REGARDING KANSAS SENATE BILL 555 (2024), THE PROPOSED KANSAS MEDICAL CANNABIS PILOT PROGRAM

NEUTRAL TESTIMONY OF PAUL J. LARKIN

Chairman Thompson and members of the committee,

My name is Paul Larkin, and I am the John, Barbara & Victoria Rumpel Senior Legal Research Fellow in the Edwin J. Meese III Center for Legal and Judicial Studies at the Heritage Foundation.[1] Among other subjects, I research issues that fit under the umbrella of drug policy. I have written on the subject of cannabis in articles published by the Heritage Foundation[2] and by private law or public policy journals.[3] I also have testified before Congress and the state legislatures in Virginia and South Carolina on that subject.[4] In my opinion, Kansas Senate Bill 555, which seeks to create a medical cannabis program, is unwise for several reasons summarized below.

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[2] *See*, *e.g.*, Paul J. Larkin, *Twenty-First Illicit Drugs and Their Discontents: Why the FDA Could Not Approve Raw Cannabis as a "Safe," "Effective," and Uniform" Drug*, THE HERITAGE FOUND., Special Report No. 275 (2023) [hereafter Larkin, *FDA and Cannabis*]; Paul J. Larkin, *Twenty-First Illicit Drugs and Their Discontents: The Failure of Cannabis Legalization to Eliminate an Illicit Market*, THE HERITAGE FOUND., Legal Memorandum No. 326 (2023); Paul J. Larkin, *Twenty-First Illicit Drugs and Their Discontents: The Potential Risks that Cannabis Use by Pregnant and Nursing Women Poses to Their Children*, THE HERITAGE FOUND., Legal Memorandum No. 319 (2022); Paul J. Larkin, Jr., *Twenty-First Illicit Drugs and Their Discontents: The Troubling Potency of Twenty-First Century Cannabis*, THE HERITAGE FOUND., Legal Memorandum No. 317 (2022).

[3] *See*, *e.g.*, Paul J. Larkin, *Driving While Stoned in Virginia*, 59 AM. CRIM. L. REV. ONLINE 1 (2022) [hereafter Larkin, *Driving While Stoned*]; Paul J. Larkin, Jr., *Reflexive Federalism*, 44 HARV. J. L. & PUB. POL'Y 523 (2021); Paul J. Larkin, Jr., *Cannabis Capitalism*, 69 BUFF. L. REV. 215 (2021); Paul J. Larkin, Jr., *Reconsidering Federal Marijuana Regulation*, 18 OHIO ST. J. CRIM. L. 99 (2020); Paul J. Larkin, Jr. & Bertha K. Madras, *Opioids, Overdoses, and Cannabis: Is Marijuana an Effective Therapeutic Response to the Opioid Abuse Epidemic?*, 17 GEO. J.L. & PUB. POL'Y 555 (2019); Paul J. Larkin, Jr., *States' Rights and Federal Wrongs: The Misguided Attempt to Label Marijuana Legalization Efforts as a "States' Rights" Issue*, 16 GEO. J.L. & PUB. POL'Y 495 (2018); Paul J. Larkin, Jr., *Marijuana Edibles and "Gummy Bears*," 66 BUFF. L. REV. 313 (2018); Paul J. Larkin, Jr., *The Medical Marijuana Delusion*, PENN. REGULATORY REV. (Dec. 17, 2018) [hereafter Larkin, *Medical Marijuana Delusion*]; Paul J. Larkin, Jr., *Medical or Recreational Marijuana and Drugged Driving*, 52 AM. CRIM. L. REV. 453 (2015) [hereafter Larkin, *Drugged Driving*].

[4] *See Hearing on S. 150, The South Carolina Compassionate Care Act*, The South Carolina General Assembly, the House of Representatives, Hearing Before Subcommittee I on Health and Environmental Affairs of the Medical, Military, Public and Municipal Affairs Committee, Written Statement of Paul J. Larkin, April 4, 2022 (Submitted April 5, 2022); Hearing on. S.B. 391, Virginia General Assembly, House of Delegates, General Laws Comm. (Feb. 24, 2022) [hereafter Larkin, *Virginia Testimony*]; "*Unlocked Potential? Small Businesses in the Cannabis Industry,*" House Comm. on Small Business, 116th Cong. (2019) (Written Statement of Paul J. Larkin, Jr.).

In short, the bill fails to recognize that the term "medical cannabis" (or "medical marijuana") is an oxymoron. The cannabis plant contains numerous biologically active compounds, known as cannabinoids. Some of them are useful. Others might be, depending on their concentration, but we do not yet know whether they are useful or harmful. Still others likely are not beneficial and might well be harmful to humans. We do not yet know the answer to those questions for every cannabinoid because neither the federal government nor Kansas has adequately studied the potential benefits of cannabinoids. What we do know is that Senate Bill 555 does not require participants in the proposed medical cannabis program to await the determination of the Food and Drug Administration (FDA) before distributing cannabis flowers, pills, tablets, patches, or ointments to patients. For 86 years, the nation has entrusted the FDA with the responsibility of protecting the public against the distribution of potentially unsafe, ineffective, and disuniform pharmaceuticals. This bill mistakenly rejects that judgment. It commits other errors too.

