CannaMD

Challenging Florida House Bill 1455

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OBJECTION SUMMARY

The prohibition preventing "qualified physicians from engaging in certain advertising for their practices relating to marijuana for medical use" is rejected for violating the First Amendment rights of qualified physicians (affirmed by *Conant v. Walters*), restraining free trade as articulated by the U.S. Supreme Court in *American Medical Association v. FTC*, and failing to find parallel precedent(s) in the healthcare, pharmaceutical, and/or alcohol industries.

The prohibition preventing qualified physicians from "certifying a certain potency of tetrahydrocannabinol in marijuana" is rejected for lacking scientific rationale, exercising legislative overreach, and interfering with the practice of medicine (understood as distinct from medicine itself, as defined by cases such as *United States of America v. Regenerative Sciences*).

A brief outline of logic follows (please see respective sections for citations and context):

Physician advertising

1. Marijuana may be federally illegal, but being a physician is not. The Courts have routinely recognized this distinction in First Amendment cases, ruling that "it is not true that a mere [medical marijuana] recommendation will necessarily lead to the commission of a federal offense" and that the federal interest in enforcing marijuana prohibition may be a legitimate concern, but it "pales by comparison" to free speech concerns. Any suggestion that television and radio restrictions placed on qualified physicians may be justified by federal government regulation (through the FCC), because of marijuana's federal prohibition, is therefore rejected. As *Conant v. McCaffrey* states: "[T]here is First Amendment protection in the practice of the learned professions."

   One might also argue that the Florida Department of Health (DOH) – which has sole authority to approve medical marijuana applications and issue identification cards required for marijuana purchase – is the ultimate "gatekeeper" for marijuana patients. As no one is suggesting censoring the DOH (which has a medical marijuana public education priority for minority populations written into Senate Bill 8A), the proposed content-based restrictions could be construed as unconstitutional on the basis of

underinclusion (a statute is underinclusive compared to its alleged purpose when it "singles out certain speech, while permitting other similar types of speech that offend the same principles").

2. The American Medical Association (AMA) used to ban physician advertising. In 1975, the Federal Trade Commission (FTC) sued the AMA, claiming the organization's anti-marketing policy constituted unreasonable "restraint of trade." After a seven-year legal battle, the U.S. Supreme Court upheld a lower court ruling barring the AMA from restricting physician advertising and the solicitation of patients.

   With the First Amendment understanding established above (affirming that qualified physician advertising is not inciting "imminent lawless action"), the proposed bill directly contradicts the Supreme Court's ruling in *American Medical Association v. FTC* and inhibits the ability of qualified physicians to fully participate within the free market.

3. The proposed bill seeks to ban physician advertising on television and radio and require DOH approval for all Internet marketing, yet similar standards cannot be found in the healthcare, pharmaceutical, and/or alcohol industries.

   Mainstream physicians are bound simply by AMA ethical guidelines and the FTC Act (FTCA) to avoid "false or misleading" and "unfair or deceptive" statements and practices. All forms of advertising and free speech remain available and intact.

   While drug companies are required to submit advertisements to the FDA, they are free to publish before approval. In 2016, the pharmaceutical industry spent $9.6 billion on direct-to-consumer advertising, producing 4.6 million ads (including 663,000 television commercials).

   The alcohol industry has adopted *internal* rules requiring at least 70% of the audience for each ad consist of persons 21 or older; however, these "voluntary self-regulatory codes" stand in stark contrast to the proposed legislation, which restricts broad categories of marketing channels and mandates all Internet advertisements receive DOH approval.

   As the FTC explains: "The First Amendment provides substantial protections to speech, and thus substantially limits the government's ability to regulate truthful, non-deceptive alcohol advertising based on concerns about underage appeal."

   Instead of restricting free speech, the FTC recommends parents practice "media literacy."

THC capping

1. Given its "high binding affinity" for CB1 receptors, THC is largely responsible for marijuana's therapeutic effects. Not surprisingly, the only three synthetic cannabis-based medications to receive FDA approval are synthetic versions of (or bare chemical similarity to) THC. Which begs the question: Why is it okay for Big Pharma to profit from high-potency THC drugs, while Florida patients can't use high-potency THC medical marijuana to treat documented health conditions under a physician's care?

2. Numerous studies have confirmed the safety and efficacy of high-THC products, finding (among other conclusions): THC can prevent the development of colitis-associated colon cancer in mice; high THC (>26.5%)/high CBD (>11%) cannabis works best for reducing stress; synthetic THC causes cessation of nightmares or a significant reduction in nightmare intensity in PTSD patients; THC reduces intraocular pressure (IOP) while CBD may, in contrast, increase IOP; and Lewis lung adenocarcinoma growth is slowed and/or stopped in THC-treated mice (who also demonstrate prolonged survival rates).

3. Not all researchers agree that the association between cannabis use and earlier age at onset of psychotic disorders (such as schizophrenia) is causal. Six points regarding methodology complications are detailed in the following pages, along with a Harvard Medical School study finding that "having an increased familial morbid risk for schizophrenia may be the underlying basis for schizophrenia in cannabis users and not cannabis use by itself."

