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Twenty-First Century Illicit Drugs and Their Discontents: The Potential Risks that Cannabis Use by Pregnant and Nursing Women Pose to Their Children

Paul J. Larkin

KEY TAKEAWAYS

Evidence reveals that perhaps 7 percent to 60 percent of women have used cannabis while pregnant or nursing, possibly thinking that maternal use is safe.

That belief is mistaken. There is no conclusive proof that cannabis use during pregnancy or nursing is "safe"—the standard for FDA approval of a drug.

Further research and education are necessary, but Congress and the states should prohibit cannabis use by pregnant or nursing women until it is proved safe.

dvocates for legalization of medical-use cannabis claim that it can alleviate the suffering of the dying, particularly individuals undergoing the end stage of cancer, or the disabling symptoms of horrific maladies, such as multiple sclerosis, that might leave some people wishing that the end were nigh.¹ In a parallel manner, advocates for legalization of recreational-use cannabis maintain that it contains an ingredient that creates a mildly euphoric feeling not entirely dissimilar to the one resulting from the use of alcohol, a drug that is and has been socially approved and legally available for centuries.2 Numerous "stoner films" have helped to make the latter point, portraying users as young, attractive, harmless, care-free, fun-loving people motivated by a "Que sera, sera!"-like attitude toward life, interested only in having a good time while imposing no collateral burden on anyone else. Think Cheech and Chong or Harold and Kumar.3

What we do *not* see portrayed in such films are claims that smoking botanical cannabis is a legitimate medical therapy or safe recreational divertissement *for pregnant or nursing women and their prenatal or post-natal children*. That scenario, however, is a reality. Numerous women use cannabis while pregnant or nursing,⁴ and THC rapidly crosses the placenta, becoming present in a child in utero (albeit in a lower quantity).⁵ Accordingly, "two different individuals may experience the potential adverse effects of cannabis," but only one has any say in the matter.⁶

Congress and the states are aware of this problem, yet no one has taken any steps to address it. In particular, despite the medical community's recommendations against maternal cannabis use, no state with a medical or recreational cannabis program makes it a crime to sell cannabis to pregnant or nursing women.⁷ That omission is quite troubling.

This *Legal Memorandum* is the fourth in a series of Heritage Foundation studies published under the overall title "Twenty-First Century Illicit Drugs and Their Discontents." This paper highlights the need to consider the effect of cannabis use by pregnant and nursing women. It also proposes some remedies for the problem. Nowadays, politicians spout the word "existential" in policy arguments more often than philosophy professors mention it when explicating Jean-Paul Sartre's *Being and Nothingness*. Concern about whether drug use by *this* generation will affect the next one and, if so, *how* truly *is* an existential topic—particularly for a child in utero. It is worthy of legislative consideration, and it is about time for elected officials to address this problem. If nothing else, it brings the subject to the attention of our elected officials in the (non-Quixotic) hope that they will act on it.

The Prevalence of Cannabis Use Among Pregnant Women

Cannabis is an illicit drug that women often use, and its use is on the rise. A 2018 article in the *Journal of the American Medical Association* concluded that marijuana use among pregnant females using the Kaiser Permanente Northern California Health Care System increased from 4.2 percent to 7.1 percent from 2009 to 2016. That overall increase reflected an individual increase in each of four age groups considered—below 18, 18–24, 25–34, and above 34 years old—with the greatest increase—12.5 to 21.8 percent—in women in the 18–24 age group. Because a higher number of women tested positive for cannabis use than admitted to having used the drug, the study suggested that self-reported surveys underestimate use.

The National Institute on Drug Abuse (NIDA) found that article persuasive, concluding in 2020 that "women were about twice as likely to screen

positive for marijuana use via a drug test than they state in self-reported measures." Also, a survey of clients of the Colorado Women's Infant and Child Program found that "[o]f all marijuana users (past, ever, current), 35.8% said that they used at some point during pregnancy, 41% since the baby was born, and 18% while breastfeeding." Finally, a 2017 Committee Opinion by the American College of Obstetricians and Gynecologists (ACOG) found that 34–60% of marijuana users continue use during pregnancy" and "18.1% of pregnant women reporting marijuana use in the past year met criteria for marijuana abuse, or dependence, or both." What is more, maternal cannabis use might have increased during the COVID-19 pandemic as women used it to relieve the stresses that event caused, whether or not they knew they were pregnant. ¹⁶

One explanation for the increase might be that the cannabis industry's model for financial success rests on people overusing cannabis. Like alcohol, cannabis follows what is called the 80/20 Rule (or Pareto's Rule): 80 percent of cannabis is consumed by 20 percent of its users. Daily cannabis users consume more than 50 percent of the amount used nationwide, an average of three to four joints daily. The result is that "the average gram of marijuana is consumed by someone who is under the influence of marijuana more than half of their waking hours. According to late New York University Professor Mark Kleiman, an expert on all things cannabis, "from the perspective of cannabis vendors, drug abuse isn't the problem; it's the target demographic. That is a disturbing prospect if users are pregnant or nursing.

In 2017, the ACOG found that "many women" believe that cannabis is "relatively safe to use during pregnancy." Even worse, a 2022 report found that approximately 70 percent of American women believe that "consumption of cannabis once or twice per week is harmless."23 The prevalence of that opinion might be attributable to the fact that cannabis retailers promote cannabinoids, the biologically active ingredients in the plant, as "safe, natural and effective ways to manage common daily ailments, including in pregnancy, such as insomnia, pain, and morning sickness."24 That marketing message is troubling, although "shocking" or "scary" and "infuriating" would be more accurate terms. But it is not surprising. "Since we can expect the legal cannabis industry to be financially dependent on dependent customers," writes Kleiman, "we can also expect that the industry's marketing practices and lobbying agenda will be dedicated to creating and sustaining problem drug use patterns."25 That scenario is especially worrisome given that we have witnessed "significant increases over the last decade in the number of pregnant women seeking substance use disorder treatment for marijuana use."26

It is bad enough that some Internet sources offer medical advice to pregnant women by touting cannabis as a treatment for the nausea that women can have during pregnancy.²⁷ It is worse when the "ganjapreneurs" in states selling cannabis permit uneducated and unlicensed "budtenders" in their employ to engage in the practice of medicine by recommending its use to pregnant women in person. That is not a hypothetical; there is evidence that at places of business selling this product in one or more of its various forms, ²⁸ this is happening: Budtenders offer their "medical" opinions about the value of cannabis use during pregnancy.²⁹ A 2018 study of Colorado cannabis dispensaries found that 69 percent of them recommended cannabis use to treat morning sickness.³⁰ A majority of dispensaries in urban (71 percent) and non-urban (63 percent) areas had an employee offer such advice.³¹ While 81.5 percent of Colorado dispensaries ultimately recommended that a customer consult with a health care provider, only 31.8 percent offered that recommendation without prompting.³²

Recommendations like those are ignorant of or disregard the opinions of the relevant federal health care agencies and professional medical organizations. That is problematic for women who lack prenatal medical care, because they will not learn those professional recommendations from an obstetrician. It is also likely that most women who lack prenatal care also do not read *The New England Journal of Medicine* or stay current with NIDA's reports, so they might not be aware of the recommendations noted above against maternal cannabis use. Atop that, Colorado law bars a physician who recommends medical cannabis for patients from being employed by a dispensary.³³ As a result, untutored suggestions by budtenders likely contribute to the misperception that cannabis use during pregnancy is perfectly safe, even though that might not be the case.

The Potentially Adverse Effects of Cannabis Use on Prenatal and Postnatal Development

There is a considerable body of research discussing the adverse effects of maternal alcohol use and cigarette smoking on fetal development.³⁴ By contrast, there are fewer studies of the effect of maternal cannabis use on a developing child.³⁵ Nonetheless, the evidence that does exist gives reason for concern.

A 2022 article in the *American Journal of Obstetrics and Gynecology* concluded that "the available evidence suggests an adverse effect from cannabis exposure on male and female reproductive health, pregnancy and fetal outcomes, and longer-term offspring health and developmental

trajectories."³⁶ Some physicians and researchers have found that cannabis use, whether by a pregnant woman or by someone else living in the same home, poses various different types of risks to a child in utero and after birth.³⁷ Among these risks are increased placement in a neonatal intensive care unit (NICU); cancer (e.g., neuroblastoma);³⁸ adverse neurodevelopment (e.g., reduced neuroplasticity—the growth, maturation, and movement of neurons during life³⁹—as well as the genesis and migration of axons and dendrites, axonal pathfinding, and synaptic transmission and pruning); impaired higher-order executive functioning (e.g., impulse control, reduced visual memory, attention) during the school-age years; autism spectrum disorder; lower birth weight (which is associated with an increase in infant morbidity and mortality, as well as long-lasting consequences such as neurosensory impairments, decreased height, and lower IQ and educational achievement); shorter gestation; spontaneous preterm birth; hyperactivity in children; and psychopathology in adolescents.⁴⁰

Yet those studies do not stand alone. The same and other researchers have found no material association between in utero cannabis use and such outcomes as fetal mortality; fetal malformations; preterm birth; newborn Apgar scores; cancer (e.g., acute myeloid leukemia); Sudden Infant Death Syndrome (SIDS); intelligence; and height or weight.⁴¹ Given those mixed results, the upshot is that there is no conclusive proof that cannabis use will or will not cause the harms noted above.⁴² There is a consensus that additional research is necessary.⁴³

The risk from maternal cannabis use does not end at birth, because a nursing mother can transfer THC to her infant.⁴⁴ Nonetheless, as with cannabis use by pregnant women, there are only estimates of the number of breastfeeding women using cannabis, and there are few data establishing the effect of THC on neonates and infants.⁴⁵ At present, it is uncertain precisely what amount of THC a nursing mother passes on to her child, what effect that amount has, and whether the benefits of breastfeeding—such as the transfer of nutrition and immune protective factors—outweigh the potential risk of exposing a newborn to THC.⁴⁶ Atop that, as in the case of maternal use during pregnancy, a number of factors, such the use of cigarettes, alcohol, and other drugs, confound the analyses.⁴⁷ Finally, it is difficult to differentiate the effects of cannabis use during pregnancy from those occurring while nursing.⁴⁸

There are several reasons why we do not yet know the answers to these questions. The available research relies largely on reports of cannabis use by women, and those reports might underestimate the amount of their use because of their authors' fear of legal repercussions.⁴⁹ There also are

a series of potentially confounding factors that complicate the interpretation of survey results. Among them are maternal use of alcohol, cigarettes, or illicit drugs other than cannabis; poor maternal nutrition; and limited prenatal care.⁵⁰

The bottom line is this: We don't know as much as we would like to know regarding the long-term effects of maternal cannabis use during pregnancy or breastfeeding on fetal and childhood developmental outcomes. The question then becomes this: What do we do in the face of this uncertainty?

