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Public health and medicine's need to respond to cannabis commercialization: A commentary

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Abstract

Cannabis legalization has resulted in rapid commercialization, making this new market increasingly attractive to tobacco, alcohol and beverage, agricultural, and pharmaceutical multinational corporations, who are well-positioned to capitalize on synergy between cannabis and their products. The fact that cannabis remains a Schedule I drug under the Controlled Substances Act is inhibiting research, which consequently prevents evidence-based regulation of modern, more potent, engineered cannabis products and their use. Without a research exemption for legitimate studies of commercially available products, cannabis' Schedule I classification makes it very difficult to conduct medical and scientific research to inform policymaking and regulation. As corporate commercialization looms large, public health organizations need to engage the issue of rapid commercialization of cannabis products and press for evidence-based policies based on public health best practices.

Cannabis legalization is accelerating with legal medical and adult-use cannabis global sales of all forms of cannabinoids estimated to go from \$9.2 billion in 2017 to \$47.3 billion in 2027 in North America, with adult-use dominating US sales (Pellechia 2018). Legalization has largely developed without baseline federal oversight or vetting of health-related claims even as corporate entities are positioning themselves at every segment of the supply chain and are creating new intellectual property. This new market is increasingly attractive to tobacco, alcohol and beverage, agricultural, and pharmaceutical multinational corporations, who are well-positioned to capitalize on synergy between cannabis and their products (Barry, Hiilamo, and Glantz 2014). Entry of these corporations with their product development, marketing, and political power will fundamentally change the market and cannabis use. These problems are aggravated by the limited research on the health effects of cannabis, leaving widely publicized therapeutic claims largely unexamined (Halvorson et al.

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DISCLOSURE

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2018). Furthermore, the increased potency of modern engineered cannabis products exceeds that of its 1960s and 1970s counterparts (ElSohly et al. 2016).

In contrast, most discussion of cannabis legalization has been retrospective, with a focus on criminal justice inequalities. In addition, the public health perspective has been largely absent from the discussion and policymaking process (Barry and Glantz 2018). The fact that cannabis remains a Schedule I drug under the Controlled Substances Act is inhibiting research, which consequently prevents evidence-based regulation of cannabis products and their use and puts the onus of regulation, oversight, and advocacy on the states and stakeholders, including public health. Medical and scientific research is needed to discover the health outcomes of engineered potent, modern cannabis products. As corporate commercialization looms large, public health organizations need to engage the issue of rapid commercialization of cannabis products and press for policies based on public health best practices.

Changes in Drug Control and Cannabis Commercialization

As of July 2019, 33 US states had legalized medical and 11 had legalized adult-use cannabis (American Nonsmokers' Rights Foundation 2019). While general cannabis cultivation and use remained illegal at the federal level, the bipartisan 2018 federal Farm Bill legalized hemp, a source of cannabidiol (CBD), subsequently opening the door to commercially packaged cannabis goods at the national level in the US (Gomez 2018). Elsewhere in North America, in October 2018, adult-use legalization took effect in Canada and the Supreme Court of Mexico ruled that bans on personal use of cannabis were unconstitutional. In October 2019, Congress of the Union of Mexico released draft legislation to legalize and regulate cannabis and its derivatives, prioritizing public health, human rights and sustainable development (Pascual 2019). With its neighbors to the north and south entering the field, the US may not be far behind.

The passage of the Farm Bill portends the manner in which federal cannabis legalization may roll out in the US. CBD is a less controversial endocannabinoid than the cannabinoid tetrahydrocannabinol (THC) (Sax 2019). CBD's non-intoxicating effects have engendered public interest that create a lower barrier to corporate entry than THC. The Food and Drug Administration (FDA) held a public hearing on the general health effects of cannabis, and cannabis-derived products (U.S. Food & Drug Administration 2019b). The public hearing included discussion of federal barriers to advancing cannabis research (Grant, 2019), including on negative or positive health outcomes for CBD (U.S. Food & Drug Administration 2019a), barriers to controlled trials for CBD, and pro- (Allworth 2019) and anti-cannabis arguments.

