of cancers in 1987.<sup>23</sup> More recently, in 2012, the IARC considered new data on alcohol's contribution to cancer, and once again concluded that “[t]here is sufficient

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<sup>15</sup> *Health, United States, 2017 – Data Finder*, NAT'L CENTER FOR HEALTH STATISTICS, [https://www.cdc.gov/nchs/hus/contents2017.htm?search=Alcohol\\_use](https://www.cdc.gov/nchs/hus/contents2017.htm?search=Alcohol_use) (last visited Feb. 4, 2020).

<sup>16</sup> Noelle K. LoConte et al., *Alcohol and Cancer: A Statement of the American Society of Clinical Oncology*, 36 J. CLINICAL ONCOLOGY 83, 83-93 (2018), <https://ascopubs.org/doi/full/10.1200/JCO.2017.76.1155>. [“ASCO Statement”]

<sup>17</sup> Ralph W. Hingson et al., *Drinking beyond the binge threshold: Predictors, consequences, and changes in the U.S.*, 52 Am. J. Prev. Med. 717(2017).

<sup>18</sup> <http://arg.org/news/drinking-norms-in-the-us/>

<sup>19</sup> *Alcohol Facts and Statistics*, NAT'L INST. ALCOHOL ABUSE & ALCOHOLISM, ([last visited](#) , 2020).

<sup>20</sup> Farhad Islami et al., *Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States*, 68 CA CANCER J. CLIN. 31, 36 (2018), <https://doi.org/10.3322/caac.21440>.

<sup>21</sup> *Institute for Health Metrics and Evaluation*, GBD Results Tool, <http://ghdx.healthdata.org/gbd-results-tool> (last visited August 21, 2020).

<sup>22</sup> *Id.* at 36, 40.

<sup>23</sup> *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Alcohol Drinking*, World Health Organization International Agency for Research on Cancer, <https://monographs.iarc.fr/wp-content/uploads/2018/06/mono44.pdf>.

evidence in humans for the carcinogenicity of alcohol consumption,” and that “[a]lcohol consumption causes cancers of the oral cavity, pharynx, larynx, oesophagus, colorectum, liver (hepatocellular carcinoma) and female breast.”<sup>24</sup> The World Health Organization reiterated this causal link in its 2018 Global Status Report on Alcohol and Health.<sup>25</sup>

The IARC reached its conclusion on the basis of epidemiologic case-control and cohort studies that demonstrate a strong association between alcohol use and increased cancer risk, and animal and other studies that shed light on the specific mechanisms by which alcohol causes cancer. The epidemiologic data reveal a strong association between increased cancer risk and consumption of all types of alcohol—beer, wine, and spirits—with the risk higher with greater consumption. The data reviewed by the IARC also indicate that even low levels of consumption (“up to 1 drink/day”) increase the risks of some cancers, including esophageal and breast cancer.<sup>26</sup>

The IARC is not the only scientific authority to conclude that alcohol increases cancer risk. In 2018, the World Cancer Research Fund and American Institute for Cancer Research (WCRF/AICR) updated their report “Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective.”<sup>27</sup> The WCRF/AICR found “strong evidence that consuming alcoholic drinks increases the risk of cancers of the mouth, pharynx and larynx; oesophagus (squamous cell carcinoma) and breast (pre- and postmenopause),” that consuming “two or more alcoholic drinks a day . . . increases the risk of colorectal cancer,” and that consuming “three or more alcoholic drinks a day . . . increases the risk of stomach and liver cancers.”<sup>28</sup> Although the report acknowledges the decreased risk of kidney cancer associated with low/moderate alcohol consumption, this did not outweigh the increased risk of other cancers and the report concludes that “[f]or cancer prevention it’s best not to drink alcohol.”<sup>29</sup>

Other public health and cancer research authorities have arrived at similar conclusions. The National Toxicology Program of the United States Department of Health and Human Services has listed alcoholic beverages as a known human carcinogen since 2000 in its biennial Report on Carcinogens consumption.<sup>30</sup> The American Society of Clinical Oncology (ASCO) issued a statement on alcohol and cancer in 2017, noting that “the relationship between drinking alcohol and cancer risk has been evaluated extensively in epidemiologic case-control and cohort studies,” and

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<sup>24</sup> *Personal Habits and Indoor Combustions*, Monograph Volume 100E, Consumption of Alcoholic Beverages, INT’L AGENCY FOR RESEARCH ON CANCER 472 (2012), <https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-17/> [“IARC Statement”].