The Past Regulation of Cannabis Use by Pregnant and Nursing Women

Until 1996, cannabis was contraband under federal and state law, so the effect of legalized cannabis use on pregnant and nursing women was not a prominent public policy issue.⁵¹ That changed in 1996 when California adopted a law⁵² allowing physicians to recommend⁵³ to patients that cannabis might be useful in treating certain maladies.⁵⁴ Other states followed suit. Today, 40-plus American jurisdictions permit cannabis to be used for medical or recreational purposes under state law.⁵⁵ Federal law still treats cannabis as contraband, however, despite several efforts by Members of Congress to repeal or revise the federal drug laws.⁵⁶

That creates the oddity (call it absurdity if you like) that because the states cannot exempt themselves from federal law, their cannabis regulatory schemes are handing out licenses to commit federal crimes. ⁵⁷ Adding to the chaos, in 2009, President Barack Obama, ostensibly exercising his discretion to decide when and how to enforce federal law, ⁵⁸ effectively gave the state-based cannabis industry a "Get Out of Jail Free" card by almost guaranteeing businesses immunity from federal prosecution if they complied with state law ⁵⁹—and thereafter studiously ignored whether they were compliant. ⁶⁰ As a direct result of the Obama Administration's approval, the cannabis business experienced tremendous growth. ⁶¹ Cannabis has become a quasi-legal commodity widely available across the land. ⁶²

Also relevant is what has *not* occurred during this period: "[C]annabis policy has raced ahead of cannabis science," and "medical marijuana in the United States has bypassed the usual process of scientific rigor that is required to make medicine available and has created a political controversy among the American public." The states did not wait for scientific proof to show that cannabis use was harmless (or nearly so) before abandoning their long-standing restraints on its sale.

The Need to Prevent or Reduce Maternal Cannabis Given Uncertainty as to Its Prenatal and Postnatal Effects

Given what we currently do and do not know, the question for society is this: How should we proceed in the face of—call it a troubling uncertainty or a well-grounded fear—that maternal cannabis use might harm a woman's developing or nursing child? Elementary principles of tort law require everyone to act on the basis of a reasonable person's judgment of the potential benefits and costs of action or inaction. A powerful case can be made that because we do not know the long-term effect of maternal highly potent cannabis use on a child in utero and because there is no explicit or implicit constitutional right to use cannabis, so society should not accept the risk that use by pregnant or nursing women would harm their children. The federal and state governments may regulate the public health, including the use of drugs, for legitimate reasons, and the protection of both a mother and her child is a legitimate ground for legislation. The argument that society should prevent or limit maternal cannabis use is rather straightforward.

First, we don't know for certain that maternal cannabis use is harmless for a developing child. According to the U.S. Substance Abuse and Mental Health Services Agency (SAMHSA), "[n]o amount of marijuana has been proven safe to use during pregnancy or while breastfeeding," ⁶⁸ let alone the hyper-potent cannabis available in states today. ⁶⁹ There is no conclusive proof that cannabis is safe for a child in the womb or in a cradle. In fact, no one would seriously dispute that point.

Second, the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)⁷⁰ prohibits the distribution of any "new" drug"⁷¹ in interstate commerce unless and until the U.S. Food and Drug Administration (FDA) has found that it is "safe" and "effective" for its intended use.⁷² That has been the law for the 80-plus years that the FDCA has been on the books, and there is no good reason to exempt cannabis from it. The FDA has deemed cannabis a "new drug"⁷³ but has never found that it passes the FDCA's test.⁷⁴ Federal agencies cannot disregard limits on their statutory authority,⁷⁵ so the FDA could not approve the distribution of cannabis without making the findings required by the FDCA. To enable the FDA to do so, an applicant would need to conduct the same type of analyses—such as formal double-blind studies, the gold standard in pharmacological testing—on cannabis use by pregnant and nursing women and then submit the results to the FDA for its review. No one has done so, and without it, the FDA cannot approve botanical cannabis.⁷⁶

Third, a child is born with a labile brain that does not mature until approximately age 21.⁷⁷ Throughout that period, the brain is more vulnerable to the adverse long-term effects of exposure to THC than an adult would be.⁷⁸ Consequently, "[f]rom prenatal exposure to unintentional childhood exposures to concerns of adolescent abuse, marijuana potentially affects pediatric patients at every stage in childhood."⁷⁹ It therefore is critical to determine what those effects might be and whether to prevent nascent harms.⁸⁰

Fourth, although there is no conclusive proof that maternal cannabis use causes severe and irremediable damage to a prenatal or postnatal child's developing brain, what we do know about the potential effects is quite troubling. As one scholar puts it, "[a]dult recreational and medical use of marijuana impacts the entire pediatric population, from prenatal through adolescents and young adulthood."⁸¹ Some studies have found an association between maternal cannabis use and serious, irreversible maladies. Moreover, many of the studies finding no adverse effect were conducted before the high-potency cannabis currently being sold became available, which renders earlier studies of dubious value today.⁸² That combination of factors should lead us to use a red stop sign, or at least a yellow warning symbol, when deciding whether to legalize cannabis.

Fifth, there is a public health consensus on the proper answer to this problem. Several federal agencies devoted to protecting the public health—the Office of the U.S. Surgeon General, the FDA, the NIDA, and the SAMHSA—recommend that women *not* use cannabis while pregnant or nursing. 83 As the SAMHSA has explained, "marijuana use during pregnancy is not safe and comes with serious, potentially deadly risks," in part because "[w]hether smoked, eaten in food (edibles), or vaped, marijuana is stronger than ever before, which makes use during pregnancy especially risky for a developing baby's health."84 The agency therefore recommends that "[a]voiding marijuana during pregnancy and breastfeeding can give your baby a healthier start in life."85 Respected private professional medical associations with the same public health mission—the ACOG and the American Academy of Pediatrics (AAP)-also recommend against maternal cannabis use. 86 In fact, even some private experts who believe that botanical cannabis has therapeutic uses nonetheless recommend against its regular use by pregnant or nursing women.⁸⁷ That medical consensus is a powerful argument against maternal cannabis use.88

A reader might ask, "If all of the above is true, how were the states able to approve the sale of medical-use or recreational use cannabis, as many have done, and why did they do so?" Each question should be answered separately.

The answer to the first question stems from the federalist system of American government. The states are free to revise or repeal their own penal laws because there is no federal constitutional requirement that they prohibit the distribution of cannabis or even have a criminal code at all.89 The Constitution tells the states what types of laws they cannot enact, such as ex post facto laws or bills of attainder, but it does not demand that they outlaw any particular conduct, even murder. 90 Moreover, the earliest medical cannabis laws came into effect pursuant to citizen-based initiatives, which allow voters to bypass the legislature and adopt a law directly. 91 The first medical marijuana law—California's Proposition 215, also known as the Compassionate Use Act—became a law in just that manner in 1996.92 Since then, no state has even attempted to assemble the type of proof that the FDA demands before it could legalize cannabis under federal law.93 That is important because, in the 80-plus years that the FDCA has been in effect, the nation has consistently reaffirmed, as a bedrock tenet of public health law, the principle that we do not approve drugs by plebiscite. 94 What that means is this: Despite the widespread prevalence of contemporary state cannabis legalization régimes, because we lack the type of scientific proof that the FDA demands before deciding whether any new drug is safe and effective, there is no reason to believe that cannabis use is harmless. 95 In sum, the states are under no obligation to have their own version of the FDCA; they can free ride on what the federal government does under that law.

As for the second question, several explanations come to mind. On the one hand, state voters were beguiled by the argument that people suffering from end-stage cancer, multiple sclerosis, or other horrific maladies were unable to obtain relief without resort to botanical cannabis. In addition, state voters saw cannabis as a physical intoxicant and social lubricant that is no more damaging than the alcohol that any adult could easily purchase or the weed that their parents and grandparents smoked at Woodstock. On the other hand, state legislators were seduced by the prospect of securing a new tax basis to underwrite yearned-for expenditures. State legislators—who often serve for only a few months without any staff to speak of—might have been oblivious to (or willfully defiant of) the nation's 80-year judgment that drugs must be proved safe and effective before being marketed. Perhaps state legislators were desirous of satisfying the demands of a pro-cannabis interest group, or willing to engage in log-rolling with their colleagues to secure passage of their own pet bills, or some combination of all that.

Whatever the reason might be, before adopting medical or recreational cannabis initiatives, no state conducted the type of review that the FDA would have demanded to learn whether botanical cannabis is "safe" and

"effective" for its intended use. Instead, states decided "to boldly go" where the federal government has not gone before, because the FDA and other allied federal health care agencies have consistently found that botanical cannabis is not a legitimate medication. The result is that states decided to take the law into their own hands without also shouldering the burden that federal law places on the FDA to ensure that only safe and effective drugs can be sold.