I. The Kansas Medical Cannabis Pilot Program

Kansas Senate Bill 555 seeks to create a "Medical Cannabis Pilot Program" to be administered by the state Secretary of Health and the Environment.[5] The program would empower that official to enter into contracts with no more than four[6] "medical cannabis operators"[7] to allow "distribution hubs"—viz., wholesale or retail stores that sell cannabis[8]—to sell "medical cannabis product[s]"—viz, a product containing one or more biologically active compounds known as cannabinoids[9]—in the form of pills, tablets, patches, and ointments, as well as the cannabis flower itself, to users.[10] Some of those products will be infused with

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[5] Senate Bill 555, § 1, at Page 1, § 4(a) at Page 4 ("There is hereby established the medical cannabis pilot program to be administered by the secretary of health and environment.").

[6] Senate Bill 555, § 4(c), at Page 5.

[7] Senate Bill 555, § 2(j), at Page 2 ("'Medical cannabis operator" or 'operator' means a person who cultivates, processes, stores, distributes, sells and delivers medical cannabis and medical cannabis products in accordance with a contract with the secretary pursuant to section 4, and amendments thereto.").

[8] Senate Bill 555, § 2(g), at Page 2 ("'Distribution hub' means a premises owned and operated by a medical cannabis operator or a pharmacy for the storage, distribution, sale and delivery of medical cannabis and medical cannabis products to patients and caregivers.").

[9] Senate Bill 555, § 2(k), at Page 2 ("'Cannabinoid' means any of the chemical compounds that are produced naturally in the plant cannabis sativa that can bind on the cannabinoid receptors in cells."); *id*. § 8(b) ("(b) On or before September 1, 2024, the secretary shall determine if pharmacies are precluded from operating distribution hubs by federal law or regulations. If the secretary determines that pharmacies are precluded from operating distribution hubs, the secretary may enter into contracts with one or more medical cannabis operators for the operation of distribution hubs. A medical cannabis operator shall not operate more than seven distribution hubs. The provisions of section 4, and amendments thereto, shall apply to any contract entered into between the secretary and a medical cannabis operator pursuant to this section."); § 8(c) ("Each distribution hub may obtain medical cannabis and medical cannabis products from one or more medical cannabis operators, including the operator that owns and operates such distribution hub. A distribution hub may sell and deliver medical cannabis and medical cannabis products to patients and caregivers in accordance with subsection (b).").

[10] Senate Bill 555, § 22(a), at Page 22 A patient who holds a valid medical cannabis certificate may: (1) Use or consume medical cannabis and medical cannabis products; (2) subject to subsection (b), purchase and possess medical cannabis and medical cannabis products; and (3) purchase and possess any paraphernalia or accessories used to administer or consume medical cannabis and medical cannabis products."); *id*. § 22(b), at

delta-9-tetrahydrocannabinol (THC), the principal psychoactive ingredient in cannabis.[11] The apparent goal is to alleviate the symptoms of only[12] the "qualifying medical conditions" diseases identified in the bill, such as AIDS, Lou Gehrig's Disease, Parkinson's Disease, and multiple sclerosis.[13]

II. The Mistakes that California Made in the Original State-Authorized Medical Cannabis Program

Senate Bill 555 would not make the same mistakes that California made in 1996 by passing Proposition 215—a citizens' initiative entitled the Compassionate Use Act—that created the nation's first state-authorized medical cannabis program.[14] Reformers argued that medical cannabis was necessary to alleviate the suffering of the dying and crippled in a manner that no other drug could effect. In truth, however, as the initiative's supporters ultimately admitted,[15] the bill was just a disguised effort to legalize recreational cannabis use.[16] "Medical marijuana advocates also took advantage of the belief that little harm and possibly some good could result from allowing medically-condemned patients to achieve some respite from their tragic predicaments by whatever means they found useful, means that harmed no one else."[17] That initiative allowed the use of old-fashioned smokable botanical-form cannabis to be deemed a legitimate medical treatment—even though the Federal Food and Drug Administration has never

page 22 ("A patient shall not purchase medical cannabis or medical cannabis products in an amount that exceeds in the aggregate 200 grams of unprocessed medical cannabis flower or 3.47 grams of tetrahydrocannabinol contained in any medical cannabis product during any 30-day period of time."). Caregivers may purchase cannabis on behalf of a patient. *Id*. § 2, at page 2 ("'Caregiver' means an individual designated on a medical cannabis certificate who is authorized to purchase and possess medical cannabis on behalf of a patient named in such medical cannabis certificate."); *id*. § 22(c), at Page 22("Caregivers who hold a valid medical cannabis certificate on which such individual is the designated caregiver may purchase and possess medical cannabis, medical cannabis products, paraphernalia and accessories used to administer or consume medical cannabis and medical cannabis products on behalf of the patient named on the medical cannabis certificate, and may reasonably assist such patient with using or consuming medical cannabis and medical cannabis products. The provisions of subsection (b) shall apply to the purchase of medical cannabis and medical cannabis products by a caregiver. No other use or consumption of any medical cannabis or medical cannabis products purchased and possessed by a caregiver on behalf of a patient shall be permitted.").

[11] Senate Bill 555, § 2(y), at Page 4 ("'Tetrahydrocannabinol' or "'HC' means the primary psychoactive cannabinoid in cannabis.").

[12] The term "only" is. not used in the bill, but the bill's text provides that the term "qualifying medical condition "*means*" the listed disease that follow, rather than say "*includes*." Senate Bill 555, § 2(u), at Page 2. The result is that the conditions listed in Section 2(u) are exclusive.

[13] Senate Bill 555, § 2, at Page 2, 3.

[14] *See* Cal. Health & Safety Code § 11362.5 (West 2024).