   Likewise, "gateway drug" and addiction claims have been contested, with the National Institute on Drug Abuse (NIDA) reporting, "The majority of people who use marijuana do not go on to use other, 'harder' substances." While a new study suggests that marijuana cannabinoid CBD may be the best treatment for cannabis use disorder, additional research confirms marijuana's positive role in other addiction models:

   An increase from one available marijuana dispensary in a county to two is associated with a 17% reduction in opioid-related overdose deaths; an increase from two to three is associated with a further 8.5% reduction. CBD treatment dose-dependently diminishes cocaine self-administration and moves the dose-response curve downward. And following medical cannabis initiation, 44% of participants report decreases in alcohol use frequency over 30 days, while 34% decrease the number of standard drinks they have per week.

Lastly, the *Journal of Economic Behavior & Organization*, *B.E. Journal of Economic Analysis & Policy*, and *Journal of Drug Issues* all report drops in crime following marijuana legalization.

4. Although illegal at the federal level, marijuana has a state-recognized "medical use" in Florida – suggesting regulatory guidance might be gained from the Food and Drug Administration (FDA). However, despite the FDA's broad scope and oft-criticized "paternalism" in drug development, never has the federal agency issued its *own* drug design protocol and/or formulary guidelines and insisted private sector manufacturers fall in line.

   It is therefore argued that the proposed bill overreaches – not by weighing the risk/benefits profile of a new drug and enacting supportive measures to ensure public safety (similar to the FDA) – but by seeking to legislate scientific innovation (through unfounded involvement in the drug design process) and mandating that physicians recommend a course of treatment *not* that's best in their professional opinion, but that's best in the eyes of the Florida state government.

5. Although detailing separate regulations for medical marijuana practitioners and manufacturers, the proposed bill tends to conflate the two (for instance, by restricting physician advertising in an identical manner to MMTC advertising), often ignoring the "practice of medicine" principle completely.

6. By imposing an arbitrary potency cap on just one of marijuana's 100-plus cannabinoids, H.B. 1455 calls into question whether rigorous scientific standards have been met and, more importantly: Whether the pioneering of rational drug design in cannabinoid-based treatment should be led by state legislators or perhaps, instead, by medical professionals.

The following pages discuss each argument in detail. Please feel free to reach me directly with any questions.

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PHYSICIAN ADVERTISING

The prohibition preventing "qualified physicians from engaging in certain advertising for their practices relating to marijuana for medical use" is rejected for violating the First Amendment rights of qualified physicians (affirmed by *Conant v. Walters*), restraining free trade as articulated by the U.S. Supreme Court in *American Medical Association v. FTC*, and failing to find parallel precedent(s) in the healthcare, pharmaceutical, and/or alcohol industries.

FIRST AMENDMENT OBJECTIONS

Marijuana is federally illegal, meaning the proposed ban on physician "radio or television advertising" likely hinges on the argument that the Federal Communications Commission (FCC) regulates radio and television. However, this position fails to recognize a critical distinction: Physicians are not the drugs they prescribe. Marijuana may be federally illegal, but being a physician is not. The Courts have routinely recognized this distinction in First Amendment cases, including *Conant v. McCaffrey*[1] which ruled:

> "A sincere [medical marijuana] recommendation alone is not a federal crime, even if the doctor foresees it could be used to facilitate a federal crime. The federal interest in enforcing the marijuana prohibition in the United States is a legitimate concern, but it pales by comparison to the free speech concerns."

Finding that the Controlled Substances Act does not authorize the government to revoke a physician's license to dispense controlled substances merely because a physician "recommends" marijuana – and that "any contrary holding would raise severe First Amendment doubts" – the Court writes:

> "Contrary to the government's argument, it is not true that a mere recommendation will necessarily lead to the commission of a federal offense. [...] To the contrary, a recommendation for marijuana may lead to actions by patients all of which are lawful under federal law and some of which are themselves protected, such as petitioning the government for a change in the prohibition itself, by the First Amendment.
>
> To hold that physicians are barred from communicating to patients sincere medical judgments would disable patients from understanding their own situations well enough to participate in the debate. [...] This factor alone persuades the Court that the balance of considerations ought to be struck firmly on the side of protecting sincere medical recommendations."

[1] *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997)

Importantly, *Conant v. McCaffrey* focused on the *act* of recommending medical marijuana, and was later upheld by *Conant v. Walters,*[2] which found that actions against physicians who engage in speech that "the patient believes to be a recommendation of marijuana" lack requisite narrow specificity under the First Amendment. The proposed bill addresses a scenario one step further removed: Physician advertisements merely *suggest* pursuing the act of recommendation (indicating an even broader breadth of First Amendment protection).

As *Conant v. Walters* reminds us:

> "Doctors who recommend medical marijuana to patients after complying with accepted medical procedures are not acting as drug dealers; they are acting in their professional role in conformity with the standards of the state where they are licensed to practice medicine.
>
> [...] It is true that by removing state penalties for the use of marijuana, a doctor's recommendation may embolden patients to buy the drug, and others to sell it to them, in violation of federal law. But the doctors only help patients obtain the drug by removing state penalties for possession and sale; they do not purport to exempt patients or anyone else from federal law, nor could they."

Lastly, one might argue that the Florida Department of Health (DOH) – which has sole authority to approve medical marijuana applications and issue identification cards required for marijuana purchase – is the ultimate "gatekeeper" for marijuana patients. As no one is suggesting censoring the DOH (which has a medical marijuana public education priority for minority populations written into state law),[3] the proposed content-based restrictions could be construed as unconstitutional on the basis of underinclusion (a statute is underinclusive compared to its alleged purpose when it "singles out certain speech, while permitting other similar types of speech that offend the same principles").[4]

As *Conant v. McCaffrey* states: "[T]here is First Amendment protection in the practice of the learned professions." We encourage legislators to vote against obstructing that protection.