Where does that leave us? With this: While there is no conclusive proof that cannabis use will or will not invariably damage a child in utero or later, an all-star lineup of federal public health care agencies and private medical organizations has strongly recommended against maternal cannabis use while pregnant or nursing. Federal and state legislators should follow those recommendations. The question is: How?

Potential Responses

Research. Additional research is necessary not only because there is a consensus that we do not yet know as much as we need to know in order to make an informed public health decision, but also because the cannabis available today is far different from the cannabis that was available when the debate over cannabis began in earnest late in the twentieth century. It is important to recognize that many of the studies finding no or minimal adverse results from maternal cannabis use did not consider the enhanced potency of cannabis that is available today. The cannabis used in the 1960s and 1970s had a THC content or 3 percent–6 percent. Today, cannabis is available in forms reflecting a fifteenfold to thirtyfold increase in potency.⁹⁷

The effective legalization of recreational-use cannabis spurred by the Obama Administration in 2009 has led businesses to develop products, including "edibles," with extremely high potency; some forms contain a 90 percent THC concentration. That is a critical fact. Pharmaceutical companies spend considerable time and resources to determine what effect a particular concentration of the active ingredient in a drug will have on a patient and what the range defining the minimum and maximum therapeutic dose may be: Too little and the drug will be ineffective; too much and it could approach the minimum fatal dose.

No reputable drug company or physician would assume that the increase from a 3 percent to a 90-plus percent active-ingredient concentration would not pose a health risk for a patient. Yet that is what ganjapreneurs do on a regular basis. Society should not make the assumption that the results of

studies on women using low-potency cannabis provide a basis for making a medical judgment about the effect of today's high-potency cannabis on maternal, fetal, or neonate health. Making that assumption, in fact, would be reckless.

Research, however, takes time, and children today can't wait for years-long studies to be completed and their results to be published even later. Those data might prove what we can only reasonably infer now, but "[s]adly, [they] will only be available *after* the damage has been done." The results will come too late for the generation of children in utero today and tomorrow who wind up being damaged by maternal cannabis use. The question, then, is what should we do in the meantime? How do we address this problem?

Education. One step is to ensure that every pregnant or breastfeeding woman is educated about the risks posed by cannabis use. Women who receive prenatal care are likely to learn about cannabis's adverse effect from their physicians. ¹⁰⁰ Not every woman seeks prenatal care, however, and the ones who do not won't hear the necessary advice in person from a medical professional. States that have legalized medical or recreational cannabis use should use other avenues to ensure that every woman of childbearing age is informed about the risks of cannabis (and illicit drug) use. One study has found that education about those risks materially decreased cannabis use by pregnant women. ¹⁰¹

The Criminal and Forfeiture Laws. Some states have required cannabis dispensaries to post signs recommending against cannabis use during the first trimester of pregnancy. That step is worthwhile but not likely to have a serious effect on this problem. In truth, it is but a pittance, a token, an attempt by cannabis dispensaries to give the appearance of compliance without actually making sure that no one in the business's employ sells cannabis to a pregnant or nursing mother. It is not likely to have any more influence on employee behavior than the restroom sign ordering employees to wash their hands before returning to work. That undesirable outcome is particularly likely if the cannabis dispensary signs are located in the same places that Caligula posted the laws: places where no one could easily read them.

In any event, we know that simple admonitions, or even legal requirements not backed up by the criminal law and rigorous enforcement, won't do the trick. How do we know that? Recall the Colorado budtenders' recommendations discussed above. The Colorado cannabis regulations then in effect required the packaging of cannabis products to bear a warning against use of such products by women who then were (or were contemplating becoming) pregnant or were nursing. (Interestingly but sadly,

Colorado's cannabis rules currently do not require a medical warning for pregnant women, which is a step backwards for the two or more people involved.¹⁰⁴) Budtenders who recommended that women use cannabis to fend off morning sickness did so in violation of the message that the Colorado labeling warnings sought to convey.

What reason do we have to believe that dispensaries will comply now if all that we do is once again require them to post signs and tell budtenders to direct women to speak with their physicians before purchasing or using cannabis? Are we supposed to say, "This time we *really* mean it"? No. If it is reasonable to presume that not all physicians will disclose the full details of an abortion procedure to their patients, ¹⁰⁵ it certainly is eminently reasonable to presume that ganjapreneurs and budtenders will not tell pregnant women about the risks of maternal cannabis use, particularly because it is not in their financial interest to do so.

In these circumstances, it is eminently sensible to make it a criminal offense knowingly to sell cannabis to a pregnant woman. The criminal law is generally society's last resort to avoid harmful conduct, brought out when people will harm others despite the teachings of the relevant moral code to refrain from knowingly injuring someone else. It is reasonable to conclude that nothing short of criminal sanctions, including imprisonment, will prove effective here. Civil penalties will be absorbed as a cost of doing business just as a tax would be. Relying on owners to dismiss budtenders who act as if they are Dr. Doug Ross on ER is not an adequate protection. Budtenders are fungible and disposable. Owners make no serious investment in their education (anyone can be inexpensively taught to say "Great buy, dude!" when making a sale) and, without skipping a beat, can replace them with someone else who is also unlicensed to prescribe medication.¹⁰⁶ The criminal law is necessary, and it should focus on the point-of-sale transactions that pose the problem, whether owners or their employees handle that aspect of the cannabis business.

Of course, dispensary owners might try to avoid the risk of imprisonment by not engaging in the actual sales that occur in their businesses. To address that problem, the government should use the forfeiture laws to police owners' conduct. Forfeiting a business might be an unduly harsh penalty for an accidental mistake, but a pattern of illegal sales can and should be suppressed by forfeiture of the relevant businesses. The federal racketeering laws and some state codes authorize the forfeiture of businesses because of the roles that otherwise legitimate businesses play in racketeering operations. Those laws are a reasonable means of deterring criminal conduct, and they are lawful even if, as is not the case here, the

conduct at issue touches on an individual's constitutional rights.¹⁰⁸ The federal and state governments may use the forfeiture laws to seize financial assets accumulated through repeated violations of the criminal laws even when doing so potentially burdens the exercise of a constitutional right, such as the First Amendment Free Speech Clause right to sell books, photographs, or videos.¹⁰⁹ In fact, narcotics traffickers could attempt to evade the forfeiture and money-laundering laws by hiding the proceeds of sales of heroin and the like by making them appear as though they are the product of cannabis sales.¹¹⁰ Dispensaries should not be allowed to perform the role of medieval churches as sanctuaries for ill-gotten goods.

Conclusion

Peter Fried, a researcher into maternal cannabis use on prenatal and postnatal children, once wrote that it is a mistake to conclude that "the absence of effects in the baby or young child is an indicant of a lack of behavioral teratogenicity of marijuana." Put more simply, the absence of proof that maternal cannabis use will harm a child is not the same as proof that it won't.

That proposition is directly applicable here. Congress and state legislators should adopt flat rules against the sale of cannabis to pregnant or breastfeeding women and make subject to the criminal and forfeiture laws any business that breaks that law. Private cannabis businesses cannot be trusted to protect women and their children against the damaging effects of cannabis use. Only by taking the actions recommended here can the government help protect the "two different individuals" who "may experience the potential adverse effects of cannabis" from the improvident decision of one of them or someone else living in the same home.

Paul J. Larkin is the John, Barbara, and Victoria Rumpel Senior Legal Research Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation. The author would like to thank John G. Malcolm, Derrick Morgan, William Poole, Meaghen McManus, Luke Niforatos, and Sarah Parshall Penry for valuable comments on an earlier iteration of this Legal Memorandum. Meaghen McManus also deserves kudos for her invaluable research assistance.

Appendix

American College of Obstetricians and Gynecologists and American Academy of Pediatricians Recommendations with Respect to Maternal Cannabis Use

The American College of Obstetricians and Gynecologists has adopted the following recommendations with respect to maternal cannabis use:¹¹²

- Before pregnancy and in early pregnancy, all women should be asked about their use of tobacco, alcohol, and other drugs, including marijuana, and other medications used for nonmedical reasons.
- Women reporting marijuana use should be counseled about concerns regarding potential adverse health consequences of continued use during pregnancy.
- Women who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use.
- Pregnant women or women contemplating pregnancy should be encouraged to discontinue use of marijuana for medical purposes in favor of an alternative therapy for which there are better pregnancy-specific safety data.
- There are insufficient data to evaluate the effect of marijuana use on infants during lactation and breastfeeding, and in the absence of such data, marijuana use is discouraged.

The American Academy of Pediatricians has adopted the following recommendations with respect to maternal cannabis use:¹¹³

1. Women who are considering becoming pregnant or who are of reproductive age need to be informed about the lack of definitive research and counseled about the current concerns regarding potential adverse effects of THC use on the woman and on fetal, infant, and child development. Marijuana can be included as part of a discussion about the use of tobacco, alcohol, and other drugs and medications during pregnancy.

