CannaMD

Florida House Bill 1455
Opposition Memo

To Whom It May Concern:

The following arguments are offered in the spirit of promoting a robust dialogue surrounding the medical efficacy of marijuana cannabinoid delta-9-tetrahydrocannabinol (THC) and the appropriateness of proposed measures affecting qualified physicians under Florida H.B. 1455.

In seeking to "cap" THC levels at 10 percent, H.B. 1455 appears to rely heavily on a study by Di Forti et al. (2019) finding that incident rates for psychotic disorders are "positively correlated" to the use of cannabis with THC potency levels greater than 10 percent.[1] However, this reliance neglects several critical points:

1. Di Forti et al. found correlation, not causation. As the *Harvard Medical School Health Blog* reminds readers, "So far, research shows only an *association* between smoking [marijuana] and developing psychosis or schizophrenia later on. That's not the same thing as saying that marijuana *causes* psychosis."[2]

2. Importantly, multiple peer-reviewed studies have concluded that cannabis use is *not* associated with psychosis, including those that appeared in *Schizophrenia Research*[3] and *The American Journal of Psychiatry*.[4]

3. The conclusion that the study's findings are "consistent with previous epidemiological and experimental evidence suggesting that the use of cannabis with a high concentration of THC has more harmful effects on mental health than does use of weaker forms" fails to mention that the three cited examples of "previous evidence" were all authored by one or more of the present study's authors.

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[1] Di Forti, M., Quattrone, D., Freeman, T.P., Tripoli, G., Gayer-Anderson, C... & the EU-GEI Wp2 Group. (2019). The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): A multicentre case-control study. *Lancet Psychiatry, 6*: 427-36.
[2] MacDonald, A. (March 2020). Teens who smoke pot at risk for later schizophrenia, psychosis. *Harvard Health Blog*. Retrieved March 17, 2021 from https://www.health.harvard.edu/blog/teens-who-smoke-pot-at-risk-for-later-schizophrenia-psychosis-201103071676
[3] 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.
[4] Wade, D. (2005). Cannabis use and schizophrenia. *American Journal of Psychiatry*, *162*(2): 401.

4. While Di Forti et al. mention a 2016 meta-analysis supporting an "association" (again: not causal link) between cannabis use and psychosis, the study authors again neglect to mention that Di Forti also wrote that study – and that a second meta-analysis was published that same year, in the peer-reviewed journal *Current Psychiatry Reports*, reaching the opposite conclusion.[5]

5. The study took place in the United Kingdom and didn't evaluate specific patient use or study the effects of specific THC ratios on patient outcomes. Instead, researchers used data published in the *European Monitoring Centre for Drugs and Drug Addiction 2016 Report* that recorded "the concentration of THC in the types of cannabis available across Europe, supplemented by national data for each included country" to calculate the "mean percentage of THC" in cannabis in various locations across Europe.

6. Lastly, despite the well known fact that CBD and other cannabinoids exert significant influence on THC and its related effects – most recently explored in *Neuorpsychopharmacology*'s 2018 article: "Clinical and Preclinical Evidence for Functional Interactions of Cannabidiol and Delta-9-Tetrahydrocannabinol"[6] – the Di Forti study does not take into account the proportion of CBD, or any of marijuana's other 100+ cannabinoids, in its study design.

As a systematic meta-analysis published by the *Archives of General Psychiatry* notes:

> "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.[7] 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[8] 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."[9]

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[5] Ksir, C. & Hart, C.L. (2016). Cannabis and psychosis: A critical overview of the relationship. *Current Psychiatry Reports*, *18*:1-12.
[6] Boggs, D.L., Nguyen, J.D., Morgenson, D., Taffe, M.A., & Ranganathan, M. (2018). Clinical and preclinical evidence for functional interactions of cannabidiol and delta-9-tetrahydrocannabinol. *Neuropsychopharmacology, 43*(1):142-54.
[7] 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? *Schizophrenia Research*, *120*(1-3): 101-7.
[8] Wade, D. (2005). Cannabis use and schizophrenia. *American Journal of Psychiatry*, *162*(2): 401.
[9] 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.

While the study authors go on to explain that "attempts to confirm the earlier onset of psychosis among cannabis users found in individual studies have been complicated by the considerable variation in methods,"[10] the issue can perhaps best be summarized by Margaret Haney, a professor of neurobiology at Columbia University Medical Center:

> "I've been doing this research for 25 years, and it's polarizing even among academics."[11]

Note: An outline of the specific methodological challenges referenced by the *Archives of General Psychiatry* is included further on under: House Bill 1455: Objection Details.

It also appears the current bill and/or its surrounding sentiments may be influenced by the anti-cannabis book, *Tell Your Children* by former *New York Times* reporter Alex Berenson. In perhaps the most concise illustration of the backlash Berenson received from the scientific community, even his former employer notes:

> "Critics, including leading researchers, have called the argument overblown, and unfaithful to the science."[12]

That Berenson's book would even be proffered as an "expert source" is surprising, given the fact that over 75 researchers from Harvard Medical School, New York University, Columbia University, and more penned an open letter refuting Brenson's claims.[13] The letter, signed by leaders such as Mark Eisenberg, Assistant Professor of Medicine at Harvard Medical School and Unit Chief of Adult Medicine at Massachusetts General Hospital Charlestown Health Care Center, accused Brensen of "attributing cause to mere associations," "cherry-picking data," and being "guilty of selection bias."[14]