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[2] *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002)

[3] Florida Senate Bill 8A (2017A) - p. 23, line 653: "The department shall allocate $10 of the identification card fee to the Division of Research at Florida Agricultural and Mechanical University for the purpose of educating minorities about marijuana for medical use…."

[4] Joyce, A.W. (2019). Prosecuting fatal speech: What Minnesota's *State v. Final Exit Network* means for assisted-suicide laws across the country. *Oklahoma Law Review, 71*(4): 1229-47.

TRADE RESTRAINT OBJECTIONS

Prior to 1975, the American Medical Association (AMA) barred physician advertising. Following *Goldfarb v. Virginia State Bar*[5] – which removed antitrust exemptions from the learned professions – the Federal Trade Commission (FTC) sued the AMA, claiming the organization's anti-marketing policy unreasonably restrained trade by banning advertising and solicitation.[6] As summarized by the *Journal of Medical Ethics*:

> "The position of the FTC is that the reason costs are high is because doctors have a monopoly on health care delivery and can thus maintain artificially high costs for their own profit. If doctors were not prohibited from advertising, it is argued, prices would come down because patients could shop for the best deals."[7]

After a seven-year legal battle, the case was settled. On March 23, 1982, the U.S. Supreme Court upheld a lower court ruling barring the AMA from restricting physician advertising and the solicitation of patients. The current *AMA Code of Ethics* reads:

> "A physician may publicize him or herself as a physician through any commercial publicity or other form of public communication (including any newspaper, magazine, telephone directory, radio, television, direct mail, or other advertising) provided that the communication shall not be misleading because of the omission of necessary material information, shall not contain any false or misleading statement, or shall not otherwise operate to deceive."[8]

As the FTC notes:

> "In the decades to come, the Commission would apply competition principles to challenge other horizontal restraints that were likely to harm consumers by restricting competition among professionals. By some estimates, well over one hundred FTC cases can trace their origin to the *AMA* case."[9]

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[5] *Goldfarb v. Virginia State Bar*, 421 U.S. 1773 (1975)
[6] *American Medical Association v. FTC*, (455 U.S. 676 (1982)
[7] Dyer, A.R. (1985). Ethics, advertising, and the definition of a profession. *Journal of Medical Ethics, 11*(2): 72-8.
[8] American Medical Association. (2021). *Advertising & Publicity: Code of Medical Ethics Opinions 9.6.1*. Retrieved March 5, 2021 from: https://www.ama-assn.org/delivering-care/ethics/advertising-publicity#
[9] Signs, K. (15 February 2015). *FTC milestone: A new age dawns for the FTC's competition work*. Federal Trade Commission. Retrieved March 6, 2021 from: https://www.ftc.gov/news-events/blogs/competition-matters/2015/02/ftc-milestone-new-age-dawns-ftcs-competition-work

We encourage legislators to vote against the proposed bill, which inhibits physicians' ability to participate as entrepreneurs within the free market and directly contradicts the Supreme Court's ruling in *American Medical Association v. FTC*.

PRECEDENT OBJECTIONS

As a (state) regulated medical program employing credentialed professionals, who recommend controlled substances for the treatment of health conditions, the medical marijuana industry may reasonably look to "mainstream" healthcare and the pharmaceutical industry for regulatory expectations. And yet – while the proposed bill seeks to not only completely prohibit all radio and television advertising, but also require that all qualified physician Internet advertising be approved by the Florida DOH – a similar standard cannot be found in either industry.

Mainstream physicians are bound simply by AMA ethical guidelines and the FTC Act (FTCA) to avoid "false or misleading" and "unfair or deceptive" statements and practices.[10] [11]All forms of advertising and free speech remain available and intact. Likewise, the pharmaceutical industry enjoys a far more relaxed framework – regularly advertising on television and radio. According to a recent review published by the *Journal of the American Medical Association*:

> "From 1997 through 2016, spending on medical marketing of drugs, disease awareness campaigns, health services, and laboratory testing increased from $17.7 to $29.9 billion. The most rapid increase was in direct-to-consumer (DTC) advertising, which increased… to $9.6 billion (32% of total spending in 2016). DTC prescription drug advertising increased… to $6 billion (4.6 million ads, including 663,000 TV commercials).
>
> [...] DTC advertising for health services increased from $542 million to $2.9 billion, with the largest spending increases by hospitals, dental centers, cancer centers, mental health and addiction clinics, and medical services (e.g., home health)."[12]

Also of note: Pharmaceutical companies are not required to submit advertisements to the Federal Drug Administration (FDA) for prior approval. (While drug companies are required to submit advertisements to the FDA, they are free to publish before approval.)[13] The FDA has no power to

[10] American Medical Association. (2021). *Advertising & Publicity: Code of Medical Ethics Opinions 9.6.1*.
[11] *Federal Trade Commission Act*, 15 U.S.C. §§ 41-58
[12] Schwartz, L.M. & Woloshin, S. (2019). Medical marketing in the United States, 1997-2016. *Journal of the American Medical Association, 321*(1): 80-96.
[13] Bell, R. A., Kravitz, R. L., & Wilkes, M. S. (1999). Direct-to-consumer prescription drug advertising and the public. *Journal of General Internal Medicine, 14*(11), 651-657.

levy fines; however, the agency may issue violation letters.[14] Unfortunately, approximately 30 FDA employees are responsible for reviewing the roughly 30,000 submissions the agency receives each year[15] – a figure that has led the General Accounting Office to conclude:

> "Misleading advertisements may have completed their broadcast life cycle before the FDA [has] issued the letters."[16]

Although not in the present context, marijuana may also be consumed with recreational intent and/or present unique threat to the underage population – which suggests a review of regulatory standards in the alcohol industry may be appropriate. Yet, once again, similar restrictions are not to be found.