- 2. As part of routine anticipatory guidance and in addition to contraception counseling, it is important to advise all adolescents and young women that if they become pregnant, marijuana should not be used during pregnancy.
- 3. Pregnant women who are using marijuana or other cannabinoid-containing products to treat a medical condition or to treat nausea and vomiting during pregnancy should be counseled about the lack of safety data and the possible adverse effects of THC in these products on the developing fetus and referred to their health care provider for alternative treatments that have better pregnancy-specific safety data.
- 4. Women of reproductive age who are pregnant or planning to become pregnant and are identified through universal screening as using marijuana should be counseled and, as clinically indicated, receive brief intervention and be referred to treatment.
- 5. Although marijuana is legal in some states, pregnant women who use marijuana can be subject to child welfare investigations if they have a positive marijuana screen result. Health care providers should emphasize that the purpose of screening is to allow treatment of the woman's substance use, not to punish or prosecute her.
- 6. Present data are insufficient to assess the effects of exposure of infants to maternal marijuana use during breastfeeding. As a result, maternal marijuana use while breastfeeding is discouraged. Because the potential risks of infant exposure to marijuana metabolites are unknown, women should be informed of the potential risk of exposure during lactation and encouraged to abstain from using any marijuana products while breastfeeding.
- 7. Pregnant or breastfeeding women should be cautioned about infant exposure to smoke from marijuana in the environment, given emerging data on the effects of passive marijuana smoke.
- 8. Women who have become abstinent from previous marijuana use should be encouraged to remain abstinent while pregnant and breastfeeding.
- 9. Further research regarding the use of and effects of marijuana during pregnancy and breastfeeding is needed.

10. Pediatricians are urged to work with their state and/or local health departments if legalization of marijuana is being considered or has occurred in their state to help with constructive, nonpunitive policy and education for families.

Endnotes

- 1. Common claims for the therapeutic uses of cannabis include treatment of chemotherapy-induced nausea and emesis, the neuropathic pain and spasticity caused by multiple sclerosis, and AIDS-induced cachexia. See, e.g., British Med. Ass'n, Therapeutic Uses of Cannabis 21–49 (1997); World Health Org., Cannabis: A Health Perspective and Research Agenda (1997); Nat'l Acad. of Scis., Eng'g, & Med., The Health Effects of Cannabis and Cannabinoids 54 Tbl. 2-2, 128 Box 4-1 (2017) [hereinafter Nat'l Acad. Cannabis Report] (listing conditions for which marijuana is a treatment for which there are varying degrees of scientific support); Nancy E. Marion, The Medical Marijuana Maze: Policy and Politics 9–15 (2014) (same); Gemayel Lee et al., Medical Cannabis for Neuropathic Pain, 22 Current Pain & Headache Rep. 8 (2018) ("Nearly 20 years of clinical data supports the short-term use of cannabis for the treatment of neuropathic pain."). Those claims have not gone unchallenged. There is no doubt that cannabis contains cannabinoids—i.e., biologically active compounds—that have legitimate medical uses. Smoking cannabis, however, is another matter. See, e.g., Paul J. Larkin, Jr., Reflexive Federalism, 44 Harv. J.L. & Pub. Pot'y 523, 593 & n.245 (2021) [hereafter Larkin, Reflexive Federalism]; Paul J. Larkin, Jr., Reconsidering Federal Marijuana Regulation, 18 Ohio St. J. Crim. L. 99, 119–27 (2020) [hereafter Larkin, Reconsidering Marijuana] (arguing that the Food and Drug Administration could not approve botanical cannabis as a "safe" and "effective" drug); 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. Pot'y 555, 571–95 (2019) (arguing that cannabis cannot provide effective analgesic relief from severe acute or chronic pain); Paul J. Larkin, Jr., Medical or Recreational Marijuana and Drugged Driving, 52 Am. Crim. L. Rev. 453, 462 n.32 (2015) [hereafter Larkin, Drugged Driving] (collecting arguments pro and
- 2. Genesis 9:20 (King James Version) (identifying Noah as the first vintner); U.S. Const. amend. XXI, § 2 (empowering the states to decide whether to allow the sale of alcohol within their borders).
- 3. See, e.g., Cheech & Chong's Up in Smoke (Paramount Pictures 1978); Harold & Kumar Go to White Castle (New Line Cinema 2004). The original film in this subculture, Reefer Madness (Motion Picture Ventures 1936), depicted madness and criminality as the product of cannabis use. Ironically, it became a cult classic among cannabis advocates as a campy depiction of opponents' absurdly over-the-top opposition to the use of cannabis. Advocates continue to use it today to lampoon opposition to cannabis use.
- 4. See infra text accompanying notes 8–27.
- 5. See, e.g., Am. Academy of Pediatrics, Marijuana Use During Pregnancy and Breastfeeding: Implications for Neonatal and Childhood Outcomes, 142 Pediatrics e20181889, at 3 (2018) [hereafter AAP, Marijuana and Pregnancy/Breastfeeding] ("Marijuana can affect the normal transport functions and physiologic status of the placenta throughout pregnancy. One study has revealed that short-term exposure to cannabidiol, a nonpsychoactive substance found in marijuana, can enhance the placental barrier permeability to pharmacologic agents and recreational substances, potentially placing the fetus at risk from these agents or drugs.... After maternal ingestion, concentrations of THC in fetal blood are approximately one-third to one-tenth of maternal concentrations.") (endnotes omitted); Anissa Bara et al., Cannabis and Synaptic Reprogramming of the Developing Brain, 22 Nat. Rev. Neuroscience 423, 428 (2021) (estimating that approximately 2.5 percent of maternal THC is transferred to the child in utero); Leeann M. Blaskowsky, Fetal and Neonatal Cannabis Exposure, in Cannabis in Medicine: An Evidence-Based Approach 403 (Kenneth Finn ed., 2020) ("As a fetus develops, the placenta serves as the critical interface for exchanging gas and nutrients (e.g., oxygen and glucose) as well as the transmission of noxious substances like marijuana, nicotine, alcohol, or other drugs of abuse.") (endnotes omitted); Hanan El Marroun et al., A Prospective Study on Intrauterine Cannabis Exposure and Fetal Blood Flow, 86 Early Human Development 231, 231 (2010) ("Biochemical and animal studies have shown that THC and its metabolites freely pass the placental barrier, and molecular research has shown that local actions of endocannabinoids in the human placenta are already present in early pregnancy.") (endnotes omitted); George Sam Wang, Pediatric Concerns Due to Expanded Cannabis Use: Unintended Consequences of Legalization, 13 J. Medical Toxicology 99, 99 (2017); Carol Blackard & Katherine Tenes, Human Placental Transfer of Cannabinoids, 311 New
- 6. Nat'l Acad. Cannabis Report, supra note 1, at 245.
- See Ala Code Ch. 2A, §§ 20-2A-1 to 20-2A-80 (West 2022); Alaska Stat. Ann. §§ 17.37.010-17.37.080, 17.38.010-17.38.900 (West 2022); Ariz. Rev. Stat. Ann. §§ 36-2801 to 36-2822, 36-2850 to 36-2865 (West 2022); Cal. Health & Safety Code §§ 11018-11018.2, 11357-11362.5, 11362.9 (West 2022); Colo. Const. Art. 18, § 16 (West 2022); Colo. Rev. Stat. Ann. §§ 25-1.5-106 to 106.5, 39-28.8-101, 39-28.8-201 to 39-28.8-308, 44-1-101 to 44-10-106 (West 2022); Conn. Gen. STAT. \$\$ 21a-240(29), 21a-408 to 21a-408v, 21a-409 to 21a-410 (West 2022); Del. Code Ann. tit. 16, Ch. 49A \$\$ 4901A-4928A (West 2022); FLA CONST. Art. 10, § 29 (West 2022); Fla Stat. Ann. §§ 381.986-381.989 (West 2022); Ga. Code Ann. Art. 5, §§ 43-34-120 to 43-34-126 (West 2022); Haw. Rev. Stat. Ann. §§ 329-121 to 329-131 (West 2022); 720 ILL. Comp. Stat. Ann. 550/1–550/19 (West 2022); Me. Rev. Stat. Ann. tit. 22, Ch. 558-C, §§ 2421–2430, 2383-B (West 2022); Mb. Const. Art. XX (text at https://ballotpedia.org/Maryland Question 4, Marijuana Legalization Amendment (2022)#Text of measure); Mb. Code, Health—General, Subtit. 33 §§ 13-3301 to 13-3316 (West 2022); Mass. Gen. Laws Ch. 94I, §§ 1-8 (West 2022); Mich. Comp. Laws §§ 333.26421-333.26430 (West 2022); Mo. Const. Art. 14, § 1 (West 2022, as amended by Ballot Initiative 3, https://www.sos.mo.gov/cmsimages/Elections/Petitions /2022-059.pdf); Vernon's Mo. Ann. Stat \$\\$ 195.805-195.820 (West 2022); Nev. Rev. Stat. Ann. \\$\\$ Chs. 678A-678D, \\$\\$\\$ 678A.005-678D.510 (West 2022); N.H. Rev. Stat. Ann. Ch. 126-X, §§ 126-X:1 to 126-X-12 (West 2022); N.J. Stat. Ann. Ch. 61, §§ 24:6i-1 to 24:6i-56 (West 2022); N.M. Stat. Ann. §§ 26-2B-1 to 26-2B-10, 26-2C-2 to 26-2C-42, 30-31C-1 (West 2022); McKinney Penal L. §\$ 222.05-222.65 (West 2022); McKinney Pub. Health L. Art. 33, Tit. V-a, §\$ 3360-3369E (West 2022); N.D. Stat. Ch. 19-24.1, §§ 19-24.1-01 to 19-24.140 (West 2022); Ohio Rev. Code Ann. Ch. 3796, §§ 3796.01-3796.31 (West 2022); 63 OKLA. STAT. ANN. §\$ 427.1-427.24 (West 2022); OR. REV. STAT. ANN. Ch. 475C, §\$ 475C.001-475C.950 (West 2022); PA STAT. §\$ 10231.101-10231.2110 (West 2022); R.I. GEN. LAWS ANN. §\$ 21-28.6-1 to 21-28.6-19 (West 2022); UTAH CODE ANN. Ch. 61A, §\$ 26-61A-101 to 26-61A-703, Tit. 58-37-3.7 (2022); VT. STAT. ANN. tit. 18, §\$ 4201, 4218, 4230-4230f, 4474b (West 2022); VA. Code Ann. §\$ 18.2-251.1 to 18.2-251.1:3, 4.1-600 to 4.1-1503 (West 2022); WASH.