The fear is that, however well intentioned and/or inadvertently, the same fate has befallen H.B. 1455. Pitting the present proposal (to "cap" THC) even further against existing peer-reviewed literature, out of the four cannabis-related medications to receive FDA approval, three are

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[10] 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.
[11] Carey, B. (17 January 2019). Does marijuana use cause schizophrenia? *The New York Times*. Retrieved March 17, 2021 from https://www.nytimes.com/2019/01/17/health/cannabis-marijuana-schizophrenia.html
[12] Carey, B. (17 January 2019).
[13] Ashford, R., Augustine, D., Barry, J., Bernstein, S., & Betsos, A. (14 February 2019). Letter from scholars and clinicians who oppose junk science about marijuana. *Drug Policy Alliance*. Retrieved March 17, 2021 from https://drugpolicy.org/resource/letter-scholars-and-clinicians-who-oppose-junk-science-about-marijuana
[14] Ashford et al. (2019).

synthetic (or man-made) versions of THC: Marinol, Syndros, and Cesamet.[15] While Cesamet is molecularly similar to THC, the FDA clearly states that the active ingredient in Marinol and Syndros is the exact same thing we're talking about today: Delta-9-THC.[16] [17] Which begs the question: Why is THC safe enough to pass FDA clinical trials, but not safe enough to benefit medical marijuana patients? Why is Big Pharma – which has multiple other investigational drug applications submitted for cannabinoids – allowed to profit off of THC, while the proposed bill seeks to restrict access to Florida patients suffering from conditions such as cancer, PTSD, and Crohn's disease?

It's been suggested that THC "just gets patients high" and that there's no medical efficacy for higher THC potency levels. Peer-reviewed data sharply contradicts this claim. [18] [19] [20] [21] [22]

It's also been suggested that peer-reviewed medical marijuana research is lacking and/or absent entirely. While it's true that initial research efforts encountered funding hurdles due to marijuana's federal scheduling, this claim couldn't be farther from the truth (as evidenced by the current memo, which cites over 30+ peer-reviewed studies in its introduction alone and 100+ total).

Lastly, in proposing a ban on all physician radio and television advertising, H.B. 1455 disregards the fact that 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

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[15] U.S. Food & Drug Administration. (1 October 2020). *FDA and cannabis: Research and drug approval process*. Retrieved March 17, 2021 from https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process

[16] Solvay Pharmaceuticals. (2004). Marinol (Dronabinol). *Federal Drug Administration (FDA) New Drug Application (NDA).* Retrieved March 17, 2021 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018651s021lbl.pdf

[17] Insys Therapeutics. (2017). *Syndros (dronabinol): Highlights of prescribing information*. Retrieved March 17, 2021 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205525s003lbl.pdf

[18] 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.

[19] Health Canada: Cannabis Legalization and Regulation Branch. (October 2018). *Information for health care professionals: Cannabis (marihuana, marijuana) and the cannabinoids*.

[20] 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.

[21] 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.

[22] 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.

concern, but it "pales by comparison" to free speech concerns.[23] 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, should therefore be rejected. As *Conant v. McCaffrey* states: "[T]here is First Amendment protection in the practice of the learned professions."

Ironically, 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."[24] 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.

While each of these subjects will be reviewed in more detail in the following pages, the above introduction should serve, if nothing else, as an indication that the present dialogue surrounding H.B. 1455 could benefit from a more balanced research-based approach and that such research is in fact available. It is my hope that, in reviewing this memo, you'll be encouraged to ask the same questions that we, within the medical marijuana and research communities, are asking. Questions such as:

- If one of the concerns surrounding physician advertising is the impact it might have on minors, it makes sense to look at how the pharmaceutical and alcohol industries handle the issue. However, the proposed bans on radio and television advertising do not mirror precedents set in either industry.[25] [26] If the Federal Trade Commission is content with the alcohol industry self-regulating advertising policies regarding minors,[27] why are we asking the government to regulate the advertising policies of state-certified and, in most cases: board-certified, physicians?

[23] *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997)
[24] *American Medical Association v. FTC*, 455 U.S. 676 (1982)
[25] 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.
[26] Federal Trade Commission. (2014). Retrieved March 7, 2021 from https://www.consumer.ftc.gov/articles/0391-alcohol-advertising
[27] Federal Trade Commission. (2014). Retrieved March 7, 2021 from https://www.consumer.ftc.gov/articles/0391-alcohol-advertising

- In addition to relieving symptoms (such as pain and anxiety), medical marijuana – and specifically, THC – has been shown to actively prevent and treat a number of diseases. For instance, the *Journal of the National Cancer Institute*[28] found that THC-treated mice with cancer show prolonged survival rates. Researchers also report that THC is "well tolerated"[29] and could "perhaps extend the life [of ALS patients] by three years or more."[30] [31] With sources such as the *Journal of Neuroimmunology* finding that THC inhibits the laboratory model of multiple sclerosis[32] and so on: What if the proposed arguments supporting H.B. 1455 are wrong? What if by restricting THC potency levels, we actually *harm* the patient population we're trying to protect by preventing access to medication that could otherwise change the course of their condition?

- Between 2010 and 2016, the rate of opioid overdoses among U.S. Veterans increased from 14.47 per 100,000 people a year to 21.08 per 100,000.[33] The *Journal of the American Medical Association* notes that Veterans are "twice as likely to die from an accidental overdose compared to the general population."[34] Given medical marijuana's proven ability to reduce opioid-related deaths[35] [36] and treat opioid addiction (and THC's very specific role in that process),[37] should we worry that the proposed bill is doing a disservice to our Veterans?