As the FTC explains:

> "The First Amendment provides substantial protections to speech, and thus substantially limits the government's ability to regulate truthful, non-deceptive alcohol advertising based on concerns about underage appeal."[17]

Instead of restricting free speech, the FTC recommends parents practice "media literacy." The alcohol industry has adopted *internal* rules requiring at least 70% of the audience for each ad consist of persons 21 or older; however, these "voluntary self-regulatory codes"[18] stand in stark contrast to the proposed legislation, which restricts broad categories of marketing channels and mandates all Internet advertisements receive DOH approval.

According to the FTC:

> "A self-regulatory regime has several advantages over government regulation. It conserves limited government resources and is more prompt and flexible than government regulation, given the substantial time required to complete an investigation or adopt and enforce a regulation.

[14] Holmer, A.F. (2002). Direct-to-consumer advertising: Strengthening our health care system. *New England Journal of Medicine, 346*(7): 526-528.
[15] Free rein for drug ads? A slowdown in FDA review has left consumers more vulnerable to misleading messages. (2003). *Consumer Reports, 68*(2): 33-37.
[16] Free rein for drug ads?
[17] Federal Trade Commission. (September 2013). *Alcohol advertising*. Retrieved March 6, 2021 from https://www.consumer.ftc.gov/articles/0391-alcohol-advertising
[18] Federal Trade Commission. (2014). *Self-regulation in the alcohol industry*.

> Finally, self-regulation is an appropriate response to concerns about the impact of alcohol advertising on youth, in light of the substantial protections afforded advertising by the First Amendment to the U.S. Constitution."[19]

While exploration of the pharmaceutical and alcohol industries provides added footing for the present objection, it's perhaps even more apt for contesting the similar restrictions proposed for medical marijuana treatment center (MMTC) advertising – for we must remain diligent in distinguishing physicians from the drugs they prescribe. The pharmaceutical and alcohol industries advertise consumable products; physicians advertise a professional service where consumable products are *discussed*.

We therefore encourage legislators to vote against the proposed bill which, as stated, violates the First Amendment and restrains trade – but also fails to find any parallel precedent in the healthcare, pharmaceutical, and/or alcohol industry.

THC CAPS

The prohibition preventing qualified physicians from "certifying a certain potency of tetrahydrocannabinol in marijuana" is rejected for lacking scientific rationale, exercising legislative overreach, and interfering with the practice of medicine.

SCIENTIFIC OBJECTIONS

Long vilified for its psychoactive effects, tetrahydrocannabinol (THC) is largely responsible for medical marijuana's therapeutic value. THC's power is believed to derive, in large part, from its "very high binding affinity"[20] for CB1 receptors in the brain. THC also binds with CB2 receptors, while cannabidiol (CBD) has "little binding affinity for either CB1 or CB2 receptors, but is capable of antagonizing them in the presence of THC." [21]

As summarized by *Frontiers in Pharmacology*:

[19] Federal Trade Commission. (2014).
[20] Vučković, S., Srebro, D., Vujović, K.S., Vučetić, C. & Prostran, M. (2018). Cannabinoids and pain: New insights from old molecules. *Frontiers in Pharmacology,* 9(1259): 1-19.
[21] Thomas, A., Baillie, G.L., Phillips, A.M., Razdan, R.K., Ross, R.A., & Pertwee, R.G. (2007). Cannabidiol displays unexpectedly high potency as an antagonist of CB1 and CB2 receptor agonists in vitro. *British Journal of Pharmacology*, 150(5): 613-23 as as cited by Vučetić et al. (2018).

> "[THC] is responsible for most of the pharmacological actions of cannabis, including the psychoactive, analgesic, anti-inflammatory, antioxidant, antipruritic, bronchodilatory, anti-spasmodic, and muscle-relaxant activities."[22] [23]

In advocating to limit the THC potency of medical marijuana, it's interesting that proponents fail to address Marinol, Syndros, and Cesamet – the only three synthetic cannabis-based medications to receive FDA approval. Perhaps it's because all three are synthetic versions of THC? According to the FDA:

> "Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC)... Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived. Cesamet, like dronabinol-containing products, is indicated for nausea associated with cancer chemotherapy."[24]

Which begs the question: Why is it okay for Big Pharma to profit from high-potency THC drugs, but Florida patients can't use high-potency THC medical marijuana to treat documented health conditions under a physician's care?

While there are countless studies confirming the medical merit of THC and high-THC products (including clinical trials for the drugs mentioned above – which satisfied federal safety and efficacy standards), the following findings drive the point home.