In May 2019, the US Department of Agriculture issued clarifying guidance stating that hemp-derived CBD could enter the flow of interstate commerce (U.S. Department of Agriculture 2019). Alongside the Farm Bill's lifting of the prohibition on international exports of hemp (U.S. Department of Agriculture 2019), the Transportation Security Administration instructed its agents not to search for cannabis and other illegal drugs (Jaeger 2019). In June 2019, the House voted to pass an extension of the Blumenthal amendment

in a rider to an appropriations bill, blocking the federal government from enforcing federal cannabis law in states where the substance is legal, including adult-use cannabis programs in the protections for the first time (Angell 2019). The same month, the House voted to pass a bill allowing banks to service cannabis businesses, something federally chartered banks were currently not allowed to do (Jaeger 2019). This bill granted the cannabis industry access to FDIC banking services and financial instruments, such as loans that have been hard to come by given the interplay of prohibition and restrictions on banks under the Controlled Substances Act (Bowling and Glantz 2019b). (As of December 2019, the bill had not passed the Senate.) In June 2019, Oregon became the first state to legalize interstate commerce of cannabis, in spite of the continuing federal prohibition (Abbott 2019), in part, a response to the glut of in-state cannabis product causing crashing market prices (Ryan 2019).

Tobacco Industry and the Cannabis Market

Tobacco companies have been considering the US cannabis market since at least 1969, when it appeared that cannabis might be legalized (Barry, Hiilamo, and Glantz 2014). A Philip Morris consultant advised that, “The company that will bring out the first marijuana smoking devices, be it a cigarette or some other form, will capture the market and be in a better position than its competitors to satisfy the legal public demand for such products” (Barry, Hiilamo, and Glantz 2014). Since 2013, Altria (parent company of Philip Morris USA) has been granted 41 US patents for vaping devices suitable for cannabis (Roberts 2018). In January 2016, Altria invested US\$20M in Israeli corporation Syqe, which manufactures a metered-dose cannabis inhaler labelled as a medical device (Roberts 2018). In December 2018, Altria purchased a US\$1.9B (45%) stake in Canadian cannabis enterprise Cronos and a \$12.8B stake (35%) in US e-cigarette company Juul and announced plans for coordinated marketing with Marlboro cigarettes (Zaleski 2018). PAX, who produced the sleek, USB-charged cannabis vape pen PAX ERA, spun-off into Juul Labs, which produced and marketed the similar Juul tobacco vape pen (Roberts 2018).

At the same time social norms have shifted toward acceptance of cannabis use, highlighting potential synergy between tobacco and cannabis. While past 30 day prevalence of high school student cigarette smoking declined (from 20.0% in 2007 to 8.8% in 2017), cannabis use remained stable (19.7% vs. 19.8%) (Centers for Disease Control 2017). The historic patterns of tobacco serving as a gateway to cannabis is reversing, with adolescent cannabis often now preceding tobacco use. Weekly cannabis use among teen non-tobacco smokers is associated with increases in subsequent tobacco initiation (OR = 8.3; 95% CI 1.9–36) and 21-year old daily cannabis smokers that were not nicotine dependent (based on the Fagerström Test for Nicotine Dependence) have triple the odds of developing nicotine dependence by age 24 compared with non-nicotine dependent cannabis nonusers (Patton et al. 2005). These findings are consistent with the tobacco companies’ early understanding that cannabinoids and nicotine could be complementary products (Barry, Hiilamo, and Glantz 2014).