[15] "Supporters of the California measure did their cause no good by immediately lighting up marijuana cigarettes after it passed last month and proclaiming that a legitimate medicinal use would include smoking a joint to relieve stress. Dennis Peron, originator of the California initiative, said afterward, 'I believe all marijuana use is medical--except for kids.' These actions made it obvious that the goal of at least some supporters is to get marijuana legalized outright, a proposition that opinion polls indicate most Americans reject." *Marijuana for the Sick*, N.Y. Times, Dec. 30, 1996, http://www.nytimes.com/1996/12/30/opinion/marijuana-for-the-sick.html.

[16] *See* Larkin, *Drugged Driving*, *supra* note 3, at 510-12.

[17] *Id*. at 510.

approved agricultural cannabis as a legitimate medical therapy for any affliction,[18] and no responsible physician would recommend inhaling burnt carbon products into one's lungs.[19] Moreover, while the California initiative legalized the sale of agricultural cannabis for a host of truly serious maladies, such as end-stage cancer and multiple sclerosis, that was just a marketing ploy. Proposition 215 also authorized a physician to recommend its use for "any other illness for which marijuana provide relief," which includes a mild feeling of sadness caused by a cloudy day, or any other condition that a physician thought could be comforted by getting "buzzed."[20] Because "[t]he claim that the plant form of marijuana can and should be smoked for medical purposes is a hobgoblin,"[21] the hypocrisy of California's "medical" cannabis Proposition 215 should be a "given."[22]

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[18] In 1938, Congress and the President teamed up to enact the Federal Food, Drug, and Cosmetic Act (FDCA), Ch. 675 § 1, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.* (2019)). The act vested in the Commissioner of Food and Drugs the responsibility to decide whether a particular compound is a "new drug," and, if it is, whether it is "safe," "effective," and "uniform." In the exercise of that authority, the U.S. Department of Health and Human Services, the parent agency for the FDA, has concluded for decades that the plant form of cannabis is a "new drug," rendering it subject to the FDCA. At the same time, the agency has never found that cannabis itself is "safe," "effective," and "uniform." *See, e.g.*, *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, FDA (Oct. 1, 2020), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd [https://perma.cc/TF56-2GRQ]; *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, FDA (Mar. 5, 2020), https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis [https://perma.cc/7HGY-KAZ4]; *FDA and Cannabis: Research and Drug Approval Process*, FDA (Oct. 1, 2020), https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process [https://perma.cc/L2QP-YETU]. In fact, no such pharmaceutical company could prove that raw cannabis satisfies those requirements. I explained in detail why that is true in my Heritage Special Report *Twenty-First Illicit Drugs and Their Discontents: Why the FDA Could Not Approve Raw Cannabis as a "Safe," "Effective," and Uniform" Drug*, *supra* note 1.

[19] "Particular chemical constituents of smoked marijuana may have medical benefits, but it is unthinkable that in the closing decade of the 20th century, American medicine would return to prescribing smoked leaves for any condition." Robert L. DuPont, Correspondence, *Medicinal Marijuana?*, 336 NEW ENG. J. MED. 1184, 1184 (1997). Dr. DuPont founded the federal government's National Institute on Drug Abuse.

[20] *See id*.

[21] Larkin, *Medical Marijuana Delusion*, *supra* note 3.

[22] *See Larkin, Drugged Driving*, *supra* note 3, at 513 n.283: "The hypocrisy of California's medical marijuana program seems by now to be universally accepted as a given. *See, e.g.*, Hank Campbell, *Junk Science And The Hypocrisy Of Medical Marijuana*, SCIENCE 2.0 (July 23, 2013, 12:25 PM), http://www.science20.com/science_20/junk_science_and_hypocrisy_ medical_marijuana-96254 ("While *medical* marijuana was sold to states for serious illness, Edward Gogek, M.D., notes, it is not the case in practice. Instead, it is sold for 'pain' 90% of the time, which is a symptom so non-specific and subjective that Ferris Buehler got a whole day off school with it."); Kerry Cavanaugh, *A "Munchies" Cafe? California Needs to Fix Its Medical Marijuana Mess*, L.A. TIMES, May 15, 2014, http://www.latimes.com/opinion/opinion-la/la-ol-amunchiescalifornia-medical-marijuana-20140515-story.html ("The sign reminded me, yet again, that California's medical marijuana system is a total joke. When voters passed the Compassionate Use Act in 1996, the ballot measure promised a way for patients with cancer, AIDS, glaucoma and other illnesses to use marijuana for pain relief. But in the absence of comprehensive state regulations, the law legalizing medical marijuana has also allowed the de facto legalization of pot for recreational use. That's led to a widespread ruse in which healthy people who want weed to go to a doctor, profess some malady and get a recommendation that allows them to buy marijuana at a dispensary. Compassionate use has become indiscriminate use."); Andrew O'Hehir, "*California, 90420": The Great Marijuana Hypocrisy*, Salon, Apr. 18, 2012, 5:55 PM, http://www.salon.com/2012/04/18/california_90420_the_great_marijuana_hypocrisy/ ("The problem with California's nudge-wink medical marijuana system is the same as the problem with weed-attitudes (*weeditudes!*) in our culture generally, whether pro or con . . . . That problem is universal hypocrisy .... Just to be clear, I grew up in Oakland and nearby Berkeley

Sadly, other states have succumbed to the same tempting hypocrisy. They have passed similar laws, perhaps for the purpose of appeasing the interest groups in favor of liberalized cannabis use, perhaps to give in to every legislator's ever-present, never-satisfied desire to find an additional activity to tax to fund favored programs, or perhaps to satisfy patients (and their families) clamoring for whatever relief cannabis's euphoria might provide the dying. The first two explanations are hardly noble ones, but the last reason is just self-delusion. "Caring without science is well intentioned kindness," but it is "not medicine."[23] Hopefully the Kansas legislature will not yield to one of those rationales. That other states have made such mistakes should not serve as a precedent for Kansas following suit.