REV. CODE ANN. §§ 69.51A.040 & 69.51A.060 (West 2022); *cf.* D.C. Stat. §§ 7-1671.01 to 7-1671.13 (West 2022). Some states address maternal cannabis use in a rather weak fashion. Arizona requires that its Department of Health Services "shall post prominently on its public website a warning about the potential dangers to fetuses caused by smoking or ingesting marijuana while pregnant or to infants while breastfeeding and the risk of being reported to the department of child safety during pregnancy or at the birth of the child by persons who are required to report." ARIZ. REV. STAT. ANN. § 36-2803(D) (West 2022). Dispensaries must also display such a warning in their facilities and on packaged goods. *Id.* §§ 36-2854.A.11, 36-2854.01.7. New Jersey requires package warning labels that say "There may be health risks associated with consumption of this product, including for women who are pregnant, breastfeeding, or planning on becoming pregnant." N.J. STAT. ANN. Ch. 61, § 24:6i-35. By contrast, numerous states flatly prohibit the sale of cannabis to minors. *See*, *e.g.*, CAL. HEALTH & SAFETY CODE § 11362.45(b); COLO. CONST. Art. 18, § 16(3); NEV. REV. STAT. ANN. Ch. 678D, §§ 678D.200.3(a), 678D.300(e); N.M. STAT. ANN. § 26-2C-30.A; OR. REV. STAT. ANN. Ch. 475C, § 475C.317(1)(A); VT. STAT. ANN. § 4230f(a).

- 8. U.S. Dep't of Health & Human Servs., Substance Abuse and Mental Health Servs. Admin., Marijuana and Pregnancy (Sept. 27, 2022) [hereafter SAMHSA, Marijuana and Pregnancy], https://www.samhsa.gov/marijuana/marijuana-pregnancy; AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 2 ("Among these illicit substances, marijuana is the substance most commonly used by pregnant women.... In studies of urban, young, and socioeconomically disadvantaged pregnant women, reported rates of marijuana use ranged between 15% and 28%.") (endnotes omitted). Women often use cannabis to address pregnancy-related nausea. See Colo. Dep't of Pub. Health & Env't, Monitoring Health Concerns Related to Marijuana in Colorado: 2014, at 76 (2015) [hereafter Colorado, Marijuana Report]; AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 3; Shalem Y. Leemaqz et al., Maternal Cannabis Use Has Independent Risk for Spontaneous Preterm Birth but Not Other Common Late Pregnancy Complications, 62 Reproductive Toxicology 77, 82 (2016) (noting anecdotal evidence to that effect).
- 9. See Giorgia Sebastiani et al., The Effects of Alcohol and Drugs of Abuse on Maternal Nutritional Profile During Pregnancy, 10 Nutrients 1008, 1009 (2018) ("Recent estimates of the prevalence of cannabis use among pregnant women in the US range between 3% and 16%. Population-based surveillance data from the National Survey on Drug Use and Health concludes that cannabis use among pregnant women in the US has increased as much as 62% between 2002 and 2014.... There is an increasing trend in prenatal cannabis use, due to the conception of need of cannabis for medical use, cannabis harmlessness, and increased access to the drug."); Kelly C. Young-Wolff et al., Letter, Rates of Prenatal Cannabis Use Among Pregnant Women Before and During the COVID-19 Pandemic, 326 JAMA, 1745, 1745 (2021).
- 10. See Wang, supra note 5, at 99; Kelly C. Young-Wolff et al., Trends in Self-Reported and Biochemically Tested Marijuana Use Among Pregnant Females in California from 2009–2016, 318 JAMA 2490, 2491 (2017).
- 11. Young-Wolff et al., supra note 10, at 2491 Fig. 2.
- 12. *Id.*; accord Steven J. Parker & Barry S. Zuckerman, *The Effects of Maternal Marihuana Use During Pregnancy on Fetal Growth*, in Marihuana and Medicine 461, 465 (Gabriel G. Nahas et al. eds., 1999) ("Had urine tests for marihuana not been performed, we would not have identified 16% of the marihuana users during pregnancy.").
- 13. See Nat'l Inst. on Drug Abuse, Cannabis (Marijuana) Research Report 25 (July 2020) [hereafter NIDA, Cannabis Report] (noting that "self-reported rates of marijuana use in pregnant females may not be an accurate measure of marijuana use") (footnote omitted).
- 14. Wang, *supra* note 5, at 99.
- 15. Am. College of Obstetricians & Gynecologists, Committee Opinion: Marijuana Use During Pregnancy and Lactation, 130 Obstetrics & Gynecology e205, e205 (Oct. 2017) (endnotes omitted) [hereafter ACOG, Marijuana Use]; see also Nora D. Volkow et al., Letter, Self-Reported Medical and Nonmedical Cannabis Use Among Pregnant Women in the United States, 322 JAMA 167 (2019). Other studies report an even higher rate of use. See Aurelia Garry et al., Cannabis and Breastfeeding, 209 J. Toxicology 596149, at 2 ("Studies conducted by North American and English teams from 1980 to 2000 show an incidence of cannabis use during pregnancy of 3% to 30% (more often 10% to 15%).").
- 16. Young-Wolff et al., supra note 9, at 1746; see also Joshua C. Black et al., Research Letter, Evaluation of Cannabis Use Among US Adults During the COVID-19 Pandemic Within Different Legal Frameworks, 5 JAMA Network Open (2022) e2250526, at 3 ("We observed higher cannabis use to relax and reduce pain, concurrent with decreasing nonmedical use of prescription drugs and use to get high, suggesting that cannabis may have been used to cope with stressors or compensate for disrupted access to prescription opioids.") (endnotes omitted); Qiana L. Brown et al., Research Letter, Trends in Marijuana Use Among Pregnant and Nonpregnant Reproductive-Aged Women, 2002–2014, 317 JAMA 207, 208 (2017) ("Among pregnant women, the prevalence of past-month marijuana use increased 62% from 2002 through 2014. Prevalence was highest among women aged 18 to 25 years, indicating that young women are at greater risk for prenatal marijuana use.").
- 17. See Or. Liouor Comm'n, 2019 Recreational Marijuana Supply & Demand Legis. Rep 18 (2019) ("Like many markets, including for alcohol, total consumption is overwhelmingly driven by the heaviest users through the '80/20 rule.' Generally, 20% of users represent 80% of total consumption."); MILES K. LIGHT ET AL., REPORT FOR THE COLO. DEP'T OF REVENUE, MARKET SIZE AND DEMAND FOR MARIJUANA IN COLORADO (2014) (a university study finding, based on 2016 Colorado data, that 22.5 percent of marijuana users consumed 71.7 percent of all the cannabis used during that year); Jonathan P. Caulkins, The Real Dangers of Marijuana, Nat'l Affairs 21, 28 (Winter 2016); Mark A.R. Kleiman, How Not to Make a Hash Out of Cannabis Legalization, Wash. Monthly (Mar./Apr./May 2014), https://washingtonmonthly.com/2014/03/02/how-not-to-make-a-hash-out-of-cannabis-legalization/; Paul J. Larkin, Jr., Cannabis Capitalism, 69 Buff. L. Rev. 215, 148 (2021) [hereafter Larkin, Cannabis Capitalism].
- 18. Caulkins, supra note 17, at 29.
- 19. *Id*.
- 20. Kleiman, supra note 17.

