REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-A-16

Subject: Powdered Alcohol

Presented by: Louis J. Kraus, MD, Chair

Referred to: Reference Committee D

(Michael D. Bishop, MD, Chair)

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Resolution 425-A-15, introduced by the Maryland Delegation and referred by the House of Delegates, asked:

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That our AMA (1) adopt policy urging the ban of the distribution and sale of powdered alcohol and (2) lobby Congress and the Administration to ban by law or regulation the distribution and sale of powdered alcohol in the U.S.

METHODOLOGY

English-language articles were selected from a search of the PubMed and Google Scholar databases using the search terms "concentrated alcohol," "crystalline alcohol," "granulated alcohol," "palcohol," and "powdered alcohol" in the article title and/or abstract. Internet sites managed by federal and state agencies and relevant public health organizations were also reviewed. Additional articles were culled from the reference lists contained in the pertinent articles and other publications.

State laws were identified though a search conducted using the legal research database, LexisNexis, as well as publicly available websites featuring state legal compilations. The same search terms used in the literature review were also utilized to identify the laws.

BACKGROUND

Excessive alcohol use, including binge drinking, heavy drinking, and use by pregnant women and those under the age of 21, is the fourth leading preventable cause of death in the United States. Excessive alcohol use led to approximately 88,000 deaths and 2.5 million years of potential life lost annually from 2006–2010. According to the National Institutes on Alcohol Abuse and Alcoholism, alcohol negatively affects the brain and nervous system, heart and cardiovascular system, esophagus and gastrointestinal tract, liver, pancreas, other tissues and organs and the immune response, and increases the risk of several cancers.

Alcohol continues to be the most common substance of abuse among American youth. ⁴ Alcohol consumption patterns vary between adults and underage youth. Among youth who drink, the proportion that reports drinking heavily is higher than that of adult drinkers, increasing from 51% in 12-to 14-year-olds to 72% among 18-to 20-year-olds. ⁵ In 2014, approximately 8.7 million

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Action of the AMA House of Delegates 2016 Annual Meeting: Council on Science and Public Health Report 4 Recommendations Adopted, and Remainder of Report Filed.

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- 1 underage Americans between the ages of 12 and 20 reported using alcohol during the past month,
- 2 including 5.3 million who reported binge alcohol use and 1.3 million who reported heavy alcohol
- 3 use.⁶
- 4 Excessive alcohol consumption contributes to more than 4,300 deaths among youth less than 21
- 5 years of age in the United States each year and accounts for more deaths than all other illicit drugs
- 6 combined.^{2,4} Underage drinking contributes to a wide range of costly health and social problems.
- 7 including motor vehicle crashes (the greatest single mortality risk for underage drinkers); suicide;
- 8 interpersonal violence; unintentional injuries such as burns, falls, and drowning; impaired brain
- 9 function and neurocognitive development; alcohol dependence; risky sexual activity; academic
- problems; and alcohol and drug poisoning. 47,8 The adolescent brain is still developing and is more
- vulnerable to alcohol-induced brain damage and cognitive impairment than the adult brain. ⁹ These
- 12 changes in the adolescent brain make it more susceptible to both addiction and increased substance
- 13 use severity.⁸

Powdered Alcohol

Powdered alcohol is defined as any powder or crystalline substance containing alcohol that is produced for direct use or reconstitution. To create powdered alcohol, alcohol is absorbed and encapsulated by a sugar derivative, such as dextrin. Powdered alcohol can be mixed with liquid to make an alcoholic beverage. Powdered alcohol dates back to the 19th century, with references in patent filings as early as 1877. Several additional patents for powdered alcohol were approved in the 1960s and 1970s. 12,13 In the 1970s, a Japanese company, Sato Foods, sold powdered alcohol as a food additive. However, these products were never used or marketed as a base for alcoholic beverages.

Powdered alcohol, as a base for alcoholic beverages, has been available outside of the United States for more than a decade. In 2005, a German company briefly sold a powdered alcohol product called Subyou online and later in retail stores. ¹⁴ Geraldi Corporation, based in Panama, distributes Subyou Be True, which is "alcohol in powder." ¹⁵ It is available in several flavors including blood orange vodka, ron tropical, lime ron, and blackberry vodka. ¹⁵ In 2007, Dutch students developed a product known as Booz2Go, but the product was never successfully marketed. ¹⁶ In 2010, Pulver Spirits sought approval by the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) for an alcoholic powder product for retail sale, but ultimately decided not to proceed because of regulatory hurdles. ¹⁷