It is also important to recognize that cannabis cannot serve as an analgesic substitute for opioids. While it is true that numerous individuals have long argued (and some government reports and private studies have even concluded[24]) that the psychoactive ingredient in cannabis has an analgesic effect for some types of pain,[25] THC cannot alleviate the type of pain characteristic of end-stage cancer; only opioids can provide the necessary relief.[26] Studies also reveal that the

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(so draw your own conclusions about my personal history), and I'm 100 percent in favor of legalizing pot. But California's current medical marijuana law is a total farce, and you can't blame people who genuinely think that drugs are evil for claiming that it amounts to soft-focus legalization. Because it does. Yes, cannabis is medically helpful, and in some cases necessary, for people with cancer or AIDS or glaucoma or certain psychiatric ailments. And of course they should be able to get it. But everybody in California knows that's not how the system works in practice. You find a sympathetic doctor (and the right ones advertise widely), and you say, 'Gee, doc, I've been feeling kinda depressed lately. Plus[,] I've been having hella headaches. Kind of seems like a recurring situation, dude.' He or she signs something, you get your ID card, and you're gold. Or Purple Urkel, or Diesel Granddaddy Mandala, as the case may be. (Blends of, y'know, medicine that are evidently for sale in downtown Oakland.) As Ix says when she first sees a legal cannabis dispensary, 'This is what heaven would be like if God were real.'"'), Chris Roberts, *Anyone Can Get Their Medicine: California Has Already Pretty Much Legalized Marijuana. And That's Okay*, SFWEEKLY, Sept. 14, 2014, http://www.sfweekly.com/sanfrancisco/chem-tales-marijuana-legalization-recreational-use/Content?oid=3154256 ("Anyone Can Get Their Medicine. Not long ago, a friend of mine visited the doctor. Afterward, I asked him for the diagnosis. 'Good news,' he said with a grin. 'I'm still sick.' A clean bill of health would have been a setback. That would mean no more marijuana. I am often asked how to legally obtain some weed in San Francisco, what ailment is required to get a medical marijuana recommendation. This fascinates people to this day, out-of-towners as well as locals. When I am honest, I say, 'About $40 and 10 minutes.'"').

[23] Gary M. Reisfield & Robert L. DuPont, *Clinical Decisions: Medicinal Use of Marijuana—Recommend Against the Medical Use of Marijuana,* 368 NEW ENG. J. MED. 866, 868 (2013) (citation omitted).

[24] One article has been cited to support the argument that cannabis can substitute for opioids as an analgesic. *See* David Powell et al., *Do Medical Marijuana Laws Reduce Addictions and Deaths Related to Pain Killers?*, 58 J. HEALTH ECON. 29 (2018)). The Powell article, however, does not consider earlier and more recent analyses showing that cannabis is not an adequate substitute for opioids and creates additional problems for people already suffering from opioid use disorder. *See, e.g.*, Fiona A. Campbell et al., *Are Cannabinoids an Effective and Safe Treatment in the Management of Pain? A Qualitative Systematic Review*, 323 BRIT. MED. J. 1, 16 (2001) ("We found insufficient evidence to support the introduction of cannabinoids into widespread clinical practice for pain management—although the absence of evidence of effect is not the same as the evidence of absence of effect. . . . Cannabis is clearly unlikely to usurp existing effective treatments for postoperative pain.").

[25] *See, e.g.*, NAT'L ACAD. OF SCIS., ENG'G, & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS 54 Tbl. 2-2, 128 Box 4-1 (2017) (listing conditions for which marijuana is a treatment, with varying degrees of scientific support); Gemayel Lee et al., *Medical Cannabis for Neuropathic Pain*, 22 CURRENT PAIN & HEADACHE REPS. 8 (2018) ("Nearly 20 years of clinical data supports the short-term use of cannabis for the treatment of neuropathic pain."); Barth Wisley et al., *Low Dose Vaporized Cannabis Significantly Improves Neuropathic Pain*, 14 J. PAIN 136 (2013).

[26] *See* Larkin, *Reflexive Federalism*, *supra* note 3, at 551-53 ("Cannabis is an insufficiently potent analgesic to mollify the severe acute pain caused by surgery, gunshot wounds, late-stage cancer, motor

hoped-for pain-relieving effect of cannabis has not panned out.[27] Besides, if every substance that offered some pain-killing benefit were deemed a "medicine," the ethanol in Wild Turkey would be on that list. Dr. Peter Bach, a physician and Director of the Center for Health Policy and Outcomes at the Memorial Sloan Kettering Cancer Center, certainly would not classify either one of those "painkillers" as a medicine. In his words, "every intoxicant would pass that sort of test because you don't experience pain as acutely when you are high. If weed is a pain reliever, so is Budweiser."[28]

III. The Mistakes that Kansas Would Make in Its Proposed Medical Cannabis Pilot Program

While Senate Bill 555 avoids the mistakes that California made—and its drafters and sponsors deserve credit for avoiding those flaws—the bill makes other mistakes in the process. They are discussed below.