Speaking specifically to the THC issue, Columbia University researchers provide an apt summation:

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[28] 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.
[29] Raman, C., McAllister, S.D., Rizvi, G., Patel, S.G., Moore, D.H., Abood, M.E. (2004). Amyotrophic lateral sclerosis: delayed disease progression in mice by treatment with a cannabinoid. *Amyotrophic Lateral Sclerosis & Other Motor Neuron Disorders, 5*(1):33-39.
[30] Raman et al. (2004).
[31] Society For Neuroscience. (2004). "Marijuana-Like Compounds May Aid Array Of Debilitating Conditions Ranging From Parkinson's Disease To Pain." *ScienceDaily*. Retrieved March 17, 2021 from www.sciencedaily.com/releases/2004/10/041027102621.htm
[32] Lyman, W.D., Sonett, J.R., Brosnan, C.F., Elkin, R., & Bornstein, M.B. (1989). Delta 9-tetrahydrocannabinol: A novel treatment for experimental autoimmune encephalomyelitis. *Journal of Neuroimmunology, 23*(1): 73-81.
[33] Lin, L., Peltzman, T., McCarthy, J.F., Olivia, E.M., Trafton, J.A. & Bohnert, A.S.B. (2019). Changing trends in opioid overdose deaths and prescription opioid receipt among veterans. *American Journal of Preventive Medicine, 57*(1): 106-10.
[34] Rubin, R. (2019). VA efforts to reduce opioid overdose deaths in at-risk Veterans. *Journal of the American Medical Association, 322*(24): 2374.
[35] Ishida, J.H., Wong, P.O., Cohen, B.E., Vali, M., Steigerwald, S., & Keyhani, S. (2019). Substitution of marijuana for opioids in a national survey of US adults. *PLOS One, 14*(10): e0222577.
[36] Flexon, J.L., Stolzenberg, L., & D'Alessio, S.J. (2019). The effect of cannabis laws on opioid use. *International Journal of Drug Policy, 74*: 152-159.
[37] Wiese, B. & Wilson-Poe, A.R. (2018). Emerging evidence for cannabis' role in opioid use disorder. *Cannabis and Cannabinoid Research, 3.1*: 179-89.

> "It has been argued that even if we are uncertain that cannabis actually causes psychosis, it is better to err on the side of caution and warn cannabis users, psychiatric patients, and the general public about this potential danger of cannabis use. However, [...] if we wish scientists to be taken seriously when we do discover real and substantial dangers, then we believe it would be better to avoid behaving like the boy who cried wolf."[38]

With gratitude for your time and respect for your attention to this complex and pressing issue,

Jessica Walters
Chief Medical Researcher
CannaMD

The remainder of the memo is divided as follows:

[38] Ksir, C. & Hart, C.L. (2016). Cannabis and psychosis: A critical overview of the relationship. *Current Psychiatry Reports*, 18:1-12.

GENERAL STATEMENT OF MEDICAL MARIJUANA BENEFITS

In 2013, neurosurgeon Dr. Sanjay Gupta made national headlines with a public apology for previously opposing medical marijuana:

> "I apologize because I didn't look hard enough, until now. I didn't look far enough. I didn't review papers from smaller labs in other countries doing some remarkable research, and I was too dismissive of the loud chorus of legitimate patients whose symptoms improved on cannabis."[39]

Gupta continued, speaking to common misconceptions concerning marijuana's federal prohibition:

> "I mistakenly believed the Drug Enforcement Agency listed marijuana as a Schedule I substance because of sound scientific proof. Surely, they must have quality reasoning as to why marijuana is in the category of the most dangerous drugs that have "no accepted medicinal use and a high potential for abuse."
>
> They didn't have the science to support that claim, and I now know that when it comes to marijuana neither of those things are true. It doesn't have a high potential for abuse, and there are very legitimate medical applications. In fact, sometimes marijuana is the only thing that works."

Despite increased acceptance from the medical community (former U.S. Surgeon General Joycelyn Elders claims "the unjust prohibition of marijuana has done more damage to public health than has marijuana itself"),[40] cannabis still carries a social stigma that has been hard to shake. While just the tip of the iceberg, the following studies highlight a wealth of research supporting Elders, Gupta, and the countless medical professionals calling for a change in the public's perception and understanding of medical marijuana.

[39] Gupta, S. (2013, August 8). Why I changed my mind on weed. *CNN Health*.
[40] Nathan, D.L., Clark, H.W., & Elders, J. (2017). The physicians' case for marijuana legalization. *American Journal of Public Health, 107*(11): 1746-7.

Study Excerpts

ALS

Peer-reviewed journal *Amyotrophic Lateral Sclerosis and Other Motor Neuron Disorders* states:

> "Our research indicates that select marijuana compounds, including THC, significantly slow the disease process and extend the life of mice with ALS."[41]

As lead study author Dr. Mary Abood explains:

> "The only FDA-approved drug for ALS, riluzole, extends life on average by about two months. Evidence from our study suggests that a marijuana-based therapy could create a much greater effect, perhaps extending life by three years or more."[42]

Follow-up studies support Abood's claim, with a number of publications – including the *Federation of American Societies for Experimental Biology Journal* – reporting similar findings:

> "These results show that cannabinoids have significant neuroprotective effects in this model of ALS."[43]

ANXIETY & PTSD

A 2016 *Frontiers in Pharmacology* study found that marijuana cannabinoid, CBD, may help post-traumatic stress disorder (PTSD) patients by reducing learned fear – a condition that triggers the fight or flight response at inappropriate times. Researchers write:

> "A growing body of literature provides compelling evidence that CBD has anxiolytic effects and recent studies have established a role for CBD in regulating learned fear by dampening its expression, disrupting its reconsolidation, and facilitating its extinction."[44]

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[41] Raman, C., McAllister, S.D., Rizvi, G., Patel, S.G., Moore, D.H., & Abood, M.E. (2004). Amyotrophic lateral sclerosis: Delayed disease progression in mice by treatment with a cannabinoid. *Amyotrophic Lateral Sclerosis and Other Motor Neuron Disorders, 5*(1):33-9.