<sup>25</sup> *Global Status Report on Alcohol and Health, 2018*. World Health Organization, <https://apps.who.int/iris/bitstream/handle/10665/274603/9789241565639-eng.pdf?ua=1&ua=1>

<sup>26</sup> 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>

<sup>27</sup> See WCRF/AICR. Diet, Nutrition, Physical Activity and Cancer: a Global Perspective. Continuous Update Project Expert Report 2018. Available at [dietandcancerreport.org](http://dietandcancerreport.org).

<sup>28</sup> World Cancer Research Fund/American Institute for Cancer Research. Continuous Update Project Expert Report 2018. Alcoholic drinks and the risk of cancer. Available at [dietandcancerreport.org](http://dietandcancerreport.org)

<sup>29</sup> *Id.*

<sup>30</sup> Alcoholic Beverage Consumption, *Report on Carcinogens*, 14th ed., NAT’L TOXICOLOGY PROGRAM, U.S. DEP’T HEALTH & HUMAN SERVS. (2016), <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/alcoholicbeverageconsumption.pdf>.

that “[e]ven modest use of alcohol may increase cancer risk.”<sup>31</sup> And the 2020 update of the American Cancer Society Guidelines for Diet and Physical Activity for Cancer Prevention advises the public that “it is best not to drink alcohol,” and that “[p]eople who do choose to drink alcohol should limit their consumption to no more than 1 drink per day for women and 2 drinks per day for men,” based on the strong evidence of a link between alcohol and cancer.<sup>32</sup>

### Cancer and “Moderate” or “Light” Drinking

While cancer risk is higher at higher levels of alcohol consumption, even small amounts of alcohol increase the risk of cancer. This is significant because most people who drink are not “heavy” drinkers.<sup>33</sup>

Researchers have tied various cancers to “light” and “moderate” drinking, usually defined as up to one and up to two drinks per day, respectively.<sup>34</sup> As noted in the recent Surgeon General’s report, “[f]or breast cancer, studies have shown that even moderate drinking may increase the risk.”<sup>35</sup> More specifically, researchers estimate that every 10 grams of ethanol consumed per day result in a five percent increase in premenopausal breast cancer risk, and an almost 10 percent risk increase for postmenopausal women.<sup>36</sup> Recent studies also revealed that “light” drinking is associated with an increased risk of cancer of the oral cavity, pharynx, and esophagus.<sup>37</sup> Researchers estimate that daily consumption of up to 1.5 drinks per day accounts for 26–35 percent of alcohol-attributable cancer deaths in the United States each year.<sup>38</sup>

In response to this research, advocates for alcohol consumption point to studies finding an association between moderate drinking and cardiovascular health benefits. However, recent high-quality studies suggest that moderate drinking does not in fact reduce cardiovascular disease risk, or otherwise improve health. As the Centers for Disease Control and Prevention explains on its website:

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,

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<sup>31</sup> 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”]

<sup>32</sup> [American Cancer Society guideline for diet and physical activity for cancer prevention.](#)

Rock CL, Thomson C, Gansler T, Gapstur SM, McCullough ML, Patel AV, Andrews KS, Bandera EV, Spees CK, Robien K, Hartman S, Sullivan K, Grant BL, Hamilton KK, Kushi LH, Caan BJ, Kibbe D, Black JD, Wiedt TL, McMahon C, Sloan K, Doyle C. *CA Cancer J Clin.* 2020 Jun 9. doi: 10.3322/caac.21591.

<sup>33</sup> See *Alcohol Facts and Statistics*, NAT’L INST. ALCOHOL ABUSE & ALCOHOLISM, *supra* note 13.

<sup>34</sup> See Abel EL, Kruger ML, Friedl J. How do physicians define “light,” “moderate,” and “heavy” drinking? *Alcohol Clin Exp Res.* 1998 Aug;22(5):979-84. doi: 10.1111/j.1530-0277.1998.tb03692.x. PMID: 9726266.

<sup>35</sup> Surgeon General’s Report, *supra* note 3, at p. 1-12.

<sup>36</sup> ASCO Statement, *supra* note 12, p.85.