A. Senate Bill 555 Would Approve the Distribution of Drugs that the FDA Has Not Found to be "Safe," Effective," and "Uniform"

In 1938, Congress and the President teamed up to enact the Federal Food, Drug, and Cosmetic Act (FDCA), to protect the nation against the interstate distribution of harmful drugs.[29] Since then, the nation has trusted the Commissioner of Food

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vehicle crashes, and similar illnesses and events. Neither cannabis nor any other drug can match the acute pain-killing effectiveness of opioids. Marijuana also is not a proven therapeutic substitute for, or complement to, opioids (or other drugs) in the treatment of chronic pain, for several reasons. In fact, people who use both drugs do not reduce their intake of opioids, and the combination of the two makes it more difficult for patients to terminate opioid use through drug treatment. In sum, marijuana is not a substitute for opioids.") (footnotes omitted).

[27] A 2017 paper published in the peer-reviewed journal *Lancet Public Health*, based on a four-year longitudinal cohort study, concluded that cannabis does not provide long-term relief from chronic non-cancer pain. Gabrielle Campbell et al., *Effect of Cannabis Used in People with Chronic Non-Cancer Pain Prescribed Opioids: Findings from a 4-year Prospective Cohort Study*, 3 Lancet Pub. Health e341 (2018). In fact, a 2019 study published by the National Academy of Sciences concluded that states with liberal cannabis laws witnessed an *increase* in opioid deaths. Chelsea L. Shover et al., *Association Between Medical Cannabis Laws and Opioid Overdose Mortality Has Reversed Over Time*, 116 Proceedings Nat'l Acad. Sci. 12624 (2019). *See also*, *e.g.*, Devan Kansagara et al., U.S. Dep't of Veterans Affs., Benefits and Harms of Cannabis in Chronic Pain or Post-Traumatic Stress Disorder: A Systematic Review (2017); Campbell et al., *supra*; Deborah S. Hasin et al., *U.S. Adults With Pain, A Group Increasingly Vulnerable to Nonmedical Cannabis Use and Cannabis Use Disorder: 2001–2002 and 2012–2013*, Am. J. Psych., Jan. 22, 2020, https://ajp.psychiatryonline.org/doi/10.1176/ appi.ajp.2019.19030284 [https://perma.cc/E622-8V6A?type=image]; Keith Humphreys & Richard Saitz, *Should Physicians Recommend Replacing Opioids with Cannabis?*, 321 JAMA 639, 639 (2019) ("There are no randomized clinical trials of substituting cannabinoids for opioids in patients taking or misusing opioids for treatment of pain, or in patients with opioid addiction treated with methadone or buprenorphine. . . . Many factors other than cannabis may affect opioid overdose deaths, such as prescribing guidelines, opioid rescheduling, Good Samaritan laws, incarceration practices, and availability of evidence-based opioid use disorder treatment and naloxone."); Suzanne Nielsen et al., *Opioid-Sparing Effect of Cannabinoids: A Systematic Review and Meta-Analysis*, 42 Neuropsychopharmacology 1752 (2017); Mark Olfson et al., *Medical Marijuana and the Opioid Epidemic: Response to Theriault and Schlesinger*, 175 Am. J. Psych. 284 (2018); Gabriel Rada, Epistemonikos Found., https://isof.epistemonikos.org/#/finding/593584b2e308 9d0fec24dc01 [https://perma.cc/BP55-CAWD]. *See generally* Larkin, Jr. & Madras, *Opioids, supra* note 3, at 571–95 (collecting studies).

[28] Peter B. Bach, *If Weed Is Medicine, So Is Budweiser*, Wall St. J. (Jan. 17, 2019, 7:23 PM), https://www.wsj.com/articles/if-weed-is-medicine-so-is-budweiser-11547770981 [https://perma.cc/9HDG-JR8E].

[29] Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.* (West 2024)).

and Drugs with the responsibility to decide whether a particular compound is a "new drug," and, if so, whether it is "safe," "effective," and "uniform."[30] The U.S. Department of Health and Human Services, the FDA's parent agency, has concluded that the plant form of cannabis is a "new drug," rendering it subject to the FDCA, and the FDA has never found that the cannabis plant itself is "safe," "effective," and "uniform" conditions that must be satisfied before any new drug may be distributed in interstate commerce.[31] Extracting THC from cannabis plants and manufacturing pills, capsules, patches, and ointments containing that ingredient is not materially different from the process of using any other agricultural product as the raw material for a hoped-for medical therapy. Opioids, for example, can be synthesized from the poppy plant. That is how pharmaceutical companies manufacture morphine.

The FDA is certainly capable familiar with this matter. That agency has approved the synthetic THC analogues dronabinol (Marinol) and nabilone (Cesamet) for treatment of chemotherapy-induced nausea and emesis, and appetite stimulation in cachexic patients suffering from cancer or HIV/AIDS wasting syndrome. The FDA has also approved Epidiolex, a purified form of cannabidiol (CBD), for use in the treatment of Dravet's Syndrome and Lennox-Gastaut Syndrome, two severely debilitating forms of childhood-onset epilepsy. So, the FDA knows how to decide whether a particular pill or tablet is helpful or harmful. Senate Bill 555 rejects that approach without offering a justification for doing so.

B. Senate Bill 555 Would Approve the Distribution of Drugs that Contain Dangerous Contaminants

Senate Bill 555 does not prohibit the appearance of dangerous toxins in pills, capsules, and the like. There is, of course, no guarantee that cannabis will not be dangerous. Dr. Nora Volkow, the Director of the National Institute on Drug Abuse, told Congress in 2020 that "in general," we lack "adequate and

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[30] *See* Larkin, *FDA and Cannabis*, *supra* note 2, at 8-23.