[42] Society For Neuroscience. (2004, October 27). Marijuana-like compounds may aid array of debilitating conditions ranging from Parkinson's disease to pain. *ScienceDaily*.

[43] Bilsland, L.G., Dick, J.R., Pryce, G., Petrosino, S., Di Marzo, V., Baker, D., & Greensmith, L. (2006). Increasing cannabinoid levels by pharmacological and genetic manipulation delay disease progression in SOD1 mice. *FASEB Journal, 20*(7): 1003-5.

[44] Jurkus, R., Day, H. L., Guimarães, F. S., Lee, J. L., Bertoglio, L. J., & Stevenson, C. W. (2016). Cannabidiol regulation of learned fear: Implications for treating anxiety-related disorders. *Frontiers in Pharmacology, 7*: 454.

Marijuana's efficacy in addressing more generalized anxiety symptoms is perhaps best illustrated by a 2019 study finding that after six months of medical marijuana treatment, 45.2% of study participants discontinued benzodiazepine use (e.g., Xanax, Valium, Ativan).[45]

CANCER

Research suggests cannabis may exert anti-cancer effects by causing cell death, modulating cell-signaling pathways[46], and inhibiting tumor invasion.[47] For instance, a 2011 study found that CBD kills breast cancer cells by inducing endoplasmic reticulum stress and inhibiting cell-signaling.[48] Likewise, colon cancer studies show that CBD has a cancer-protective effect and reduces cell proliferation.[49]

Perhaps most exciting, the National Cancer Institute notes that:

> "Cannabinoids appear to kill tumor cells but do not affect their non-transformed counterparts and may even protect them from cell death."[50]

CROHN'S DISEASE

In 2011, the *Israel Medical Association Journal* detailed findings from the first-ever study on cannabis use in Crohn's disease. Conducting retrospective interviews, researchers noted:

> "The results indicate that cannabis may have a positive effect on disease activity, as reflected by reduction in disease activity index and in the need for other drugs and surgery."[51]

Perhaps of most interest, the study authors add:

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[45] Purcell, C., Davs, A., Moolman, N., & Taylor, S.M. (2019). Reduction of benzodiazepine use in patients prescribed medical cannabis. *Cannabis and Cannabinoid Research, 4*(3): 214-18.
[46] Guzmán M. (2003). Cannabinoids: Potential anticancer agents. *Nature Reviews Cancer, 3*(10), 745-55.
[47] Vaccani, A., Massi, P., Colombo, A., Rubino, T., & Parolaro, D. (2005). Cannabidiol inhibits human glioma cell migration through a cannabinoid receptor-independent mechanism. *British Journal of Pharmacology, 144*(8), 1032-36.
[48] Shrivastava, A., Kuzontkoski, P.M., Groopman, J.E., & Prasad, A. (2011). Cannabidiol induces programmed cell death in breast cancer cells by coordinating the cross-talk between apoptosis and autophagy. *Molecular Cancer Therapeutics, 10*(7), 1161-72.
[49] Aviello, G., Romano, B., Borrelli, F., Capasso, R., Gallo, L., Piscitelli, F., Di Marzo, V., & Izzo, A. A. (2012). Chemopreventive effect of the non-psychotropic phytocannabinoid cannabidiol on experimental colon cancer. *Journal of Molecular Medicine, 90*(8), 925-34.
[50] PDQ Integrative, Alternative, and Complementary Therapies Editorial Board. PDQ Cannabis and Cannabinoids. Bethesda, MD: National Cancer Institute. Updated 11/06/2020. PMID: 26389198.
[51] Naftali, T., Lev, L.B., Yablecovitch, D., Half, E., & Konikoff, F.M. (2011). Treatment of Crohn's disease with cannabis: An observational study. *The Israel Medical Association Journal: 13*(8), 455-8.

> "The central effect of cannabinoids may induce a sensation of general well-being, which could contribute to the feeling that cannabis use is beneficial. However, this general effect wears off with time as tolerance develops, while the positive effect of cannabis on disease activity in our patients was maintained for an average period of 3.1 years."