<sup>37</sup> 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>

<sup>38</sup> 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]



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.<sup>39</sup>

More recently, the 2020 Dietary Guidelines Advisory Committee (DGAC) recommended continuing the advice against initiating alcohol consumption for health reasons, stating that “[t]he observational evidence base with respect to alcohol consumption is insufficient to recommend drinking at any level.”<sup>40</sup> Based on cancer studies and other evidence on alcohol and all-cause mortality, the 2020 DGAC concluded that “in terms of health, among those who consume alcohol, drinking less is better for health than drinking more.”<sup>41</sup> Accordingly, the Committee recommended in its report that the next Dietary Guidelines for Americans advise the general public: “Do not begin to drink alcohol or purposefully continue to drink because you think it will make you healthier.”<sup>42</sup> Moreover, “for those who drink alcohol,” according to the DGAC, “recommended limits are up to 1 drink per day for both women and men.” Previous dietary guidelines had recommended no more than two drinks per day for men, but the 2020 DGAC explained that “based on meta-analyses and studies with continuous risk curves, the preponderance of evidence indicates that risks are increased at levels above 1 drink per day on average for both men and women.”<sup>43</sup>

Thus, while ambiguity surrounds past studies claiming to demonstrate an association between light or moderate alcohol consumption and protective effects on cardiovascular or other health, the scientific evidence linking alcohol consumption to cancer is well-established and growing. Consumers have a right to information about this strong evidence of significant harm.<sup>44</sup>

### **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]

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<sup>39</sup> CDC. “Moderate Drinking” <https://www.cdc.gov/alcohol/fact-sheets/moderate-drinking.htm> (last updated in December, 2019) (last visited September \_\_, 2020) 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 disease](#)External. *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 cohorts](#)External. *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 adults](#)External. *Am J Prev Med* 2005;28(4):369–73.

<sup>40</sup> p22

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* At 26.

<sup>43</sup> 2020 DGAC, Ch 11, p. 21-22

<sup>44</sup> By analogy, even tobacco use may generate some health benefits, such as a reduced risk of Parkinson's disease documented among smokers. Yet smoking is universally recognized as harmful because the increased risk of cancer far outweighs these minimal benefits.

carcinogen.”<sup>45</sup> In Canada, a pilot program in the Yukon required a warning, similar to the one proposed here, that “[a]lcohol can cause cancer, including breast and colon cancers.”<sup>46</sup> 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.<sup>47</sup>

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

Public health authorities began identifying alcohol as a carcinogen decades ago.<sup>48</sup> Yet the available evidence on consumer perceptions, while limited, indicates that few consumers are aware of the link between alcohol use and cancer. As mentioned above, the American Institute for Cancer Research’s most recent (2019) survey shows that just 45 percent of adults identify alcohol as a cancer risk.<sup>49</sup> In the National Cancer Institute’s 2019 Health Information National Trends Survey, only 32 percent of respondents identified cancer as a health condition that can result from drinking too much alcohol.<sup>50</sup> Unfortunately, these findings are consistent with other studies on consumer awareness of alcohol’s contribution to cancer.

For example, in a 2010 study of 439 women, only 30 percent of respondents agreed or strongly agreed that alcohol can cause breast cancer and only 41 percent believed alcohol could cause colorectal cancer.<sup>51</sup> Even among groups with heightened cancer risk in the United States, awareness of alcohol’s dangers is limited. A 2015 study of 593 survivors of colorectal cancer—a cancer for which alcohol is an established risk factor<sup>52</sup>—found that “15% had never heard of recommendations to limit alcohol,” and 11 percent were only “slightly familiar” with those recommendations. The researchers also 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.”<sup>53</sup>

### **Rotating Warning Labels are More Effective than Static Labels**

In addition to adding a cancer warning to alcoholic beverage labels, rotating that warning statement with the other, existing health warning statements would improve public health. Researchers have found that, in the tobacco context, “health warnings that are new or periodically

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<sup>45</sup> International Alliance for Responsible Drinking, Health Warning Labeling Requirements, <http://www.iard.org/resources/health-warning-labeling-requirements/> (last visited June \_\_, 2019).

<sup>46</sup> 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>

<sup>47</sup> Public Health (Alcohol) Act 2018, available at: <https://www.oireachtas.ie/en/bills/bill/2015/120/>

<sup>48</sup> See, e.g., Alcohol drinking. Lyon: World Health Organization, International Agency for Research on Cancer. 1988. ISBN 978-92-832-1244-7., p. 8, available at: <https://publications.iarc.fr/62>.