Pharmaceutical, agriculture, alcohol and beverage industry activity

Major corporations from the pharmaceutical, agriculture, alcohol and beverage industries are also entering the global cannabis market. In 1998, GW Pharmaceuticals, manufacturer of the CBD-based seizure pharmaceutical Epidiolex, entered into a joint agreement with Hortapharm, the world's largest repository of cannabis seeds, to use their seeds for research. In 2003, GW Pharmaceuticals and German Bayer AG agreed to jointly conduct research on a cannabis extract, and in 2007 Monsanto and Bayer AG agreed to trade technologies, giving Monsanto access to the world's most extensive catalog of cannabis strains (Brown 2016). The Farm Bill will make it easier for agricultural giants such as Monsanto to enter the cannabis market. Arizona-based fentanyl manufacturer Insys Therapeutics, maker of the synthetic THC medication Syndros, financed a significant portion of the successful 2016 "No" campaign on an Arizona ballot initiative to legalize adult-use cannabis (Ingraham 2017), perhaps to protect its pharmaceutical market.

In 2018, Constellation Brands, owner of Corona beer, bought a \$4B USD interest in the Canadian cannabis company Canopy Growth (Dorfman 2018) which has since acquired the vertically integrated U.S.-based Acreage Holdings cannabis production firm in a \$3.4B USD deal (Ayers, Caputi, and Leas 2019). Coors (US-based) and Molson (Canada-based) partnered with the Canadian cannabis company HEXO to develop cannabis-infused beverages (Miles 2018) and U.S. craft brewery New Belgium produced the hemp heart-infused "The Hemporer" beer (Ross 2018). Coca-Cola expressed interest in developing CBD-infused beverages, Heineken's Lagunitas beer developed a non-alcoholic hop water beverage infused with THC, and alcoholic beverage giant Diageo has explored investment opportunities (Miles 2018). Because the beverage, pharmaceutical, food, and agriculture industries have not been investigated as vigorously as other related industries, such as the tobacco industry, their entry into the cannabis market may not engender the same immediate public skepticism as tobacco industry corporate or political activity. This situation may allow these industries to capitalize on shifting public norms of acceptance of cannabis, and influence the political and regulatory agenda-setting surrounding legalization and production of cannabis products to maximize profits at the expense of public health (Barry and Glantz 2018).

Difficulty conducting research inhibits evidence-based regulation

As of October 2019, cannabis was still classified as a Schedule I drug under the Controlled Substances Act, which is defined as one with a high potential for abuse, no currently accepted medical treatment use, and lack of accepted safety for use under medical supervision. This classification makes it very difficult to conduct medical and scientific research to inform policymaking and regulation. The fact that cannabis (except hemp containing CBD) remains on Schedule I means that performing research requires specific approvals from the US Drug Enforcement Administration which are extremely difficult and time-consuming to obtain and can take years. In addition, research is only permitted on cannabis grown at one farm in Mississippi under contract with the National Institute of Drug Abuse (NIDA). It is illegal for researchers to purchase or analyze dispensary or other products that are widely available. These products are of greater diversity in content and

formulation than what is available through the NIDA drug supply. Under the Safe and Drug Free Schools Act, the sanction for universities violating these procedures could include termination of all federal funding. NIDA Director Nora D. Volkow, M.D. testified before the House Committee on Appropriations on April 2, 2019 that, “indeed the moment that a drug gets a Schedule I, which is done in order to protect the public so they don’t get exposed to it, it makes research much harder, and this is because you actually have to go through a registration process, that is actually lengthy and cumbersome, but also, it restricts the source where you can get the particular drug that you are interested in investigating, and this is something that we worked with. Cannabis, is a perfect example or marijuana...” (House Appropriations Committee 2019). Scott Gottlieb, former Commissioner of the FDA, echoed these concerns, stating in an August 2019 interview that state-level cannabis’ impact on public health issues, including youth use and product safety and standardization, demanded federal action, but that federal legalization was likely a few political cycles away from being realized (CSPAN User-Created Clip 2019).