DIABETES

Cannabis users demonstrate a lower risk for diabetes, with a recent study concluding:

> "In a robust multivariate model controlling for socio-demographic factors, laboratory values and comorbidity, the lower odds of diabetes mellitus among marijuana users was significant […] Marijuana use was independently associated with a lower prevalence of diabetes mellitus."[52]

Speaking of his own separate research, Harvard Medical School professor Dr. Murray Mittleman writes:

> "The most important finding is that current users of marijuana appeared to have better carbohydrate metabolism than non-users. Their fasting insulin levels were lower, and they appeared to be less resistant to the insulin produced by their body to maintain a normal blood-sugar level."[53] [54]

EPILEPSY

In a randomized double-blind placebo-controlled trial performed at 30 clinic centers, researchers found that the addition of CBD to traditional seizure medication significantly decreased the rate of drop (or atonic) seizures.[55]

Another cannabinoid, CBDV, has recently gained attention with a 2012 study concluding:

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[52] Rajavashisth, T.B., Shaheen, M., Norris, K.C., Pan, D., Sinha, S.K., Ortega, J., & Friedman, T.C. (2012). Decreased prevalence of diabetes in marijuana users: Cross-sectional data from the National Health and Nutrition Examination Survey (NHANES) III. *British Medical Journal Open, 2*(1): e000494.
[53] Penner, E.A., Buettner, H., & Mittleman, M. A. (2013). The impact of marijuana use on glucose, insulin, and insulin resistance among US adults. *The American Journal of Medicine, 126*(7), 583-9.
[54] Szalavitz, M. (2013, May 21). Marijuana: The next diabetes drug? *Time*.
[55] Devinsky, O., Patel, A. D., Cross, J.H., Villanueva, V., Wirrell, E.C., Privitera, M., Greenwood, S.M., Roberts, C., Checketts, D., VanLandingham, K.E., Zuberi, S.M., & GWPCARE3 Study Group. (2018). Effect of cannabidiol on drop seizures in the Lennox-Gastaut Syndrome. *The New England Journal of Medicine, 378*(20): 1888-97.

> "The significant anticonvulsant effects and favorable motor side effect profile demonstrated in this study identify CBDV as a potential standalone anti-epileptic drug or as a clinically useful adjunctive treatment alongside other anti-epileptic drugs."[56]

GLAUCOMA

A position statement from the American Glaucoma Society acknowledges:

> "It has been definitively demonstrated, and widely appreciated, that smoking marijuana lowers IOP [intraocular pressure] in both normal individuals and in those with glaucoma, and therefore might be a treatment for glaucoma."[57]

While this lowering effect is not without its fair share of controversy, a review published by the *Journal of Clinical Medicine* highlights additional benefits:

> "Another interesting aspect of cannabinoid usage in glaucoma is connected with the neuroprotective capabilities of these molecules."[58]

HIV/AIDS

Cannabis has long been recognized as an effective treatment for HIV/AIDS symptoms and medication side effects. According to a 2004 study published by the *Journal of Acquired Immune Deficiency Syndrome*:

> "A substantial percentage of cannabis users viewed it as beneficial for relief of symptoms commonly associated with HIV/AIDS. Relief from anxiety and depression were among the most frequently reported reasons for smoking cannabis, followed by appetite stimulation and relief of nausea."[59]

As researchers note:

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[56] Hill, A.J., Mercier, M.S., Hill, T.D., Glyn, S.E., Jones, N.A., Yamasaki, Y., Futamura, T., Duncan, M., Stott, C.G., Stephens, G.J., Williams, C.M., & Whalley, B.J. (2012). Cannabidivarin is anticonvulsant in mouse and rat. *British Journal of Pharmacology, 167*(8), 1629-42.
[57] Jampel, H. (2009, August 10). Position statement on marijuana and the treatment of glaucoma. *American Glaucoma Society*.
[58] Passani, A., Posarelli, C., Sframeli, A.T, Perciballi, L., Pellegrini, M., Guidi, G., & Figus, M. (2020). Cannabinoids in glaucoma patients: The never-ending story. *Journal of Clinical Medicine, 9*(12):3978.
[59] Prentiss, D., Power, R., Balmas, G., Tzuang, G., & Israelski, D. M. (2004). Patterns of marijuana use among patients with HIV/AIDS followed in a public health care setting. *Journal of Acquired Immune Deficiency Syndrome, 35*(1), 38-45.

> "This finding is particularly relevant to issues of antiretroviral medication adherence (ART). Nausea and anorexia are frequently cited as reasons for delayed or missed doses and discontinuation of ART."

MIGRAINES

In 2016, *Pharmacotherapy* published results of a retrospective chart review analyzing medical marijuana use in 121 migraine patients. The study showed marijuana successfully prevented migraines; patients who used marijuana experienced 5.8 less migraine days a month. Moreover, patients also reported that marijuana stopped migraines in-progress.[60]

These findings support a separate study presented at the Third Congress of the European Academy of Neurology which concluded:

> "We were able to demonstrate that cannabinoids are an alternative to established treatments in migraine prevention."[61]

MULTIPLE SCLEROSIS

A five-week double-blind placebo-controlled study found that multiple sclerosis patients who used whole-plant cannabis-based medication (including cannabinoids THC and CBD) experienced reduced pain intensity.[62]

The same 2005 study also found that cannabis-based medication decreased sleep disturbances, leading researchers to conclude:

> "Cannabis-based medicine is effective in reducing pain and sleep disturbance in patients with multiple sclerosis related central neuropathic pain and is mostly well tolerated."

OBESITY

In 2011, the *American Journal of Epidemiology* reviewed two population-based nationally representative studies exploring the relationship between marijuana use and obesity. After analyzing results from over 50,000 respondents, researchers concluded:

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[60] Rhyne, D.N., Anderson, S.L., Gedde, M., & Borgelt, L.M. (2016). Effects of medical marijuana on migraine headache frequency in an adult population. *Pharmacotherapy, 36*(5), 505-10.
[61] EMJ Neurology. (2017). Review of the 3rd European Academy of Neurology Congress 2017. *European Medical Journal, 5*(1):12-29.
[62] Rog, D. J., Nurmikko, T.J., Friede, T., & Young, C.A. (2005). Randomized, controlled trial of cannabis-based medicine in central pain in multiple sclerosis. *Neurology, 65*(6), 812-19.