<sup>49</sup> See AICR *supra* note 3.

<sup>50</sup> 2019 Health Information National Trends Survey, National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services, [https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK\\_Cycle=10&qid=1678](https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=10&qid=1678).

<sup>51</sup> Wang C, et al. (2010). Beliefs about the causes of breast and colorectal cancer among women in the general population. *Cancer Causes Control*, <https://pubmed.ncbi.nlm.nih.gov/19787437/>.

<sup>52</sup> See IARC Statement, *supra* note 13.

<sup>53</sup> 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>

updated are likely to have greater impact than ‘older’ warnings, even in the absence of changes in size and position.”<sup>54</sup> Ample evidence indicates that consumers perceive new or updated warnings as “novel,” making these warnings more effective at communicating potential health risks.<sup>55</sup> One study of warning labels in the United Kingdom, United States, Australia, and Canada, for example, found that awareness of risks associated with tobacco increased substantially among United Kingdom consumers after that country updated its warning label.<sup>56</sup> Other researchers have identified a similar “wear-out” effect and advised that warnings be “changed periodically to maintain effectiveness.”<sup>57</sup>

Researchers in the tobacco context have documented that a stock of rotating warnings, tailored to various groups, can be effective to counteract this “wear-out” effect.<sup>58</sup> In general, health warning labels have received praise as “a low-cost, effective measure,”<sup>59</sup> due to their simplicity, compatibility with societal norms, and observability.<sup>60</sup> All of these attributes contribute to health warning labels’ effectiveness in diffusing information to the public. However, studies show that not all warning labels are equal. Indeed, a systematic review examining 32 studies across 20 countries concludes that strengthening warnings increases population-wide knowledge about health risks and that “changing warning statements to include novel content may particularly increase knowledge of the content covered in the messages.”<sup>61</sup>

One of the reasons for this increased knowledge is that different groups of consumers tend to find different messages most compelling. One review of alcohol labeling policies, for example, notes that “health warnings on labels must consider the target audience, drink type, possible drinking venue and patterns of consumption . . . Rotating prominent warnings . . . could ensure that relevant messages reach all consumer profiles.”<sup>62</sup> Indeed, some consumers, such as cancer survivors, will have much greater interest in the new warning message proposed in this petition, whereas others (such as pregnant women) may find elements of the existing warning most compelling. By requiring “a larger number of warnings to rotate on packages,” TTB could “allow

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<sup>54</sup> Hammond, D. (2011, May 23). Health warning messages on tobacco products: a review.

<https://tobaccocontrol.bmj.com/content/tobaccocontrol/20/5/327.full.pdf>.

<sup>55</sup> Hammond, D. *et al.* (2007, May 14). Communicating Risk to Smokers: The Impact of Health Warnings on Cigarette Packages. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1868456/>

<sup>56</sup> *Ibid*

<sup>57</sup> Hitchman, S. C. *et al.* (2014, May). Changes in effectiveness of cigarette health warnings over time in Canada and the United States, 2002-2011. <https://www.ncbi.nlm.nih.gov/pubmed/24323572/>

<sup>58</sup> *Ibid*; *see also* Noar, S. M. *et al.* (2016, July 13). The impact of strengthening cigarette pack warnings: Systematic review of longitudinal observational studies. Retrieved from

<https://www.sciencedirect.com/science/article/pii/S0277953616302921>

<sup>59</sup> Hiilamo, H., Crosbie, E., & Glantz, S. A. (2012, October 23). The evolution of health warning labels on cigarette packs: the role of precedents, and tobacco industry strategies to block diffusion.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3725195/>

<sup>60</sup> *Ibid*; *see also* Rogers EM. (2003) Diffusion of innovations. New York: Free Press, p.224.

<sup>61</sup> Noar, S. M. *et al.* (2016, July 13). The impact of strengthening cigarette pack warnings: Systematic review of longitudinal observational studies.

<https://www.sciencedirect.com/science/article/pii/S0277953616302921>

<sup>62</sup> Martin-Moreno, J. M. *et al.* (2013, May 8). Enhanced labelling on alcoholic drinks: reviewing the evidence to guide alcohol policy. <https://academic.oup.com/eurpub/article/23/6/1082/438396>.

for greater targeting of subgroups,” thereby commanding greater attention to health warning text.<sup>63</sup> Eventually, TTB could add to the stock of rotating warnings advice for moderating or avoiding alcohol consumption.