THC: Supporting studies

In a Candadian clinical trial that administered nabilone (sold as Cesamet in the United States) to PTSD patients, researchers found:

> "The majority of patients (72%) receiving nabilone experienced either cessation of nightmares or a significant reduction in nightmare intensity. Subjective improvement in sleep time, the quality of sleep, and the reduction of daytime flashbacks and night sweats were also noted by some patients."[25]

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[22] Vučković et al. (2018).
[23] Note: This assessment should *not* be taken to preclude or minimize the role of CBD or other cannabinoids in any of the highlighted activities.
[24] U.S. Food & Drug Administration. (1 October 2020). *FDA and cannabis: Research and drug approval process*. Retrieved March 7, 2021 from https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process
[25] Fraser, G.A. (2009). The use of a synthetic cannabinoid in the management of treatment-resistant nightmares in Post-traumatic Stress Disorder (PTSD). *CNS Neuroscience & Therapeutics, 15*: 84-8.

Moving away from synthetic cannabinoids, Washington State University researchers studied varying ratios of THC and CBD in inhaled cannabis, finding:

> "High THC (>26.5%)/high CBD (>11%) cannabis was best for reducing perceived symptoms of stress."[26]

Speaking to the wide range of conditions that benefit from THC, glaucoma researchers report:

> "The limited evidence from small clinical studies suggests oral administration of THC reduces intraocular pressure (IOP) while oral administration of CBD may, in contrast, cause an increase in IOP."[27]

In a more recent study, researchers injected mice with a carcinogenic agent. Half of the subjects were also injected with a THC solution. The mice that didn't receive THC exhibited colonic tumors, while those that were provided with THC exhibited *no tumors*, had markedly lower levels of colonic inflammation, and displayed fewer of the symptoms associated with ulcerative colitis – leading study authors to conclude:

> "THC can prevent the development of colitis-associated colon cancer in mice."[28]

This finding echoes some of the earliest work in cannabis and cancer research. In 1975, the *Journal of the National Cancer Institute* published a study that paved the way for modern marijuana research. After administering THC (delta-9 and delta-8) and cannabinol (CBN) – another phytocannabinoid – to mice with Lewis lung adenocarcinoma, researchers noticed that tumor growth slowed and/or stopped. THC-treated mice also showed prolonged survival rates:

> "Lewis lung adenocarcinoma growth was retarded by the oral administration of delta-9-THC, delta-8-THC, and CBN, but not CBD. Animals treated for 10 consecutive days with delta-9-THC, beginning the day after tumor implantation, demonstrated a dose-dependent action of retarded tumor growth. Mice treated for 20 consecutive days with delta-8-THC and CBN had reduced primary tumor size. CBD showed no inhibitory effect on tumor growth. Delta-9-THC, delta-8-THC, and CBN increased the

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[26] Cuttler, C., Spradlin, A., & McLaughlin, R.J. (2018). A naturalistic examination of the perceived effects of cannabis on negative affect. *Journal of Affective Disorders, 235*(1): 198-205.
[27] Health Canada: Cannabis Legalization and Regulation Branch. (October 2018). *Information for health care professionals: Cannabis (marihuana, marijuana) and the cannabinoids*.
[28] Becker, W., Alrafas, H. R., Wilson, K., Miranda, K., Culpepper, C., Chatzistamou, I., Cai, G., Nagarkatti, M., & Nagarkatti, P. S. (2020). Activation of cannabinoid receptor 2 prevents colitis-associated colon cancer through myeloid cell deactivation upstream of IL-22 production. *iScience, 23*(9): 101504.

> mean survival time (36% at 100 mg/kg, 25% at 200 mg/kg, and 27% at 50 mg/kg, respectively), whereas CBD did not."[29]

Twenty years later, another study found similar results: Mice and rats given various doses of THC exhibited a "significant" dose-related decrease in the incidence of hepatic adenoma tumors and hepatocellular carcinoma (the most common type of liver cancer), as well as a decrease in benign tumors in other organs.[30]
As summarized by the *British Journal of Pharmacology*:

> "There is evidence that in addition to eliciting responses in healthy animals, cannabinoid receptor activation by delta-9-THC can also ameliorate clinical signs or delay syndrome progression in animal models of certain disorders."[31]

However, in seeking to restrict THC potency, the proposed bill completely disregards the wealth of research indicating the efficacy of medical marijuana – and THC, specifically – in disease treatment, and instead reduces marijuana's role to one of strictly palliative care.

This reductionist view is not only unfounded, but poses an unfair threat to patients who – if the proposed bill is passed – will be denied the opportunity to purchase medication which may, as the research suggests, ameliorate or delay disease progression.

THC: Criticism rebuttal

Lastly, critics of cannabis legislation have warned that medical marijuana – and again, THC specifically – will lead to increased prevalence of psychotic disorders, addiction, and crime. However, peer-reviewed research paints a more complex picture.

a. Psychotic disorders

In a systematic meta-analysis published by the *Archives of General Psychiatry*, study authors note:

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[29] Munson, A.E., Harris, L.S., Friedman, M.A., Dewey, W.L., & Carchman, R.A. (1975). Antineoplastic activity of cannabinoids. *Journal of the National Cancer Institute, 55*(3): 597-602.
[30] Chan, P.C., Sills, R.C., Braun, A.G., Haseman, J.K., & Bucher, J.R. (1996): Toxicity and carcinogenicity of delta-tetrahydrocannabinol in Fischer rats and B6C3F1 mice. *Fundamental and Applied Toxicology, 30*(48): 109-17.
[31] Pertwee, R. G. (2008). The diverse CB1 and CB2 receptor pharmacology of three plant cannabinoids: Delta9-tetrahydrocannabinol, cannabidiol and delta9-tetrahydrocannabivarin. *British Journal of Pharmacology, 153*(2): 199-215.