In 2014, the TTB initially approved and then later retracted the labels for Lipsmark, LLC's powdered alcohol product, Palcohol. After minor labeling changes were accomplished, the TTB granted approval for the sale of Palcohol in the United States.¹⁸

PUBLIC HEALTH CONCERNS

A number of potential health harms led to calls for state and federal regulators to ban the sale of Palcohol. In Baltimore, pediatricians, emergency physicians, and public health leaders expressed concerns including:

[p]owdered alcohol is easier to conceal, facilitating use by youth...[and making] oversight more difficult for parents, teachers, and law enforcement officials. Powdered alcohol may also lead to greater and unintentional alcohol consumption, which can lead to poisoning, motor vehicle accidents, and even death.¹⁹

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Powdered alcohol differs from other alcoholic products, in that the final alcohol concentration will depend on the amount of powder or liquid used in mixing the beverage. Concerns have been raised that multiple packets of powdered alcohol could be mixed together or that powdered alcohol could be mixed with liquid alcoholic beverages instead of water to increase alcohol concentrations. Packets of powdered alcohol could also be mixed with energy drinks, a combination (caffeine and alcohol) that has previously raised safety concerns.

Furthermore, concerns have been raised that powdered alcohol will make it easy to "spike" nonalcoholic beverages. ^{20,21} Since the product is in powdered form, it could be self-administered via nasal insufflation ("snorted") (as initially acknowledged though later retracted on Palcohol's website), to induce rapid intoxication. ²¹ Palcohol flavors include rum, vodka, and three cocktail varieties, powderita, cosmopolitan, and lemon drop; some of these flavors may be more appealing to youth.

THE PALCOHOL RESPONSE TO PUBLIC HEALTH CONCERNS

Palcohol founder, Mark Phillips, posted a video on the product's website and wrote a letter to the editor, published in JAMA, disagreeing with public health concerns. 22,23 Mr. Phillips specifically addressed snorting the product, which he argues is unlikely because it is painful and physically impossible to snort enough powder to equal one drink. 22,23 In terms of spiking someone's drink, he argued that this will be difficult given the time it takes for the powder to dissolve. He also addressed the issue of the product being easy to conceal by showing a mockup of the product's container, which is designed to be used as a cup. The dimensions of the package are 4 inches by 6 inches with a 2 inch gusset. In terms of access by children, he argued that the product will only be sold in stores to individuals who are 21 years of age and older. Phillips addressed concentration issues by noting that Palcohol is only 10% alcohol by volume and "if multiple packets are added to less liquid, it becomes mush."

REGULATORY AUTHORITY AND ACTIONS

The 21st Amendment granted states the authority to create regulatory and enforcement systems for the sale and consumption of alcoholic beverages. However, the Federal government retains a role in the regulation of alcohol products given their authority to tax and regulate interstate commerce.

Federal

Federal authority to regulate alcohol is currently split among several agencies. In November 1987, the Bureau of Alcohol, Tobacco, and Firearms (now the TTB)^a signed a memorandum of understanding with the FDA clarifying the enforcement responsibilities of each agency with respect to alcoholic beverages considered adulterated under the Federal Food, Drug, and Cosmetic Act.²⁵ The TTB, which falls under the Department of Treasury, has the authority to review the formulation and labeling of distilled spirits products.²⁴ The FDA has the authority to take action with respect to adulterated food products, including alcohol.²⁵ The Federal Trade Commission regulates the advertising of alcoholic beverages.

As noted above and consistent with its authority, the TTB approved labels for Palcohol in 2015. The label indicates that the product is 58% alcohol by weight and 12% alcohol by volume. ¹⁸ The

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^a The Bureau of Alcohol, Tobacco, and Firearms still exists within the Department of Justice, but was reorganized under the Homeland Security Act of 2002, with the tax functions being transferred to the Department of Treasury.

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- label contains the standard government warning regarding drinking alcohol during pregnancy and the risk of birth defects as well as the fact that alcoholic beverages impair one's ability to drive a car or operate machinery and cause health problems. On March 12, 2015, Senator Charles Schumer (D-NY) introduced S.728, the Sober Truth on
- 5 Preventing (STOP) Underage Drinking Reauthorization Act. In addition to reauthorizing the
- 6 program to reduce underage drinking for FY2016 FY2019, the bill would make it unlawful to
- 7 "make, sell, distribute, or possess powdered alcohol." The bill provides a penalty for violators
- 8 including a fine of not more than \$5,000, imprisonment for not more than 1 year, or both. ²⁶ The
- 9 STOP ACT, which has no cosponsors, was referred to the Committee on Health, Education, Labor, and Pensions.

and Pensions

On March 13, 2015, the FDA reported that consistent with the agency's authority, they "evaluated the regulatory status of the non-alcohol ingredients" in these products. The FDA concluded that the ingredients used were in compliance with FDA regulations and are "typical of ingredients found in many processed foods." Furthermore, the FDA indicated that it did not have concerns that the ingredients, when added to the alcoholic beverage products, would render the product as adulterated under the Federal Food, Drug, and Cosmetic Act. The FDA indicated that it did not have concerns adulterated under the Federal Food, Drug, and Cosmetic Act.