- 21. It is also disturbing if they are using alcohol or cigarettes, which a goodly number do. See, e.g., Tina Birk Irner, Substance Exposure in Utero and Developmental Consequences in Adolescence: A Systematic Review, 18 Child Neuropsychology 521, 522 (noting that a 2002–2003 survey found that 33 percent of pregnant women drank alcohol and 20 percent smoked cigarettes), 543 (noting that studies found that "[h]eavy alcohol exposure" (five or more drinks per occasion, nine or more drinks per week) seems "to have serious developmental consequences" that affect one's attention, executive functioning, working memory, behavior, and socioemotional functioning) (2012). Moreover, there is a significant association between paternal cannabis use and sudden infant death syndrome (SIDS). See Hillary Klonoff-Cohen & Phung Lam-Krulick, Maternal and Paternal Recreational Drug Use and Sudden Infant Death Syndrome, 155 Archives of Pediatric Med. 765, 767–69 (2001).
- 22. ACOG, Marijuana Use, supra note 15, at e205 (endnotes omitted).
- 23. Jamie O. Lo et al., *Impact of Cannabinoids on Pregnancy, Reproductive Health and Offspring Outcomes*, 227 Am. J. Obstetrics & Gynecology 571, 573 (2022).
- 24. Id.
- 25. Kleiman, *supra* note 17.
- 26. NIDA, Cannabis Report, *supra* note 13, at 25 (footnote omitted); *see also*, *e.g.*, ACOG, *Marijuana Use*, *supra* note 15, at e205 (noting that 18.1 percent of pregnant women reporting cannabis use within the past year satisfied the criteria for cannabis abuse or dependence); Caitlin E. Martin et al., *Recent Trends in Treatment Admissions for Marijuana Use During Pregnancy*, 9 J. Addiction Medicine 99 (2015).
- 27. AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 3 (noting that "the use of marijuana is being touted on social media as an effective and safe treatment of nausea and vomiting of pregnancy" even though "there are currently no indications for its use during pregnancy; the American College of Obstetricians and Gynecologists (ACOG) clearly stated this in its Committee Opinion in 2015.") (endnote omitted); Nora D. Volkow et al., The Risks of Marijuana Use During Pregnancy, 317 JAMA 129, 129 (2017).
- 28. Cannabis is marketed in various forms other than smokable products, such as ingestible foods, candies, sauces, and the like, known as edibles, as well as lotions. See, e.g., Paul J. Larkin, Jr., Marijuana Edibles and "Gummy Bears," 66 Buff. L. Rev. 313, 316–20 (2018).
- 29. See NIDA, Cannabis Report, supra note 13, at 25; George Sam Wang et al., Cannabis and the Impact on the Pediatric and Adolescent Population, in Finn ed., supra note 5, at 134 ("In states that do allow medical marijuana, many of the prescribers and marijuana dispensaries do not have medical training..."); Betsy Dickson et al., Recommendations from Cannabis Dispensaries About First-Trimester Cannabis Use, 131 Obstetrics & Gynecology 1031 (2018).
- 30. Dickson et al., supra note 29.
- 31. *Id*.
- 32. *Id*.
- 33. Employees at Colorado medical marijuana dispensaries "must hold a valid Employee license." 1 Co. ADC § 212-3:5-615.A.2 (West 2022). The license application prepared by the Marijuana Enforcement Division of the Colorado Department of Revenue provides that that a "Yes" answer to Question 4 disqualifies someone from working in the cannabis industry. Colo. Dep't of Revenue, Marijuana Enforcement Division, Marijuana Employee License Application DR 8517, at 2 (Oct. 28, 2022) ("4. Are you a licensed Physician making marijuana patient recommendations? (Medical Only).... [¶] STOP! If you answered YES to any of the above questions, by Colorado law you cannot obtain or hold a Colorado Marijuana Employee license. I have thoroughly read and understand the questions above, and understand that I cannot hold a Colorado Marijuana license if I answered 'Yes' to any of the questions above.") (emphasis in original; internal punctuation omitted).
- 34. See, e.g., CNTRS. FOR DISEASE CONTROL & PREVENTION, FETAL ALCOHOL SPECTRUM DISORDERS (FASDs) (Oct. 31, 2022); PETER W. NATHANIELSZ, LIFE BEFORE BIRTH: THE CHALLENGES OF FETAL DEVELOPMENT 158–62 (2021); Peter A. Fried et al, Growth and Pubertal Milestones During Adolescence in Offspring Prenatally Exposed to Cigarettes and Marijuana, 23 Neurotoxicology & Teratology 431, 431 (2001) [hereafter Fried et al., Growth]; Peter A. Fried et al., Differential Effects on Cognitive Functioning in 9- to 12-Year Olds Prenatally Exposed to Cigarettes and Marijuana, 20 Neurotoxicology & Teratology 293, 293 (1998) [hereafter Fried et al., Cognitive Functioning].
- 35. See, e.g., Peter A. Fried, *Pregnancy, in* Cannabis and Cannabinoids: Pharmacology, Toxicology, and Therapeutic Potential 269, 269 (Franjo Grotenhermen & Ethan Russo eds., 2002); Volkow et al., *supra* note 27, at 129; *cf.* Sebastiani et al., *supra* note 9, at 1016 ("Few data report the nutritional status of pregnant marijuana users, nor is it known what effect marijuana exposure may have on specific nutrients.").
- 36. Lo et al., *supra* note 23, at 572; see Bara et al., *supra* note 5, at 423 ("The endocannabinoid (eCB) system (ECS)...which mediates the actions of THC, plays a critical regulatory role throughout all developmental stages, from the determination of cell fate and neuronal migration to the regulation of signaling pathways and synaptic transmission in the mature central nervous system (CNS). Therefore, the supraphysiological impact on the ECS by cannabis exposure during critical periods of development could change the normal trajectory of cellular processing and neurocircuitry, leading to behavioural disturbances later in life.").
- 37. See, e.g., Nat'l Acad. Cannabis Report, supra note 1, at 245–46 ("A rapidly growing body of evidence indicates that endocannabinoids [endogenously produced chemical compounds that bind to the same CB1 brain receptors as THC and interact with the brain in much as same way as dopamine, serotonin, and endorphins] play roles in a broad array of critical neurodevelopmental processes" such as "early neural stem cell survival and proliferation to the migration and differentiation of both glial [the nervous system's connective tissue, especially in the brain, spinal cord, and ganglia] and neuronal lineages, as well as neuronal connectivity and synaptic function."); Nathanielsz, supra note 34, at 132 ("Drugs of abuse have marked and

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- long-lasting effects on the developing fetal brain."); Wang et al., *Cannabis and the Impact on the Pediatric and Adolescent Population, in* Finn ed., *supra* note 5, at 143 ("Negative effects of cannabis on the developing brain are particularly noted in the perinatal/prenatal period and during early adolescence.") (footnote omitted).
- 38. See Elizabeth C. Bluhm et al., *Maternal Use of Recreational Drugs and Neuroblastoma in Offspring: A Report from the Children's Oncology Group (United States)*, 17 CANCER CAUSES & CONTROL 663, 663, 666–67 (2006) ("Our results suggest that maternal use of marijuana around the time of pregnancy, particularly in the first trimester, is associated with increased risk of neuroblastoma in offspring. These results differ from a recent Children's Cancer Group study of childhood acute myeloid leukemia (AML), which suggested a decreased risk from maternal marijuana use and no association with paternal marijuana use prior to or during pregnancy. However, our findings further expand previous investigations of parental marijuana use in the prenatal period as a potential risk factor for other childhood cancers. Robinson et al. found an increased, but imprecise risk of acute non-lymphoblastic leukemia (ACNLL) among children whose mothers used marijuana and other mind-altering substances prior to or during pregnancy.... Kuitjen et al. identified an elevated risk of astrocytoma with maternal use of marijuana between 1 month prior to conception and childbirth.... There was an increased risk of rhabdomyosarcoma with maternal use of marijuana...or cocaine...in the 12 months before birth. A large study of acute lymphoblastic leukemia (ALL) revealed increased risks associated with maternal...paternal...or both parents'...use of mind-altering drugs, of which marijuana was predominant....") (citations and endnotes omitted).
- 39. See Moheb Costandi, Neuroplasticity (2016).
- 40. See, e.g., NIDA, CANNABIS REPORT, supra note 13, at 25 ("There is no human research connecting marijuana use to the chance of miscarriage, although animal studies indicate that the risk for miscarriage increases if marijuana is used early in pregnancy. Some associations have been found between marijuana use during pregnancy and future developmental and hyperactivity disorders in children. Evidence is mixed as to whether marijuana use by pregnant women is associated with low birth weight or premature birth, although long-term use may elevate these risks. Research has shown that pregnant women who use marijuana have a 2.3 times greater risk of stillbirth."); Office of the Surgeon General, U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain (Aug. 29, 2019) (last accessed Nov. 1, 2022), https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction -and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html; Bara et al., *supra* note 5, at 426–28 (adverse downstream consequences in the endocannabinoid system regarding neuronal proliferation, migration, differentiation, and maturation); David A.A. Baranger et al., Letter, Association of Mental Health Burden with Prenatal Cannabis Exposure from Early Childhood to Early Adolescence: Longitudinal Findings from the Adolescent Brain Cognitive Development (ABCD) Study, JAMA Pediatrics, https://jamanetwork.com/journals/jamapediatrics/article-abstract /2795863 (published online Sept. 12, 2022) (same, "persisting vulnerability" to broad spectrum psychopathology as children progress through early adolescence, which might lead to "greater risk for psychiatric disorders and problematic substance use as children enter peak periods of vulnerability in later adolescence") (endnote omitted); Daniela Calvigioni et al., Neuronal Substrates and Functional Consequences of Prenatal Cannabis Exposure, 23 EUROPEAN CHILD & ADOLESCENT PSYCHIATRY 931 (2014); Daniel J. Corsi et al., Letter, Maternal Cannabis Use in Pregnancy and Child Neurodevelopmental Outcomes, 26 Nature Medicine 1536 (2020) (finding an association between maternal cannabis use and an increased risk of autism spectrum disorder in her offspring); Nancy L. Day et al., Effect of Prenatal Marijuana Exposure on the Cognitive Development of Offspring at Age Three, 16 Neurotoxicology & Teratology 169, 174 (1994) (finding that, "on average, children exposed prenatally to marijuana will have a lower IQ compared with children who were not exposed."); P.A. Fried, The Ottawa Prenatal Perspectives Study (OPPS): Methodological Issues and Findings—It's Easy to Throw the Baby Out with the Bath Water, 56 Life Scis. 2159, 2159 (1995) [hereafter Fried, Ottawa Study] (same, decreased performance on visual perceptual tasks, language comprehension, sustained attention, and memory in elementary school-age children); J.K.L. Gunn et al., Prenatal Exposure to Cannabis and Maternal and Child Health Outcomes: A Systematic Review and Meta-Analysis, 6 BMJ Open e009986 (2016); Yasmin L. Hurd et al., Cannabis and the Developing Brain: Insights into Its Long-Lasting Effects, 39 J. Neuroscience 8250 (2019); Lo et al., supra note 23; Greg Marchand et al., Birth Outcomes of Neonates Exposed to Marijuana in Utero: A systematic Review and Meta-analysis, 5 JAMA NETWORK OPEN e2145653 (2022) (decreased Apgar score at one minute and increased risk of NICU admission); Hannan El Marroun et al., Intrauterine Cannabis Exposure Affects Fetal Growth Trajectories: The Generation R Study, 48 J. Am. Acad. CHILD & Adolescent Psychiatry 1173 (2009); Torri D. Metz et al., Maternal Marijuana Use, Adverse Pregnancy Outcomes, and Neonatal Morbidity, 217 Am. J. Obstetrics & Gynecology 418e1-8 (2017); Sarah E. Paul et al., Associations Between Prenatal Cannabis Exposure and Childhood Outcomes: Results from the ABCD Study, 78 JAMA Psychiatry 64 (2021) (greater risk of psychopathology during middle adolescence); Gregory Rompala et al., Maternal Cannabis Use Is Associated with Suppression of Immune Gene Networks in Placenta and Increased Anxiety Phenotypes in Offspring, 118 Proceedings Nat'l Acad. Sci. e2106115118, at 4 (2021) (increased anxiety, aggression, and hyperactivity in young children); Emily J. Ross et al., Developmental Consequences of Fetal Exposure to Drugs: What We Know and What We Still Must Learn, 40 Neuropsychopharmacology 61, 72 (2015) ("Perhaps most striking is that even in their early 20s, exposed individuals still have deficits in visuospatial working memory and impulsivity...") (citation omitted); Kristen E. Sonon et al., Prenatal Marijuana Exposure Predicts Marijuana Use in Young Adulthood, 47 Neurotoxicology & Teratology 10 (2015); Michael W. Varner et al., Association Between Stillbirth and Illicit Drug Use and Smoking During Pregnancy, 123 Obstetrics & Gynecology 113 (2014); Volkow et al., supra note 15, at 167; Xinyu Wang et al., In Utero Marijuana Exposure Associated with Abnormal Amygdala Dopamine D2 Gene Expression in the Human Fetus, 56 Biological Psychiatry 909, 913 (2004) (in utero cannabis exposure might impair later emotional behavior); Barry Zuckerman et al., Effects of Maternal Marijuana and Cocaine Use on Fetal Growth, 320 New Eng. J. Med. 762 (1989).
- 41. See, e.g., ACOG, Marijuana Use, supra note 15, at e206 & e209 (no association between maternal cannabis use and structural anatomical fetal defects, fetal mortality, preterm birth, or reduced birth weight); Colorado, Maruuana Report, supra note 8, at 76–78 (after conducting a literature review, finding (1) moderate evidence that maternal use is associated with decreased growth in children and decreased academic ability, cognitive functioning, and attention that might not appear until adolescence; (2) limited evidence of stillbirth, SIDS, later delinquent behavior, and heart defects; (3) mixed evidence on other issues, such as preterm delivery; and (4) insufficient proof of psychosis, breastfeeding-related SIDS, and future adolescent use); Franjo Grotenhermen, Nonpsychological Adverse Effects, in Handbook of Cannabis 674, 675, 679–80 (Roger G. Pertwee ed., 2016) (possible association between cannabis use and