> "Not all researchers agree that the association between cannabis use and earlier age at onset [of psychotic disorders, particularly schizophrenia] is causal. Sevy et al.[32] argue that the association between cannabis use and earlier age at onset could be explained by demographic variables, including lower socioeconomic status and the proportion of male cannabis users. Wade[33] has suggested that the apparent association between earlier age at onset and cannabis use might simply be owing to older patients with first-episode psychosis being less likely to use cannabis."[34]

Detailing the difficulties in establishing a causal link between cannabis use and psychotic disorder development, researchers write:

> "[A]ttempts to confirm the earlier onset of psychosis among cannabis users found in individual studies have been complicated by the considerable variation in the methods used to examine the association between the age at onset of psychosis and substance use. First, there are differences in the way substances have been examined. Some studies use an omnibus measure of substance use, while others have specifically examined the associations between age at onset and use of alcohol or cannabis. Second, there are differences in the patient populations because some studies include patients with affective psychoses (psychotic depression and mania),whereas others limit samples to patients with a diagnosis of schizophrenia and related disorders. A third area of methodological variation is whether the studies examined substance use at the time of initial presentation to mental health services or later in the course of established psychotic illness. A fourth difference is in the nature of the control group, because some studies use psychotic patients with no reported substance use as controls, whereas the control groups of other studies include psychotic subjects who used drugs other than the drug under study. A fifth point of variation across studies relates to the age range of included patients, because many early-psychosis services only see individuals younger than a certain age, which is a potentially important confounding factor because cannabis use is more prevalent among younger people. Perhaps most importantly, few studies explicitly state whether the substance was being used prior to the onset of psychosis, which makes it difficult to draw causal inferences from a reported association."[35]

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[32] Sevy, S., Robinson, D.G., Napolitano, B., Patel, R.C., Gunduz-Bruce, H., Miller, R., McCormack, J., Lorell, B.S., & Kane, J. (2010). Are cannabis use disorders associated with an earlier age at onset of psychosis? S*chizophrenia Research*, *120*(1-3): 101-7.
[33] Wade, D. (2005). Cannabis use and schizophrenia. American Journal of Psychiatry, 162(2): 401.
[34] Large, M., Sharma, S., Compton, M.T., Slade, T., & Nielssen, O. (2011). Cannabis use and earlier onset of psychosis: A systematic meta-analysis. *Archives of General Psychiatry, 68*(6): 555-61.
[35] Large et al. (2011).

While the *Archives of General Psychiatry* study itself "lends weight to the view that cannabis use precipitates schizophrenia and other psychotic disorders," a study by Harvard researchers several years later reached a different conclusion:

> "The results of the current study suggest that having an increased familial morbid risk for schizophrenia may be the underlying basis for schizophrenia in cannabis users and not cannabis use by itself."[36]

b. Addiction and "gateway" drug claims

Likewise, "gateway drug" and addiction claims have been contested, with the National Institute on Drug Abuse (NIDA) reporting:

> "[T]he majority of people who use marijuana do not go on to use other, "harder" substances. Also, cross-sensitization is not unique to marijuana. Alcohol and nicotine also prime the brain for a heightened response to other drugs and are, like marijuana, also typically used before a person progresses to other, more harmful substances."[37]

The NIDA's statement builds on an earlier report by the Drug Policy Research Center which found:

> "[T]the phenomena supporting claims that marijuana is a gateway drug also support the alternative explanation: that it is not marijuana use but individuals' opportunities and unique propensities to use drugs that determine their risk of initiating hard drugs."[38]

And while the definition of marijuana addiction or "cannabis use disorder" has been increasingly criticized in the wake of state-level medical legalization, *Lancet Psychiatry* recently published a study that adds some levity:

> "In the first randomised clinical trial of cannabidiol for cannabis use disorder, cannabidiol 400 mg and 800 mg were safe and more efficacious than placebo at reducing cannabis use."[39]

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[36] Proal, A.C., Fleming, J., Galvez-Buccollini, J.A., & Delisi, L.E. (2014). A controlled family study of cannabis users with and without psychosis. *Schizophrenia Research, 152*(1):283-8.
[37] NIDA. (8 April 2020). *Is marijuana a gateway drug?*. Retrieved March 7, 2021 from https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-gateway-drug
[38] Morral, A.R., McCaffrey, D.F., & Paddock, S.M. (2002). *Using marijuana may not raise the risk of using harder drugs*. Retrieved March 7, 2021 from https://www.rand.org/pubs/research_briefs/RB6010.html.
[39] Freeman, T.P., Hindocha, C., Baio, G., Shaban, N.D.C., Thomas, E.M.... & Curran, H.V. (2020). Cannabidiol for the treatment of cannabis use disorder: A phase 2A, double-blind, placebo-controlled, randomised, adaptive Bayesian trial. *The Lancet Psychiatry, 7*(10): 865-874.