> "The prevalence of obesity was significantly lower in cannabis users than in non-users […] The proportion of obese participants decreased with the frequency of cannabis use."[63]

Addressing widely held stereotypes, the authors add:

> "This cross-sectional analysis indicated that despite the evidence that cannabis use stimulates appetite in clinical trials and laboratory studies, cannabis users are actually less likely to be obese than non-users in the general population."

Likewise, a study from 2006 found that even though marijuana use may be correlated with increased caloric intake, it is not associated with higher body mass index (BMI) or glucose levels.[64]

PAIN

After administering standardized doses of smoked marijuana using a uniform puff and breath-hold procedure, researchers found that:

> "...a linear analgesic [pain relief] dose response for… cannabis substantiated previous empirical reports of pain relief."[65]

The study authors concluded that marijuana reduced pain intensity and unpleasantness equally, meaning that (like opioids) cannabis does not rely on a relaxing or tranquilizing effect, but rather "reduces both the core component of nociception and the emotional aspect of the pain experience to an equal degree."

PARKINSON'S DISEASE

In 2014, *Clinical Neuropharmacology* reported that marijuana improves Parkinson's motor symptoms including tremors, rigidity, and bradykinesia, as well as non-motor symptoms such as

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[63] Le Strat, Y., & Le Foll, B. (2011). Obesity and cannabis use: results from 2 representative national surveys. *American Journal of Epidemiology, 174*(8), 929-33.
[64] Rodondi, N., Pletcher, M.J., Liu, K., Hulley, S.B., Sidney, S., & Coronary Artery Risk Development in Young Adults (CARDIA) Study (2006). Marijuana use, diet, body mass index, and cardiovascular risk factors (from the CARDIA study). *The American Journal of Cardiology, 98*(4), 478-84.
[65] Wilsey, B., Marcotte, T., Tsodikov, A., Millman, J., Bentley, H., Gouaux, B., & Fishman, S. (2008). A randomized, placebo-controlled, crossover trial of cannabis cigarettes in neuropathic pain. *The Journal of Pain, 9*(6), 506-21.

pain and sleep disorders.[66] Follow-up studies appear to support these results, with a 2015 survey finding:

> "Cannabis was rated as the most effective therapy for sleep and mood improvement amongst all complementary and alternative medications."[67]

Likewise, the *Journal of Psychopharmacology* reports:

> "We found significant improvements in measures of functioning and well-being of Parkinson's disease patients treated with CBD compared to a group that received placebo."[68]

Respiratory Health: Risks Rebuttal

Any claim of substantial evidence of a statistical association between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes stands in contrast to what is considered the largest and longest study ever to consider the issue of marijuana and impaired lung function.

According to a twenty-year study published by the *Journal of the American Medical Association*, researchers found that:

> "Occasional and low cumulative marijuana use was not associated with adverse effects on pulmonary function."[69]

Interestingly, results also suggest that low and moderate levels of marijuana use may even improve lung function, as measured by two lung capacity tests: FEV1 and FVC. As associate professor of epidemiology and biostatistics at the University of California and lead study author Dr. Mark Pletcher explains:

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[66] Lotan, I., Treves, T. A., Roditi, Y., & Djaldetti, R. (2014). Cannabis (medical marijuana) treatment for motor and non-motor symptoms of Parkinson disease: An open-label observational study. *Clinical Neuropharmacology, 37*(2), 41–44.
[67] Finseth, T.A., Hedeman, J.L., Brown, R.P., Johnson, K.I., Binder, M.S., & Kluger, B.M. (2015). Self-reported efficacy of cannabis and other complementary medicine modalities by Parkinson's disease patients in Colorado. *Evidence-based Complementary and Alternative Medicine, 2015*: 874849.
[68] Chagas, M.H., Zuardi, A.W., Tumas, V., Pena-Pereira, M.A., Sobreira, E.T., Bergamaschi, M.M., dos Santos, A.C., Teixeira, A.L., Hallak, J.E., & Crippa, J.A. (2014). Effects of cannabidiol in the treatment of patients with Parkinson's disease: An exploratory double-blind trial. *Journal of Psychopharmacology, 28*(11): 1088-98.
[69] Pletcher, M.J., Vittinghoff, E., Kalhan, R., Richman, J., Safford, M., Sidney, S., Lin, F., & Kertesz, S. (2012). Association between marijuana exposure and pulmonary function over 20 years. *Journal of the American Medical Association, 307*(2):173-81.

> "FEV1 and FVC both actually increased with moderate and occasional use of marijuana […] It's a weird effect to see and we couldn't make it go away."

A systematic review by Health Canada drew similar conclusions:

> "The association between chronic heavy cannabis smoking (without tobacco) and chronic obstructive pulmonary disease, is unclear, but if there is one, is possibly small."[70]

As *Respiratory Care* warns:

> "Although much is known about tobacco smoke, less is known about marijuana smoke, and inferences cannot be made about one based on the other."[71]

Importantly, in a retrospective cohort study of 64,855 participants, researchers found:

> "Marijuana use was not associated with tobacco-related cancers or with cancer of the following sites: colorectal, lung, melanoma, breast."[72]

Likewise, a population-based case-control study of 611 lung cancer patients revealed that chronic low cannabis exposure was not associated with an increased risk of lung cancer or other upper aerodigestive tract cancers.[73] Furthermore, the same study found no positive associations with any cancer type (oral, pharyngeal, laryngeal, lung, or esophagus) when adjusting for several confounders, including cigarette smoking.