adolescent cognitive impairment and visual-motor coordination, but unlikely that cannabis causes embryonic or fetal malformations and inconsistent epidemiological data on birth weight); David M. Fergusson et al., *Maternal Use of Cannabis and Pregnancy Outcome*, 109 Br. J. Obstetrics & Gynecology 21 (2002) (no increased risk of perinatal morbidity, mortality, or NICU admission); Fried et al., *Growth*, *supra* note 34, at 435 (no association height, weight, or ratio of weight to height); Fried et al., *Cognitive Functioning*, *supra* note 34, at 304 (same, with later global intelligence); Franjo Grotenhermen, *Review of Unwanted Actions of Cannabis and THC*, *in* Grotenhermen & Russo eds., *supra* note 35, at 241; Gunn et al., *supra* note 40, at 6 (no association with lower Apgar scores); Klonoff-Cohen & Lam-Krulick, *supra* note 21, at 767–68 (same, SIDS); Greg Marchand et al., *supra* note 40, at 9 (same, mean gestational age, Apgar scores at five minutes, and mean infant length); K. Trivers et al., *Parental Marijuana Use and Risk of Acute Myeloid Leukemia: A Report from the Children's Cancer Group (United States and Canada*), 20 Pediatric & Perinatal Epidemiology 110 (2006) (same, acute myeloid leukemia). *See generally* AAP, *Marijuana and Pregnancy/Breastfeeding*, *supra* note 5, at 3–6 (summarizing the evidence pro and con on the effects of maternal cannabis use).

- 42. See, e.g., Nat'l Acad. Cannabis Report, supra note 1, at 254.
- 43. See, e.g., NIDA, CANNABIS REPORT, supra note 13, at 24–25; ACOG, Marijuana Use, supra note 15, at e208.
- 44. SAMHSA, Marijuana and Pregnancy, supra note 8; AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 8–9. That is perhaps due to THC's high lipophilicity. Wang, supra note 5, at 100.
- 45. "There are few data about the frequency of use of marijuana by women while breastfeeding. A report from Colorado, where marijuana is legal for some, surveyed women attending the Special Supplemental Nutrition Program for Women, Infants, and Children program in the state's largest local health department. It revealed that 7.4% of mothers younger than 30 years of age and 4% of mothers older than 30 years of age were current marijuana users. Of all marijuana users (past, ever, current), 35.8% said that they had used at some point during pregnancy, 41% had used since the infant was born, and 18% had used while breastfeeding." AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 8 (endnote omitted); see also, e.g., Bara et al., supra note 5, at 428 (estimating that 15 percent of breastfeeding women use cannabis); Garry et al., supra note 15, at 3.
- 46. AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 8–9; Wang et al., Cannabis and the Impact on the Pediatric and Adolescent Population, in Finn ed., supra note 5, at 137; Wang, supra note 5, at 100.
- 47. Garry et al., supra note 15, at 3.
- 48. See AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 9.
- 49. See, e.g., Bonni Goldstein, Cannabis Is Medicine 142 (2020).
- 50. See, e.g., ACOG, Marijuana Use, supra note 15, at e205 ("It is difficult to be certain about the specific effects of marijuana on pregnancy and the developing fetus, in part because those who use it often use other drugs as well, including tobacco, alcohol, or illicit drugs, and in part because of other potential confounding exposures."); Nathanielsz, supra note 34, at 158, 197–225; Marijuana Legalization, supra note 40, at 60-61; Goldstein, supra note 49, at 142; Leslie L. Iversen, The Science of Marijuana 169–70 (2d ed. 2008).
- 51. See, e.g., Richard J. Bonnie and Charles H. Whitebread II, The Marijuana Conviction: A History of Marijuana Prohibition in the United States (Lindesmith Ctr. 1999) (1974) (discussing that history).
- 52. The original California law, Proposition 215, was known as the Compassionate Use Act of 1996. Larkin, *Drugged Driving*, *supra* note 1, at 468. For the current California law, see Cal. Health & Safety Code §§ 11362.5, 11362.7-11362.83 (West 2022).
- 53. Physicians cannot prescribe cannabis. Congress placed cannabis in CSA Schedule I, which prohibits its use for any purpose. 21 U.S.C. § 812(b)(1)(A)–(C) (2018) (noting that drugs placed in Schedule I have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and a lack of accepted safety for use of the drug or other substance under medical supervision"); *id.* § 829 (setting prescription standards for drugs in Schedules II–V); *id.* § 841(a) (defining prohibited acts). Exceeding federal prescription limitations can lead to prosecution and conviction. *See* Ruan v. United States, 142 S. Ct. 2370 (2022); United States v. Moore, 423 U.S. 122 (1975) (both ruling that a physician can be convicted for distributing a controlled substance outside the boundaries of professional medical practice). Nonetheless, the U.S. Court of Appeals for the Ninth Circuit ruled that the First Amendment Free Speech Clause prohibits the government from adopting a viewpoint-based restriction on private communications between a physician and a patient regarding potential medical treatment options. *See* Conant v. McCaffrey, 172 F.R.D. 681, 694–95 (N.D. Cal. 1997) (issuing preliminary injunction), 2000 WL 1281174 (N.D. Cal. Sept. 7, 2002) (issuing permanent injunction).
- 54. The term "patients" has to be read with a great deal of liberality. In some instances, all it takes is "\$40 and 10 minutes" to get a medical cannabis prescription. 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 [https://perma.cc/4EQH-CTVV] ("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.'").
- 55. As of November 9, 2022, 37 states, three territories, and the District of Columbia permitted the use of cannabis for medical purposes, while 18 states, two territories, and the District of Columbia permitted recreational-use cannabis. See Nat'L Conf. of State Legislators (Nov. 9, 2022), https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx. On November 8, Maryland and Missouri voted to legalize cannabis use, raising to 20 the number of states with recreational-use laws. See Tyler Olson, Marijuana Legalized in These States in the Midterm Elections, Fox News, Nov. 9, 2022, https://www.foxnews.com/politics/voters-states-legalized-marijuana-midterm-elections.