Discussing the conclusion that the best treatment for cannabis use disorder may actually be a cannabis compound, study co-author Tom Freeman notes:

> "Most people who use cannabis do so without significant problems."[40]

But while marijuana addiction may not be a major concern, cannabis use has been shown to play a positive role in other addiction models. According to the *British Medical Journal*:

> "An increase from one available [marijuana] dispensary in a county to two is associated with a 17% reduction in opioid-related overdose deaths; an increase from two to three is associated with a further 8.5% reduction."[41]

Likewise, *Pharmacology, Biochemistry, and Behavior* found:

> "CBD treatment dose-dependently diminished cocaine self-administration and moved the dose-response curve downward."[42]

Lastly, the *International Journal of Drug Policy* reports:

> "Following medical cannabis initiation, 44% of participants reported decreases in alcohol use frequency over 30 days, and 34% decreased the number of standard drinks they had per week."[43]

c. Crime

According to a 2019 report in the *Journal of Economic Behavior & Organization*:

> "The concern that legalizing cannabis for recreational purposes may increase crime occupies a prominent position in the public debate about drugs. Our analysis suggests that such a concern is not justified. We reach conclusions in line with what Becker and

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[40] Pattillo, A. (28 July 2020). *First-of-its kind study finds a counterintuitive use for prescription CBD*. Inverse. Retrieved March 7, 2021 from https://www.inverse.com/mind-body/cbd-treatment-for-cannabis-use-disorder
[41] Hsu, G. & Kovács, B. (2021). Association between county level cannabis dispensary counts and opioid related mortality rates in the United States: Panel data study. *British Medical Journal, 372*: m4957.
[42] Rodrigues, L.A., Caroba, M., Taba, F.K., Filev, R., & Gallassi, A.D. (2020). Evaluation of the potential use of cannabidiol in the treatment of cocaine use disorder: A systematic review. *Pharmacology, Biochemistry, and Behavior, 196*: 172982.
[43] Lucas, P., Boyd, S., Milloy, M-J., & Walsh, Z. (2020). Reductions in alcohol use following medical cannabis initiation: Results from a large cross-sectional survey of medical cannabis patients in Canada. *International Journal of Drug Policy, 86*: 102963.

> Murphy (2013)[44] expected when advocating the full decriminalization of the drugs market, namely a crime drop: rapes dropped in WA by, approximately, between 15% and 30%, and property crimes fell by between 10% and 20%, an effect entirely driven by reduced thefts, which decreased by between 13% and 22%."[45]

Supporting research is offered by *The B.E. Journal of Economic Analysis & Policy*, which writes:

> "Our results from analyzing the history of depenalization and medical marijuana laws show a clear connection between medicinal use and reductions in non-drug crime. These findings are robust to a wide array of identification concerns and consistent with the reallocation of policing effort, a reduction in cartel and supplier-related violence, and substitution away from competing substances linked to crime.
>
> In recent decades as crime fell across the nation, states that adopted medical marijuana laws saw approximately 5 % larger reductions in robberies, larcenies, and burglaries following the passage of medicinal use than those states that did not."[46]

Examining the potential spillover effect of recreational marijuana legalization in Colorado and Washington state, the *Journal of Drug Issues* reports similar findings:

> "Results provide some evidence suggesting a spillover crime reduction effect of legalization, as reflected by the significant decreases in the rates of property crime, larceny, and simple assault in the Colorado region that includes six neighboring states."[47]

Of added interest, California had 8.3% fewer traffic fatalities in 2018 (the year it launched recreational marijuana shops), than it did in 2017.[48]

With this knowledge in mind, we encourage legislators to vote against the proposed bill which fails to recognize the established benefits of THC and instead supports the theory that high-THC

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[44] Becker, G. & Murphy, K. (2013). Have we lost the war on drugs? *The Wall Street Journal*.
[45] Dragone, D., Prarolo, G., Vanin, & Zanella, G. (2019). Crime and the legalization of recreational marijuana. *Journal of Economic Behavior & Organization, 159*: 488-501.
[46] Huber, A. III, Newman, R., & LaFave, D. (2016). Cannabis control and crime: Medicinal use, depenalization and the war on drugs. *The B.E. Journal of Economic Analysis & Policy*, *16*(4).
[47] Wu, G., Boateng, F.D., & Lang, X. (2020). The spillover effect of recreational marijuana legalization on crime: Evidence from neighboring states of Colorado and Washington state. *Journal of Drug Issues, 50*(4): 392-409.
[48] California Office of Traffic Safety. (2021). *California Traffic Safety Quick Stats*. Retrieved March 7, 2021 from https://www.ots.ca.gov/ots-and-traffic-safety/score-card/

consumption will increase the prevalence of psychotic disorders, addiction, and crime (points that have all been persuasively countered by scientific literature).

OVERREACH OBJECTIONS

Although illegal at the federal level, marijuana has a state-recognized "medical use" in Florida[49] – suggesting regulatory guidance might be gained from the Food and Drug Administration (FDA), which is charged with "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices…".[50]

However, despite the FDA's broad scope and oft-criticized "paternalism"[51] in drug development, manufacturing, and approval, never has the federal agency issued its *own* drug design protocol and/or formulary guidelines and insisted private sector manufacturers fall in line. Remaining mindful of the distinction between physicians and the drugs they prescribe – and the proposed bill's separate, if not similar, regulation of each – it should also be noted that the AMA places *no* restriction on the prescribing practices of physicians:

> "Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient."[52]

Despite criticism from the *Harvard Law Bill of Health* that it "all too often" overuses its "vast powers to regulate the manufacture and distribution of drugs,"[53] the FDA still has never gone as far as the proposed bill (capping individual compounds that may contribute to a drug's risk profile).