[31] *See, e.g.*, *Cannabis Policies for the New Decade: Hearing Before the House Commerce Comm. Subcomm. on Health*, 116th Cong. 1–4 (2020) [hereinafter *House Cannabis Hearing*] (statement of Douglas C. Throckmorton, Dep. Dir. For Reg'y Programs, U.S. Food & Drug Adm'n), https://docs.house.gov/meetings/IF/IF14/20200115/110381/HHRG-116-IF14-Wstate-ThrockmortonD-20200115.pdf [https://perma.cc/Y2PF-X36D]; Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds, Dec. 20, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys [https://perma.cc/ RP9Y-CBDP]; Warning Letters and Test Results for Cannabidiol-Related Products: 2015–2019, Nov. 26, 2019; last accessed Jan. 14, 2020), https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products [https://perma.cc/55EV-KMLC] (warning letters issued to companies selling unapproved new drugs containing cannabidiol, a non-psychoactive substance in marijuana that the FDA has not approved for use in any drug for any purpose); *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, FDA, Oct. 1, 2020, https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd [https://perma.cc/TF56-2GRQ]; *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, FDA, Mar. 5, 2020, https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis [https://perma.cc/7HGY-KAZ4]. That case cannot be made. *See* Larkin, *FDA and Cannabis*, *supra* note 2, at 8-23.

well-controlled studies" to test the safety and efficacy of the cannabis sold in states with legalized medical-use or recreational-use régimes.[32] As a result, "individuals across the country are using cannabis strains and extracts that have not undergone the rigorous clinical trials required to show that they are safe and effective for medical use, and are not regulated for consistency or quality."[33] The ancient age of the cannabis plant does not prove that it is safe, [34] nor is that age proof that the FDA would find that today's cannabis products are safe.[35] In fact, commercial cannabis can contain a "hodgepodge" of more than 400 compounds, some of which are dangerous contaminants.[36]

Senate Bill 555 attempts to avoid those problems in several ways. It empowers the Secretary of Health and Environment to enter into a contract with a laboratory for batch testing purposes.[37] The bill also directs that laboratory to establish "compliance thresholds" for harmful substances such as microbials (e.g., *E. coli*, fungi, mold), toxins (e.g., aflatoxins), pesticides (e.g., organophosphates), and heavy metals (e.g., arsenic, cadmium, lead, mercury).[38] And the bill directs the remediation or destruction of batches that do not meet these safety standards.[39]

The problem, however, is that Senate Bill 555 does not explain why the compliance standard for such obvious contaminants should not be *zero*. Why should *any* amount of *E. coli,* aflatoxin, organophosphate pesticides, and heavy metals like arsenic, cadmium, lead, or mercury be allowed in *any* product sold in Kansas. Why is that a reasonable approach to protecting public health? Does the

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[32] Statement of Nora Volkow, Dir., Nat'l Inst. on Drug Abuse 7 (Jan. 15, 2020), *in House Cannabis Hearing*, *supra* note 31.

[33] *Id*.

[34] "At the outset, it is important to note that the age of the cannabis plant does not prove that it is 'safe.' One argument advanced in favor of cannabis' safety is that cannabis was used for medical purposes for centuries without scientific proof of its safety and efficacy. That is true but irrelevant. 'Prior to the twentieth century, drug manufacturers could hawk any potion, claim treatment of any ailment, and hail efficacy or potency on a bottle's label, all in the name of increasing sales. Only in that century did American society reject a laissez faire approach to drug regulation. The Pure Food and Drug Act of 1906 required the contents of drugs to be disclosed, and the FDCA prohibited the commercialization of drugs until the FDA had found them to be safe, effective, and uniform. Accordingly, the historical treatment of cannabis in the 17th, 18th, or 19th centuries, whether in America or the rest of the world, is of no importance. What truly matters is how this nation treats cannabis today." Larkin, *FDA and Cannabis*, *supra* note 2, at 8-9 (footnotes omitted);

[35] *Id*. at 9 ("Much of the cannabis sold in states with medical or recreational cannabis programs has not undergone rigorous testing to ensure that is does not contain dangerous toxins.").

[36] Robert L. DuPont, The Selfish Brain: Learning from Addiction 148 (2019 ed. 1997).

[37] Senate Bill 555, § 7(a) & b), at Page 8 ("(a) No batch of medical cannabis or medical cannabis products shall be sold unless a sample from such batch has been tested and certified for use or consumption by the state contracted laboratory. Each contract shall specify batch size, testing and certification requirements and the identity of the state contracted laboratory. The batch size for medical cannabis shall not be more than 10 pounds and the batch size for medical cannabis products shall not be more than five liters or the equivalent of such amount. (b) The secretary shall enter into a contract with a laboratory for the purpose of conducting compliance and quality assurance testing of medical cannabis and medical cannabis products produced by medical cannabis operators.").

[38] Senate Bill 555, § 7(d), at Page 9 ("Testing standards developed by the state contracted laboratory shall establish compliance thresholds for each of the following categories: (1) Microbials; (2) mycotoxins; (3) residual solvents; (4) pesticides; (5) moisture content; and (6) heavy metals.").