 State

States have the authority to regulate the production, sale, and distribution of alcohol within their borders. Alcohol laws and regulations vary widely from state to state, and may be more restrictive than federal regulations. ²⁸ Although many states license private businesses to sell alcohol, 17 states control alcohol sales themselves. ²⁹

In 1980, Alaska was the first state to prohibit the sale of alcohol unless it was in liquid form. ¹⁰ The law was amended in 1995 to specifically prohibit alcohol in powdered form. In 2014, three states (Louisiana, South Carolina, and Vermont) enacted statutory bans on powdered alcohol. In 2015, approximately 90 bills were introduced in 40 jurisdictions on powdered alcohol. ³⁰ Twenty-three states (Alabama, Connecticut, Georgia, Hawaii, Illinois, Indiana, Kansas, Maine, Maryland, Michigan, Minnesota, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Tennessee, Utah, Virginia, and Washington) enacted statutory bans on powdered alcohol in 2015. In 2016, Idaho, Massachusetts, and West Virginia enacted legislation banning powdered alcohol. California, Florida, Kentucky, Maryland, Missouri, and Rhode Island are currently considering legislation to ban the product (see Figure 1).

 The laws enacted in Maryland and Minnesota are unique in that they provide for a temporary ban on the sale of powdered alcohol through June of 2016.³⁰ The Minnesota statute calls on the Director of the Division of Alcohol and Gambling Enforcement as well as the Commissioner of the Department of Health to make recommendations for legislation addressing any concerns.³¹ The Commissioner of Health subsequently recommended a ban on the manufacture, importation, distribution or sale of powdered alcohol in Minnesota.²⁰ The legislature, to date, has not taken action on this recommendation. Maryland is currently considering legislation that would establish a permanent ban on powdered alcohol.

Of the states that have enacted laws, 20 establish penalties for violating the ban on powdered alcohol. Several states also include provisions providing for the suspension and revocation of licenses and permits for violators. Twelve state statutes include an exemption allowing the use of powdered alcohol by groups (hospitals, state institutions, private colleges or universities, pharmaceutical or biotechnology companies) conducting *bona fide* scientific research. Several states have defined powdered alcohol for the purpose of regulating it. These states include

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California, Colorado, Delaware, and New Mexico. Colorado's law authorizes the state licensing authority to adopt rules establishing a mechanism for regulating the manufacture, purchase, sale, possession, and use of powdered alcohol.³² It also authorizes the state's Department of Revenue to promulgate rules concerning the excise tax applied to powdered alcohol at 60.26 cents per liter based on the recommended amount of water specified to be added by the manufacturer's packaging.³²

In states that control alcohol sales themselves, legislative approval may not be required to ban powdered alcohol. For example, the state's liquor control boards in Maryland, Massachusetts, New Hampshire, and Pennsylvania made the decision to outlaw powdered alcohol products. 33-36

DISCUSSION

 As the federal agency responsible for regulating alcohol products, TTB has limited statutory authority and expertise to directly address public health and safety issues. ²¹ Similarly, the FDA's role in regulating alcohol products involves reviewing the safety of the non-alcohol ingredients rather than examining the overall public health and safety issues related to use of the product. ²¹ Therefore, decisions regarding the potential health and safety threat of alcohol products are often made at the state level.

Nevertheless, the FDA has previously acted to address harmful alcohol-containing products. For example, state and federal regulators were encouraged to act when young people became ill and died after consuming pre-mixed caffeinated alcohol drinks.³⁷ In 2010, after a year of studying the issue, the FDA sent warning letters to four companies marketing malt alcoholic beverages containing added caffeine.³⁸ The FDA warned that caffeine, as used in these products, is an "unsafe food additive" and therefore the product is "adulterated" under the Federal Food, Drug and Cosmetic Act.³⁸ In response, the four companies ceased adding caffeine to their products, and, by summer 2011, malt-based beverages with added caffeine were no longer available in the U.S.