## LEGAL BASIS

In passing the ABLA, Congress found “that the American public should be informed about the health hazards that may result from the consumption or abuse of alcoholic beverages,” and “determined that it would be beneficial to provide a clear, nonconfusing reminder of such hazards.”<sup>64</sup> Toward that end, Congress required that the following 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:

### 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.<sup>65</sup>

Congress further specified that this statement “shall be located in a conspicuous and prominent place on the container of such beverage,” and gave regulators 90 days after passage of the Act to determine the size, type, and design of the warning statement.

On February 14, 1990, the Bureau of Alcohol, Tobacco and Firearms (ATF) issued final regulations in 27 C.F.R. Part 16 implementing the ABLA.<sup>66</sup> The regulations require that the words “GOVERNMENT WARNING” appear in capital letters and in bold type, but the remainder of the warning statement may not appear in bold type. Since those regulations were issued, the warning statement has remained unchanged. However, the scientific understanding of alcohol’s health impacts, and of the alcohol health warning label’s efficacy, has continued to evolve.

Congress intended for alcoholic beverage labeling requirements to likewise evolve over time to accommodate new scientific evidence. The ABLA directs the TTB to engage “in consultation with the Surgeon General” in order to update the health warning statement if “available scientific information would justify a change in, addition to, or deletion of the statement.”<sup>67</sup> 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.”<sup>68</sup>

When Congress passed the ABLA in 1988, scientific understanding of the link between alcohol and cancer was still rudimentary. According to the Surgeon General’s 1988 Report on

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<sup>63</sup> Hammond, D. (2011, May 23). Health warning messages on tobacco products: a review. <https://tobaccocontrol.bmj.com/content/tobaccocontrol/20/5/327.full.pdf>.

<sup>64</sup> 27 U.S.C. § 213.

<sup>65</sup> *Id.* at § 215(a).

<sup>66</sup> 55 FR 5414.

<sup>67</sup> 27 U.S.C. § 217

<sup>68</sup> *Id.*

Nutrition and Health, “[s]moking and alcohol appear to act synergistically to increase the risk for cancers of the mouth, larynx, and esophagus,” but the evidence demonstrating “a role of alcohol in other types of cancers such as those of the liver, rectum, breast, and pancreas” was “[l]ess conclusive and somewhat conflicting.”<sup>69</sup> Over three decades later, the evidence is no longer conflicting or inconclusive. Alcohol causes cancer.<sup>70</sup>

Given the abundant evidence showing that alcohol causes cancer, the existing warning is clearly inadequate. The proviso that alcohol “may cause health problems” so grossly understates alcohol’s health impacts as to be practically misleading, and TTB should revisit this existing warning language. Moreover, this statement was written nearly three decades ago, before the completion of large prospective cohort studies and genetic research conclusively demonstrating that alcohol causes cancer, or the raft of studies showing increased cancer risk resulting from even “moderate” drinking. Cancer research over the past three decades justifies an “addition” to the health warning statement. TTB must follow its statutory duty to report that information to Congress.

## CONCLUSION

In light of the strong scientific evidence that consumption of alcohol increases the risk of cancer—including cancer of the oral cavity, esophagus, larynx, pharynx, liver, stomach, colorectum, and female breast—the agency must act decisively and report to Congress on the need for a label on alcohol stating that consumption may increase the risk of cancer.

## CERTIFICATION

The undersigned certifies that to the best of their knowledge and belief this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner that are unfavorable to the petition.



Thomas Gremillion, Consumer Federation of America  
On behalf of:  
Alcohol Justice  
American Institute for Cancer Research  
American Society of Clinical Oncology  
American Public Health Association

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<sup>69</sup> The Surgeon General's Report on Nutrition and Health: Summary and Recommendations. 1988, p. 14.

<sup>70</sup> *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES. (HHS), OFFICE OF THE SURGEON GENERAL. 6-11 (Nov. 2016), <https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf> [“Surgeon General’s Report”].

Breast Cancer Prevention Partners  
Consumer Federation of America  
Center for Science in the Public Interest  
The U.S. Alcohol Policy Alliance