These results led researchers to conclude:

> "[Our study] suggests that the association of these cancers with marijuana, even long-term or heavy use, is not strong and may be below practically detectable limits."

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[70] Health Canada. (2018). Information for health care professionals: Cannabis (marihuana, marijuana) and the cannabinoids.
[71] Martinasek, M.P., McGrogan, J.B., & Maysonet, A. (2016). A systematic review of the respiratory effects of inhalational marijuana. *Respiratory Care, 61*(111): 1543-51.
[72] Sidney, S., Quesenberry, C.P., Friedman, G.D., & Tekawa, I.S. (1997). Marijuana use and cancer incidence (California, United States). *Cancer Causes Control, 8*(5): 722:8.
[73] Hashibe, M., Morgenstern, H., Cui, Y., Tashkin, D.P., Zhang, Z.F., Cozen, W., Mack, T.M., & Greenland, S. (2006). Marijuana use and the risk of lung and upper aerodigestive tract cancers: Results of a population-based case-control study. *Cancer Epidemiology, Biomarkers & Prevention, 15*(10): 1829-34.

In 2006, another set of researchers conducted a systematic review assessing 19 studies that evaluated premalignant or malignant lung lesions in persons 18 years or older who inhaled marijuana. As summarized by the study authors:

> "[These] observational studies failed to demonstrate statistically significant associations between cannabis inhalation and lung cancer after adjusting for tobacco use."[74]

Supporting this conclusion, Health Canada notes:

> "At present, no conclusive positive associations can be drawn between cannabis smoking and incidence of lung or upper airway cancer."[75]

Summary

In addition to the stated health benefits, medical marijuana has also been shown to decrease opioid dependence, cocaine addiction, and alcohol use. 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."[76]

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

> "CBD treatment dose-dependently diminished cocaine self-administration and moved the dose-response curve downward."[77]

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

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[74] Mehra, R., Moore, B.A., Crothers, K., Tetrault, J., & Fiellin, D.A. (2006). The association between marijuana smoking and lung cancer: A systematic review. *Archives of Internal Medicine, 166*(13): 1359-67.
[75] Health Canada. (2018). Information for health care professionals: Cannabis (marihuana, marijuana) and the cannabinoids.
[76] 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.
[77] 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.

> "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."[78]

Again, while just a small sampling of the research supporting medical marijuana's efficacy and rightful place in modern medicine, the studies above provide apt rationale for the passion exhibited by medical cannabis advocates, physicians, and patients – a passion we can only hope will be increasingly reflected in public dialogue and future legislative policies.

[78] 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.

HOUSE BILL 1455: OBJECTION DETAILS

PHYSICIAN ADVERTISING

The prohibition preventing "qualified physicians from engaging in certain advertising for their practices relating to marijuana for medical use" is opposed 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*[79] 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.

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

> 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."

Importantly, *Conant v. McCaffrey* focused on the *act* of recommending medical marijuana, and was later upheld by *Conant v. Walters,*[80] 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),[81] 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").[82]

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[80] *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002)
[81] 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…."
[82] 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.

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.

TRADE RESTRAINT OBJECTIONS

Prior to 1975, the American Medical Association (AMA) barred physician advertising. Following *Goldfarb v. Virginia State Bar*[83] – 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.[84] 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."[85]

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."[86]

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."[87]

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[83] *Goldfarb v. Virginia State Bar*, 421 U.S. 1773 (1975)
[84] *American Medical Association v. FTC*, 455 U.S. 676 (1982)
[85] Dyer, A.R. (1985). Ethics, advertising, and the definition of a profession. *Journal of Medical Ethics, 11*(2): 72-8.
[86] 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#
[87] 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:

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.[88] [89]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)."[90]

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.)[91] The FDA has no power to

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https://www.ftc.gov/news-events/blogs/competition-matters/2015/02/ftc-milestone-new-age-dawns-ftcs-competition-work

[88] American Medical Association. (2021). *Advertising & Publicity: Code of Medical Ethics Opinions 9.6.1*.

[89] *Federal Trade Commission Act*, 15 U.S.C. §§ 41-58

[90] Schwartz, L.M. & Woloshin, S. (2019). Medical marketing in the United States, 1997-2016. *Journal of the American Medical Association, 321*(1): 80-96.

[91] Bell, R. A., Kravitz, R. L., & Wilkes, M. S. (1999). Direct-to-consumer prescription drug

levy fines; however, the agency may issue violation letters.[92] Unfortunately, approximately 30 FDA employees are responsible for reviewing the roughly 30,000 submissions the agency receives each year[93] – 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."[94]

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."[95]

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"[96] 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.

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advertising and the public. *Journal of General Internal Medicine, 14*(11), 651-657.
[92] Holmer, A.F. (2002). Direct-to-consumer advertising: Strengthening our health care system. *New England Journal of Medicine, 346*(7): 526-528.
[93] 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.
[94] Free rein for drug ads?
[95] Federal Trade Commission. (September 2013). *Alcohol advertising*. Retrieved March 6, 2021 from https://www.consumer.ftc.gov/articles/0391-alcohol-advertising
[96] 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."[97]

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 opposed 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"[98] 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." [99]

Speaking to the critical role of CB1 receptors, *The Journal of Clinical Investigation* writes:

[97] Federal Trade Commission. (2014). Retrieved March 7, 2021 from https://www.consumer.ftc.gov/articles/0391-alcohol-advertising

[98] 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.