This point is perhaps best illustrated by the FDA's 2007 implementation of Risk Evaluation and Mitigation Strategies (REMS). The REMS drug safety program focuses on preventing,

[49] Florida Senate Bill 8A (2017A)
[50] U.S. Food & Drug Administration. (28 March 2018). *FDA: What we do*. Retrieved March 7, 2021 from https://www.fda.gov/about-fda/what-we-do
[51] Epstein, R.A. (1 October 2013). *Government overreach threatens lives*. Hoover Institute. Retrieved March 7, 2021 from https://www.hoover.org/research/government-overreach-threatens-lives
[52] American Medical Association. (2010). The AMA Code of Medical Ethics' opinions on the sale and dispensing of health-related products. *American Medical Association Journal of Ethics, 12*(12): 925-27.
[53] Epstein, R. (30 September 2013). Government regulation of the practice of medicine: How the FDA overreaches the regulation of medical practice. *Harvard Law Petrie-From Center Bill of Health*. Retrieved March 7, 2021 from https://blog.petrieflom.law.harvard.edu/2013/09/30/government-regulation-of-the-practice-of-medicine-how-the-fda-overreaches-the-regulation-of-medical-practice-2/

monitoring and/or managing a specific serious risk by "informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event."[54]

As an example:

Zyprexa Relprevv is an injectable anti-psychotic used to treat schizophrenia. Zyprexa can cause serious reactions following injection called post-injection delirium sedation syndrome. Symptoms – including sedation, coma, and delirium – occurred in clinical studies within three hours after treatment. According to the FDA, "the risk of post-injection delirium sedation syndrome is present with every injection." To reduce that risk, the FDA required Zyprexa's manufacturer to develop a REMS. The FDA did *not* seek to "cap" individual compounds that may contribute to sedation, coma, or delirium, and they certainly didn't suggest pharmacology rules regarding Zyprexa be written into law.

As summarized by the *European Journal of Pharmacology*:

> "To meet the challenges of ideal drugs, an efficient method of drug development is demanding. The process of drug development is challenging, time consuming, expensive, and requires consideration of many aspects." [55]

By imposing an arbitrary potency cap on just one of marijuana's 100-plus cannabinoids, the proposed bill calls into question whether these demands have been met and, more importantly: Whether the pioneering of rational drug design in cannabinoid-based treatment[56] should be led by state legislators or perhaps, instead, by medical professionals.

We encourage legislators to vote against the proposed bill which overreaches into the private sector – not by weighing the risk/benefits profile of a new drug and enacting supportive measures to ensure public safety (similar to the FDA) – but by seeking to legislate scientific innovation (through unfounded involvement in the drug design process) and mandating that physicians recommend a course of treatment *not* that's best in their professional opinion, but that's best in the eyes of the Florida state government.

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[54] U.S. Food & Drug Administration. (8 August 2019). *Risk Evaluation and Mitigation Strategies (REMS)*. Retrieved March 7, 2021 from https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems

[55] Mandal, S., Moudgil, M., & Mandal, S.K. (2009). Rational drug design. *European Journal of Pharmacology, 625*: 90-100.

[56] Huang, S., Xiao, P. & Sun, J. (2020). Structural basis of signaling of cannabinoids receptors: Paving a way for rational drug design in controlling multiple neurological and immune diseases. *Signal Transduction and Targeted Therapy, 5*: 127.

PRACTICE INTERFERENCE OBJECTIONS

Pharmaceutical drugs have long been distinguished from the practice of medicine (importantly: the FDA can regulate the former, but not the latter).[57] While medical marijuana – legal at the state level, but illegal at the federal level and thereby unregulated by the FDA – is a unique example, its similar application in medical contexts to pharmaceutical drugs warrants a closer look at the "practice of medicine" principle.

Perhaps most hotly contested in *United States of America v. Regenerative Sciences, LLC* (which considered whether reinjecting harvested stem cells into the same person from whom they were removed constituted a practice of medicine or a manufacturing of drugs),[58] the principle holds that the act of *practicing* medicine is distinct from medicine itself. According to Florida Statutes 458.305:

> "'Practice of medicine' means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition."

Although detailing separate regulations for medical marijuana practitioners and manufacturers, the proposed bill tends to conflate the two (for instance, by restricting physician advertising in an identical manner to MMTC advertising) and often ignores the practice of medicine principle completely.

As summarized by the Ohio Academy of Family Physicians:

> "Reducing the practice of medicine to a set of mandates or requirements undermines the patient-physician relationship. Often, these laws are proposed without regard to scientific evidence and ignore the health care needs of a patient. Legislation which mandates certain physician behavior or communication without regard to the best interests of patients could result in avoidable harm to a patient; delayed care; duplicative or unnecessary expense; and, patient distrust."[59]

We encourage legislators to vote against the proposed bill which, at best, blurs the line between the practice of medicine and medicine and, at worst, usurps the role of qualified physicians by nullifying their professional judgment.

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[57] Epstein, R. (30 September 2013).
[58] *United States of America v. Regenerative Sciences, LLC*, 741 F.3d 1314
[59] Ohio Academy of Family Physicians. (13 October 2013). *Policy Statement: Interference with the practice of medicine laws*. Retrieved March 7, 2021 from https://www.ohioafp.org/public-policy/state-legislative-regulatory-issues/legislative-interference-with-the-practice-of-medicine/