In the case of powdered alcohol, the FDA does not have concerns regarding adulteration. However, with 32 states banning the product either through the legislative process or by a decision of the state alcohol control board, concerns clearly exist regarding the potential harms of the product, particularly to minors. Although selling alcohol to youth under age 21 is illegal in all 50 states and the District of Columbia, underage youth find it relatively easy to acquire alcohol, often from adults. The creator of Palcohol touts the product as "light and compact," which will likely raise the attractiveness of the product to youth. The harms that could arise from mixing powdered alcohol with liquid alcohol or even with energy drinks raises the potential for dangerous patterns of use. A 2015 national poll found that 90% of adults are concerned that powdered alcohol will be misused by people under the age of 21 and 60% of adults favor a complete ban on powdered alcohol in their states. The product alcohol will be a good adults favor a complete ban on powdered alcohol in their states.

 Given the unavailability of the product, no research has been conducted to either substantiate or disprove these concerns. However, it has been argued that in the absence of data proving that the product is safe, the precautionary principle should be applied.²¹ The precautionary principle states that, "in cases of serious or irreversible threats to the health of humans or ecosystems, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures."⁴¹

POLICY STATEMENTS

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Current AMA policy does not address powdered alcohol. However, our AMA has numerous 1 policies addressing the harmful effects of alcohol on youth (See Appendix A). AMA policy 2 3 supports environmental strategies to reduce youth access to, and high consumption of, alcohol. 4 Furthermore, AMA policy supports banning the marketing of alcohol products that appeal to youth under the age of 21. Among members of the Federation, the American College of Emergency 5 6 Physicians adopted a resolution supporting a ban on powdered alcohol in 2015. 42 7 8 **CONCLUSION** 9 10 Alcohol is the most widely used substance of abuse among America's youth. Excessive alcohol use 11 is responsible for 4,300 deaths among underage youth every year. 4 Current AMA policy supports efforts to reduce youth access to and high consumption of alcohol. Previous experience with novel 12 alcohol products that appealed to youth, including alcohol energy drinks, has demonstrated the 13 14 potential for overuse and harm. For these reasons, the Council believes our AMA should support a ban on powdered alcohol. 15 16 17 RECOMMENDATIONS 18 19 The Council on Science and Public Health recommends that the following recommendation be 20 adopted, and the remainder of the report be filed. 21 22 That our American Medical Associate supports federal and state laws banning the manufacture, importation, distribution, and sale of powdered or crystalline alcohol intended 23 24 for human consumption. (New HOD Policy)

Fiscal note: Less than \$500

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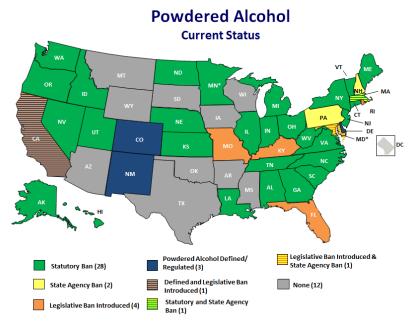
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FIGURE 1



^{*} Temporary Statutory Ban (MD, MN)

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APPENDIX A

H-60.941 Effects of Alcohol on the Brains of Underage Drinkers

Our AMA encourages increased medical and policy research on the harmful effects of alcohol on adolescents and young adults and on the design and implementation of environmental strategies to reduce youth access to, and high consumption of, alcohol.

H-60.92 5 Effects of Alcohol on the Brains of Underage Drinkers

Our AMA supports creating a higher level of awareness about the harmful consequences of underage drinking.

H-30.961 Student Life Styles

Our AMA (1) supports educational programs for students that deal with the problem of alcoholism and drugs, and (2) encourages educational institutions to continue or institute efforts to eliminate the illegal and inappropriate use of alcohol and other drugs on their premises or at their functions.

D-60.973 Prevention of Underage Drinking: A Call to Stop Alcoholic Beverages with Special Appeal to Youths

1. Our AMA will advocate for a ban on the marketing of products such as alcopops, gelatin-based alcohol products, food-based alcohol products, alcohol mists, and beverages that contain alcohol and caffeine and other additives to produce alcohol energy drinks that have special appeal to youths under the age of 21 years of age. 2. Our AMA supports state and federal regulations that would reclassify Alcopops as a distilled spirit so that it can be taxed at a higher rate and cannot be advertised or sold in certain locations.

D-30.997 Eliminate Underage Alcohol Consumption

Our AMA will support evidence-based public health/environmental policies to curtail destructive and high-risk drinking.

D-170.998 Alcohol and Youth

Our AMA will work with the appropriate medical societies and agencies to draft legislation minimizing alcohol promotions, advertising, and other marketing strategies by the alcohol industry aimed at adolescents.