[39] Senate Bill 555, § 7(e), at Page 9 ("All batches of medical cannabis or medical cannabis product that are determined to be noncompliant with the testing thresholds shall be either remediated or destroyed by the medical cannabis operator who submitted the test sample for such batch. The state contracted laboratory shall provide guidance on the method of remediation for noncompliant batches. All remediated batches shall be resubmitted for testing to ensure compliance after remediation has been completed.").

state health code permit those contaminants in any other drugs sold in Kansas? The people for whom this bill is supposed to alleviate their suffering are already very or deathly ill, so why should they be exposed to poisons like those? Senate Bill 555 does not address those questions. Nor does the bill explain why the FDA would permit a drug to be distributed in interstate commerce that contains such contaminants. Finally, the bill does not explain why Kansas should expose its citizens to dangerous contaminants that the FDA would not allow to be contained in drugs that are sold to residents in other states.

It should. There is no good reason why Kansas legislators should avoid taking a position on those questions and accepting responsibility for the distribution and use of harmful contaminants by directing a state-contracted laboratory to decide just how much danger a cannabis product should pose. That is not the appropriate action of a responsible legislator. Insofar as the issue would be based on a scientific estimate of the amount of E. coli or mercury that should be allowed in pharmaceuticals sold in that state, the legislature is in a position to convene a hearing so that it can obtain the opinions of physicians, toxicologists, scientists, and others who are experts on the subject. Insofar as that judgment might need to be updated on an annual basis, the state legislature can reconvene whatever hearings are necessary, or seek the opinion of the Kansas Secretary of Health and Environment.

C. Senate Bill 555 Does Not Address the Problem of Drug-Impaired Driving

Cannabis, like alcohol, impairs a driver's ability to handle a motor vehicle safely.[40] "Today there is a wealth of evidence that marijuana is an impairing

[40] "Like alcohol, THC impairs a driver's ability to handle a vehicle safely. That effect does not automatically or rapidly dissipate. It can last for hours; in long-term heavy users, it can last for up to several weeks. Unfortunately, a goodly number of users reported driving under the influence of cannabis. What is worse, a considerable number of individuals believe that cannabis use does not impair their ability to drive safely (or actually improves their driving skills), a conclusion that is demonstrably false." Larkin, *Driving While Stoned*, *supra* note 3, at 7–8 (footnotes omitted); *see also, e.g.*, British Med. Ass'n, Therapeutic Uses of Cannabis 19-20, 66 (1997); European Monitoring Cntr. For Drugs and Drug Addiction, Drugs Use, Impaired Driving and Traffic Accidents 33-41 (2d ed. 2014); Nat'l Acad. Scis., Eng'g & Med., The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research 227-30 (2017); Nat'l Inst. on Drug Abuse, Cannabis (Marijuana) Research Report 7-8 (2020); Nat'l Highway Traffic Safety Admin., Marijuana, Alcohol, and Actual Driving Performance 39-40 (1999); Robert L. DuPont, Inst. For Behavior & Health, Commentary: Marijuana Impaired Driving: A Serious Public Safety Problem (2011); Robert L. DuPont et al., Inst. for Behavior & Health, Drugged Driving Research: A White Paper (2011); Rebecca L. Hartman & Marilyn A. Huestis, *Cannabis Effects on Driving Skills*, 59 Clin. Chemistry 478, 478 (2013) ("Epidemiologic data show that risk of involvement in a motor vehicle accident (MVA) increases approximately 2-fold after cannabis smoking."); Larkin, *Driving While Stoned*, *supra* note 3, at 7-12 & nn.24-43; Thomas D. Marcotte et al., *Driving Performance and Cannabis Users' Perception of Safety: A Randomized Clinical Trial*, 79 JAMA Psychiatry 201, 206–07 (2022) ("In this study of 191 regular cannabis users randomized to smoke THC or placebo cigarettes ad libitum, we found worse performance in the THC group on a measure of overall driving simulator performance as well as specific driving challenges, including a divided attention task, adding to a growing literature that THC negatively impacts driving ability. . . . In a placebo-controlled parallel study of regular cannabis users smoking cannabis with different THC content ad libitum, there was statistically significant worsening on driving simulator performance in the THC group compared with the placebo group. The THC content of the cannabis and intensity of prior cannabis use were not associated with driving outcomes; participants self-titrated in a manner that yielded similar reductions in driving performance, despite achieving different THC blood concentrations."); Danielle McCartney et al., *Determining the Magnitude and Duration of Acute Δ^9-Tetrahydrocannabinol (Δ9-THC)-Induced Driving and Cognitive Impairment: A Systematic and*

substance that affects skills necessary for safe driving."[41] Cannabis use enhances the risk of roadway, crashes, maimings, and fatalities, and thereby poses a serious national problem.[42] In 2010, Gil Kerlikowski, Director of the Office of National Drug Policy in the Obama Administration, found that drug-impaired driving is as serious a problem as the better-known problem of alcohol-impaired driving and deserves the same aggressive response.[43] Cannabis' impairing effect is aggravated when a user also consumes alcohol, a not-infrequent occurrence. "The psychoactive ingredient in each drug—THC- and ethanol, respectively—amplifies the effect of the other, making a cocktail of the two a particularly dangerous combination."[44] As a result, a person who has consumed THC and ethanol can be incapable of safe driving even if he or she does not have a sufficient quantity of alcohol in his or her blood to fail the standard 0.08 grams per deciliter (g/dL) blood-alcohol test.[45]

In its current form Senate Bill 555 will exacerbate the problem of drug-impaired driving in Kansas. Kansas Bill 555 recognizes that problem because Section 22(d) makes clear that authorization to use cannabis for medical purposes is not permission to "drive while stoned."[46] Numerous proposals would address this problem. Among them are the following:

- **Proposal:** Apply to every driver under age 21 who tests positive for any illicit or impairing drug, including cannabis and impairing prescription drugs, the same zero-tolerance standard specified for alcohol, the use of which in this age group is illegal.
- **Proposal:** Apply to every driver found to have been impaired by drugs, including cannabis, the same remedies and penalties that are specified for alcohol-impaired drivers, including administrative or judicial license revocation.
- **Proposal:** Test every driver involved in a crash that results in a fatality or a serious injury (including injury to pedestrians) for alcohol and impairing drugs, including cannabis.