Rapid commercialization is outpacing state and federal regulatory rulemaking, with myriad permutations of novel and traditional cannabis products quickly becoming available to the public in spite of cannabis’ Schedule I status. This situation became acutely evident in the face of the widespread appearance of severe lung disease in (mostly) youth and young adults vaping THC, nicotine, and both products that was identified in fall 2019 (Perrine et al. 2019). Despite the serious lung disease (and deaths) it is practically impossible to study the THC devices that people are actually using because THC remains on Schedule I (Richtel 2019). Creating a research exemption by executive action to allow study of commercially available products in research projects that are approved by federally-recognized institutional review boards that review human and animal research would break this logjam and allow important work to be conducted without opening the floodgates of illicit use under the guise of “research.” Such an exemption would also streamline the process for getting DEA registration to study cannabis (e.g., by creating a separate schedule for research purposes).

In the longer run, descheduling or rescheduling cannabis that operates coextensively with a research exemption would allow research to be performed more efficiently and on a wider array of cannabis products that are actually on the market, so that claims regarding risks and benefits could be fully vetted by the scientific community, the FDA, and the states. When the Farm Bill legalized hemp, Congress explicitly reserved the FDA’s authority and jurisdiction to regulate all cannabis broadly, under its food and drug authorities (U.S. Food & Drug Administration 2018). The expansion of state legalization of medical and adult-use cannabis has bypassed the federal regulatory scheduling structure. This situation makes it more important for health advocates to press the federal government to create an emergency research exemption and reverse or modify cannabis’ Schedule I designation and facilitate needed research and product regulation, particularly for therapeutic claims. Doing so would provide accurate evidence to permit public health authorities, regulators, policy makers to make evidence-based policy and health professionals to respond to questions from their patients and their families regarding cannabis.

The FDA has not exercised jurisdiction over cannabis products that are produced within the state-level legalization structures because these products are still federally illegal under the Controlled Substances Act. One impact of descheduling cannabis would be increased FDA involvement, which would permit assessment of medical claims for cannabis products using standard protocols for assessing drug efficacy and safety. While the states have been requiring limited warning labels on cannabis products (Barry and Glantz 2018), the fact that cannabis products (other than hemp) cannot enter interstate commerce under federal law prevents the FDA from mandating universal warning labels in spite of rapidly advancing commercialization, proliferation of product and electronic devices, and global competition.

Conclusion

Modern cannabis' increased potency over its 1960s and 1970s forebears, and largely unknown health effects, combined with modern product and electronic delivery device commercialization and engineering, may result in measurable population-level epidemiological effects. In light of the rapidly changing market with the entry of major multinational corporations, public health and medical professionals need to play a more visible role in shaping the policy environment to avoid the emergence of new permutations of the tobacco, pharmaceutical, agriculture, alcohol and beverage industries that will develop and promote myriad cannabis products whose health effects have been largely unexamined (Hudak 2016). This situation underscores the need to shift thinking of related public health issues as individual "drug silos" but rather across "psychoactive pleasure drug" industries and interwoven products and consumption and the associated regulatory and control challenges.

To date, the major voluntary health and medical organizations have largely remained on the sidelines of the cannabis legalization debate (Orenstein and Glantz 2019). These organizations need to actively engage these issues at the state and national levels, including seeking an immediate research exemption. A research exemption (from Schedule I status) to allow purchase of dispensary products would allow research to move more expeditiously and would allow researchers to study a greater diversity of products, which could lead to the rescheduling of cannabis if there are proven medical benefits (besides CBD). In addition, rescheduling or descheduling cannabis would facilitate FDA assuming jurisdiction to regulate therapeutic claims and restrict the market to products that are reasonably safe for human use. Until the eventuality of federal cannabis legalization when the federal agencies will have a clearer mandate to regulate cannabis, responsibility to regulate the cannabis market has fallen to the states. As a result, it is important for public health advocates to press states to fill the void by advocating for public health best practices at the state level (Barry and Glantz 2018, Bowling and Glantz 2019b, Bowling and Glantz 2019a, Orenstein and Glantz 2020), including (1) marketing and advertising restrictions (Ayers, Caputi, and Leas 2019); (2) required health warnings and appropriate labeling regarding therapeutic claims of hemp and other cannabis products; and (3) integrated effects of tobacco and cannabis interactions, including the bidirectional gateway effect of cannabis and tobacco, into public education programs.

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