[99] 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).

> "It has been shown that acute, high doses of CB1 agonists or cannabinoids produced anxiety-like effects in rats. We observed here that chronic administration of high, but not low, doses of HU210 exert anxiolytic- and antidepressant-like effects." [100]

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 man-made 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."[101]

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."[102]

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[100] Jiang, W., Zhang, J., Xiao, L., Van Cleemput, J. Ji, S-P., Bai, G., & Zhang, X. (2005). Cannabinoids promote embryonic and adult hippocampus neurogenesis and produce anxiolytic- and antidepressant-like effects. *The Journal of Clinical Investigation, 115*(11): 3104-16.
[101] 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
[102] 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."[103]

Researchers also report that THC is "well tolerated"[104] and could perhaps extend the life of ALS patients by three years or more.[105] [106] As study co-author Mary Abood explains:

> "We found that treatment with THC delayed disease progression by seven days and extended survival by six days in the mouse model. This corresponds to three years in human terms. [...] The only FDA approved drug for ALS, riluzole, extends life on average by about two months."[107]

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."[108]

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."[109]

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[103] 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.
[104] Raman, C., McAllister, S.D., Rizvi, G., Patel, S.G., Moore, D.H., Abood, M.E. (2004). Amyotrophic lateral sclerosis: delayed disease progression in mice by treatment with a cannabinoid. *Amyotrophic Lateral Sclerosis & Other Motor Neuron Disorders, 5*(1):33-39.
[105] Raman et al. (2004).
[106] Society For Neuroscience. (2004). "Marijuana-Like Compounds May Aid Array Of Debiliating Conditions Ranging From Parkinson's Disease To Pain." ScienceDaily. Retrieved March 17, 2021 from www.sciencedaily.com/releases/2004/10/041027102621.htm
[107] Society For Neuroscience. (2004).
[108] Health Canada: Cannabis Legalization and Regulation Branch. (October 2018). *Information for health care professionals: Cannabis (marihuana, marijuana) and the cannabinoids*.
[109] 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.

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 mean survival time (36% at 100 mg/kg, 25% at 200 mg/kg, and 27% at 50 mg/kg, respectively), whereas CBD did not."[110]

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.[111]

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."[112]

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.

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[110] 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.
[111] 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.
[112] 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.

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:

> "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.[113] 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[114] 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."[115]

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

[113] 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? *Schizophrenia Research*, *120*(1-3): 101-7.
[114] Wade, D. (2005). Cannabis use and schizophrenia. *American Journal of Psychiatry*, 162(2): 401.
[115] 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.

> 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."[116]

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."[117]

Joining a growing body of literature, *The Journal of Clinical Investigation* details the *neuroprotective* role of cannabis (in particular cannabinoids that act on CB1 receptors, like THC):

> "[S]ince adult hippocampal neurogenesis is suppressed following chronic administration of opiates, alcohol, nicotine, and cocaine, the present study suggests that cannabinoids are the only illicit drug that can promote adult hippocampal neurogenesis following chronic administration."

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."[118]

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[116] Large et al. (2011).
[117] 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.
[118] 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

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."[119]

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."[120]

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."[121]

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."[122]

Cannabis and Cannabinoid Research notes:

> "Growing pre-clinical and clinical evidence appears to support the use of cannabis for these purposes. The evidence summarized in this article demonstrates the potential

[119] 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.
[120] 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.
[121] 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
[122] 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.

> cannabis has to ease opioid withdrawal symptoms, reduce opioid consumption, ameliorate opioid cravings,prevent opioid relapse, improve opioid use disorder treatment retention, and reduce overdose deaths."[123]

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

> "CBD treatment dose-dependently diminished cocaine self-administration and moved the dose-response curve downward."[124]

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."[125]

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 Murphy (2013)[126] 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%."[127]

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

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[123] Wiese, B. & Wilson-Poe, A.R. (2018). Emerging evidence for cannabis' role in opioid use disorder. *Cannabis and Cannabinoid Research, 3.1*: 179-89.
[124] 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.
[125] 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.
[126] Becker, G. & Murphy, K. (2013). Have we lost the war on drugs? *The Wall Street Journal*.
[127] Dragone, D., Prarolo, G., Vanin, & Zanella, G. (2019). Crime and the legalization of recreational marijuana. *Journal of Economic Behavior & Organization, 159*: 488-501.

> "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."[128]

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."[129]

Of added interest, California had 8.3% fewer traffic fatalities in 2018 (the year it launched recreational marijuana shops), than it did in 2017.[130]

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 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[131] – 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…".[132]

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[128] 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).
[129] 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.
[130] 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/
[131] Florida Senate Bill 8A (2017A)
[132] 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

However, despite the FDA's broad scope and oft-criticized "paternalism"[133] 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."[134]

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,"[135] 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, 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."[136]

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

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[133] 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

[134] 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.

[135] 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/

[136] 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

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." [137]

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[138] 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.

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).[139] 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),[140] the principle holds that the act of *practicing* medicine is distinct from medicine itself. According to Florida Statutes 458.305:

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[137] Mandal, S., Moudgil, M., & Mandal, S.K. (2009). Rational drug design. *European Journal of Pharmacology, 625*: 90-100.
[138] 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.
[139] Epstein, R. (30 September 2013).
[140] *United States of America v. Regenerative Sciences, LLC*, 741 F.3d 1314

> "'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."[141]

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.

[141] 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/