Meta-Analysis, 126 NEUROSCI. & BEHAV. REVS. 175, 184 (2021) ("Δ9-THC impairs aspects of driving performance and demonstrate that the magnitude and duration of this impairment depends on the dose provided, route of administration and frequency with which cannabis is used.").

[41] Robert L. DuPont et al., *Marijuana-Impaired Driving: A Path Through the Controversies, in* CONTEMPORARY HEALTH ISSUES ON MARIJUANA 183, 186 (Kevin A. Sabet & Ken. C. Winters eds., 2018).

[42] *See*, *e.g*., Larkin, *Virginia Testimony*, *supra* note 4, at 7-10.

[43] OFFICE OF NATIONAL DRUG CONTROL POLICY, NATIONAL DRUG STRATEGY 2010, at 23 (July 2010).

[44] Larkin, *Driving While Stoned*, *supra* note 3, at 9-10 (footnote omitted).

[45] "[A] a large number of people who use cannabis combine it with alcohol. The psychoactive ingredient in each drug—THC and ethanol, respectively—amplifies the effect of the other, making a cocktail of the two a particularly dangerous combination." Larkin, *Driving While Stoned*, *supra* note 3, at 9-10 (footnotes omitted); *see also*, *e.g*., Larkin, *Drugged Driving*, *supra* note 3, at 478-79 & nn.105-08 (collecting studies).

[46] "Nothing in this section shall be construed to authorize a patient to operate a motor vehicle, watercraft or aircraft while under the influence of medical cannabis or medical cannabis products. No patient or caregiver shall possess medical cannabis or medical cannabis products while operating or traveling in any motor vehicle, watercraft or aircraft unless such medical cannabis or medical cannabis products are contained in the original, sealed packaging obtained from the distribution hub. Any medical cannabis or medical cannabis products in a motor vehicle, watercraft or aircraft that are not contained in the original, sealed packaging shall be considered unlawful possession under this act, and neither the patient or the caregiver, if designated, shall have a privilege in any prosecution for unlawfully possessing a controlled substance under K.S.A. 21-5706, and amendments thereto, or unlawfully possessing drug paraphernalia under K.S.A. 21-5709, and amendments thereto." Senate Bill No. 555, § 22(d), at Pages 22-23.

- **Proposal:** Test every driver arrested for driving while impaired for both alcohol and impairing drugs, including cannabis.
- **Proposal:** Require state and local law enforcement officers to use reliable oral fluid testing technology at the roadside for every driver arrested for impaired driving.
- **Proposal**: Collect data on all crashes in which cannabis is suspected to have contributed to the crash and report that data to the National Highway Traffic Safety Administration.
- **Proposal:** Require hospitals, emergency care, and related facilities to collect/collate/publish alcohol/drug/polydrug data.
- **Proposal:** Create a database collecting the information for alcohol- and drug-impaired driving arrests and convictions that is accessible by state and local law enforcement officers and transmit that information to the FBI for its National Crime Information System database.
- **Proposal**: Require that every person applying for a driver's license and renewing a past license to be informed of all prescription drugs that can impair driving, as well as all illicit drugs.
- **Proposal**: Implement a "*24/7 Sobriety*" program like the one in South Dakota.[47]
- **Proposal:** Require that the Commonwealth's DWI recordkeeping separately classify alcohol, drugs, and polydrug use.
- **Proposal:** Lower the Blood-Alcohol Content Threshold from 0.08 g/dL to 0.05—or 0.0—for every driver who has consumed cannabis.
- **Proposal:** Fund pilot projects in various districts to determine how many people are driving while impaired by drugs or alcohol.
- **Proposal:** Improve the training for state and local law enforcement officers necessary to recognize drug-impaired drivers.
- **Proposal:** Prohibit anyone who has consumed cannabis from driving for 24 hours after use.[48]

Unfortunately, Senate Bill 555 contains none of these proposals. It should add all or at least some. That would not eliminate all of the problems in the bill, but it might actually save lives by reducing the likelihood that someone who is "one toke over the line"[49] will get behind the wheel of a car.

Thank you for the opportunity to submit this statement.

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[47] *See* Paul J. Larkin, Jr., *Swift, Certain, and Fair Punishment—24/7 Sobriety and HOPE: Creative Approaches to Alcohol- and Illicit Drug-Using Offenders*, 105 J. of Crim. L. & Criminology 39 (2016).

[48] That rule would follow from the one that physicians apply to patients who have received general anaesthesia. Physicians advise them not to drive for 24 hours (or more) after receiving general anesthesia, and want those patients to be driven home by a responsible third-party, because the drugs that induce general anesthesia also impair cognitive and psychomotor functions necessary for safe vehicle handling. *See*, *e.g.*, Emory N. Brown et al., *General Anesthesia, Sleep, and Coma*, New Eng. J. Med. 2638, 2647–48 (2010); Frances Chung et al., *What Is the Driving Performance of Ambulatory Surgical Patients After General Anaesthesia?*, 103 Anesthesiology 951, 954 (2005).

[49] Mike Brewer & Tom Shipley, *One Toke Over the Line* (1971), on *Tarkio* (Kama Sutra Records 1970).