- 56. See, e.g., S. 4591, the Cannabis Administration and Opportunity Act, 117th Cong. (2022) (proposing to deschedule cannabis from the Controlled Substances Act).
- 57. The Supremacy Clause of Article VI of the Constitution makes federal law superior to state law when the two conflict. U.S. Const. art. VI, cl. 2. Accordingly, states cannot exempt their residents from federal law by adopting their own regulatory programs. See Gonzales v. Raich, 545 U.S. 1, 23–33 (2005) (rejecting the argument that a state medical marijuana program available only for bona fide state residents should be exempt from federal regulation under the Commerce Clause); United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 494-95 (2001) (rejecting a medical necessity defense to federal prosecution in a state with a medical marijuana program).
- 58. Obama's decision was more a forbidden suspension of the law than an exercise in discretionary law enforcement. See Paul J. Larkin, Wholesale-Level Clemency: Reconciling the Pardon and Take Care Clauses, 18 U. St. Thomas L. Rev. (forthcoming 2023) (manuscript 15–28) (discussing a forbidden "suspension" of the law).
- 59. See Memorandum from David W. Ogden, Deputy Att'y Gen., to Selected U.S. Attorneys regarding Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana (Oct. 19, 2009); Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Just., for United States Attorneys regarding Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use 1 (June 29, 2011); Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Just., for United States Attorneys regarding Guidance Regarding Marijuana Enforcement 3 (Aug. 29, 2013); Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Just., for United States Attorneys regarding Guidance Regarding Marijuana Related Financial Crimes 2 (Feb. 14, 2014).
- 60. See Gov't Accountability Off., State Marijuana Legalization: DOJ Should Document Its Approach to Monitoring the Effects of State Marijuana Legalizations 8–9 (Dec. 2015).
- 61. See, e.g., Wang et al., Cannabis and the Impact on the Pediatric and Adolescent Population, in Finn ed., supra note 5, at 137 ("The increased presence of the medical marijuana industry did not begin until the release of the Ogden memo in 2009."); Zachary S. Price, Federal Nonenforcement: A Dubious Precedent, in Marijuana Federalism: Uncle Sam and Mary Jane 123 (Jonathan H. Adler ed., 2020).
- 62. See, e.g., Larkin, Cannabis Capitalism, supra note 17, at 224–43.
- 63. Archie Bleyer & Brian Barnes, Comment & Response, *Opioid Death Rate Acceleration in Jurisdictions Legalizing Marijuana Use*, 178 JAMA INTERNAL MED. 1280. 1280 (2018).
- 64. Kevin Sabet et al., What Is the Evidence of Marijuana as Medicine?, in Contemporary Health Issues on Marijuana 256 (Kevin A. Sabet & Ken C. Winters eds., 2018).
- 65. See, e.g., United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) (Learned Hand, J.) ("[T]he [ship] owner's duty, as in other similar situations, to provide against resulting injuries is a function of three variables: (1) The probability that she will break away; (2) the gravity of the resulting injury, if she does; (3) the burden of adequate precautions. Possibly it serves to bring this notion into relief to state it in algebraic terms: if the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P: i.e., whether B is less than PL."); Prosser and Keeton on Torts §§ 32–33, at 173–208 (5th ed. W. Page Keeton gen'l ed., 1984) (describing the reasonable person standard and its application). The precautionary principle advanced in environmental law also counsels hesitation in the face of severe, large-scale, and potentially irremediable effects. See, e.g., Cass R. Sunstein, Laws of Fear: Beyond the Precautionary Principle. Avoid steps that will create a risk of harm. Until safety is established, be cautious: do not require unambiguous evidence. In a catchphrase, better safe than sorry. In ordinary life, pleas of this kind seem quite sensible, indeed a part of ordinary human rationality. People buy smoke alarms and insurance. They wear seatbelts and motorcycle helmets, even if they are unlikely to be involved in an accident. Shouldn't the same approach be followed by rational regulators as well?") (emphasis in original; footnote omitted).
- 66. See, e.g., Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022) (ruling that there is no federal constitutional right to abortion); Harmelin v. Michigan, 501 U.S. 957 (1991) (upholding over an Eighth Amendment Cruel and Unusual Punishments Clause challenge a sentence of life imprisonment without the possibility of parole for the possession of 672 grams of cocaine); Powell v. Texas, 392 U.S. 514 (1968) (upholding over an Eighth Amendment Cruel and Unusual Punishments Clause challenge a conviction for being drunk in public and rejecting the claim that the offender could not avoid doing so because of his alcoholism); James Clark Distilling Co. v. Western Maryland R. Co., 242 U.S. 311, 320 (1917) ("That government can, consistently with the due process clause, forbid the manufacture and sale of liquor and regulate its traffic, is not open to controversy; and that there goes along with this power full police authority to make it effective, is also not open."); Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (ruling that terminally ill patients have no constitutional right to use potentially life-saving drugs not approved by the FDA); Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) (same).
- 67. See, e.g., Dobbs, 142 S. Ct. at 2284; Gonzales v. Carhart, 550 U.S. 124, 157–58 (2007).
- 68. SAMHSA, Marijuana and Pregnancy, supra note 8.
- 69. See Paul J. Larkin, Twenty-First Century Illicit Drugs and Their Discontents: The Troubling Potency of Twenty-First Century Cannabis, Heritage Found., Legal Memorandum No. 133 (Nov. 1, 2022) [hereafter Larkin, Cannabis Potency] (describing the increase in cannabis's potency over the past few decades).
- 70. Ch. 675 § 1, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 et seq (2018)).
- 71. A "new drug" includes "[a]ny drug...[that] is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed..." 21 U.S.C. § 321(p)(1); 21 C.F.R. § 310.3(h) (2021).

- 72. See, e.g., 21 U.S.C. § 355(a) (2012) (forbidding distribution of a new drug in interstate commerce without prior FDA approval). Pharmaceutical companies must conduct extensive clinical testing to prove that a new drug is safe and effective for its intended purposes before the FDA will approve it. That testing generally comes in three phases. Phase I encompasses initial clinical testing in humans to assess toxicity; pharmacodynamics (the effect of a drug on the body); pharmacokinetics (the movement of a drug through a body and action of the body on the drug); and (only preliminarily) potential therapeutic benefits. Phase II is designed to explore, and Phase III to confirm or refute, the therapeutic effects of a drug on a particular disease or condition. See 21 C.F.R. § 312.21 (2022). Drug companies test the effect of a drug's potency on animals before conducting tests on humans. After obtaining those results, pharmaceutical companies then conduct Phase 1 tests. The potential toxicity of a drug is an essential feature of the early stages of a drug trial because no drug can be deemed safe if the minimum lethal dose and the potential adverse long-term effects are unknown. For a summary of the testing and approval process that ordinary pharmaceuticals must undergo before the FDA can approve them as safe and effective, see, e.g., Rick Ng, Drugs: From Discovery to Approval 136-206 (2d ed. 2009); Mikkael A. Sekeres, Drugs and the FDA 51, 79-80, 91, 96 (2022). Proof of purity, which ensures that all doses are the same, results from manufacturing controls. See 21 C.F.R. § 314.50 (2022). The FDA examines the drug proponent's manufacturing practices to ensure that the drug has a consistent quality and the drug's labeling to satisfy itself that the quantity of active and inactive ingredients is accurate and the directions for use are helpful to a patient. See, e.g., 21 U.S.C. §§ 351(a)(2)(B), 352, 352(b), (c)-(f), 355(a), (b) & (d) (2018); 21 C.F.R. Pt. 200 Subpt. A (2018) (General Labeling Provisions); id. Pt. 201 (Labeling); id. Pt. 211 (Current Good Manufacturing Practices for Finished Pharmaceuticals); FDA, Compliance Program Guidance Manual § 7346.832 (2010); Wyeth v. Levine, 555 U.S. 555, 566-68 (2009); Brian F. Thomas & Mahmoud A. ElSohly, The Analytical Chemistry of Cannabis 11 (2016) ("The quality, safety, and efficacy of starting material are basic prerequisites in the pharmaceutical industry.").
- 73. The FDA deems cannabis a "new drug." See, e.g., 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) [hereinafter Gottlieb Statement], 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] ("Cannabis or cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S.").
- 74. The FDA has consistently made it clear that it has not found that smokable cannabis is safe and effective because "[it] has not been proven in scientific studies to be a safe and effective treatment for any disease or condition." Letter from Peter Hyun, Acting Ass't Att'y Gen'l, to Senators Elizabeth Warren & Cory A. Booker (Apr. 12, 2022); see also Larkin, Reflexive Federalism, supra note 1, at 593 & n.244.
- 75. See, e.g., Nat'l Fed. Indep. Bus. v. OSHA, 142 S. Ct. 661, 664–65 (2022); Ala. Ass'n of Realtors v. HHS, 141 S. Ct. 2485, 2489 (2021).
- 76. For the argument that the FDA could never approve botanical cannabis as a safe and effective drug, see Larkin, *Reconsidering Marijuana*, supra note 1, at 118–24.
- 77. Nora D. Volkow et al., Adverse Health Effects of Marijuana Use, 370 New Eng. J. Med. 2219, 2220 (2014).
- 78. See, e.g., Bara et al., supra note 5, at 429 ("Brain development during childhood that is marked by the emergence of increased neural connectivity is highly sensitive to environmental stimuli and activity-dependent experiences such as drug exposure."); Volkow et al., supra, note 77, at 2220 (noting that animal studies have shown that "prenatal or adolescent exposure to THC can recalibrate the sensitivity of the reward system to other drugs and that prenatal exposure interferes with cytoskeletal dynamics, which are critical for the establishment of axonal connections between neurons.") (endnotes omitted).
- 79. Wang, *supra* note 5, at 99.
- 80. It is also important to recognize that cannabis use by other people in the same household creates second-hand smoke that also poses risks for a pregnant or nursing mother and her child. See Bara et al., supra note 5, at 436; Wang et al., Cannabis and the Impact on the Pediatric and Adolescent Population, in Finn ed., supra note 5, at 136–37.
- 81. Wang et al., Cannabis and the Impact on the Pediatric and Adolescent Population, in Finn ed., supra note 5, at 133.
- 82. For a discussion of the high-potency cannabis sold today, see Larkin, Cannabis Potency, supra note 69.
- 83. See SAMHSA, Marijuana and Pregnancy, supra note 8; NIDA, Cannabis Report, supra note 13; U.S. Food & Drug Admin, Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Products Obtained Off the Street (Oct. 4, 2019); Office of the Surgeon General, supra note 40; U.S. Dep't of Health & Human Servs., Off. of the Surgeon Gen'l, The Surgeon General's Warning on Marijuana, Morbidity and Mortality Weekly Report (Aug. 13, 1982), https://www.cdc.gov/mmwr/preview/mmwrhtml/00001143.htm [https://perma.cc/9KLB-FZFU]; see also, e.g., Volkow et al., supra note 27 (Doctor Volkow is the NIDA Director).
- 84. SAMHSA, Marijuana and Pregnancy, supra note 8.
- 85. *Id.*
- 86. ACOG, Marijuana Use, supra note 15, at e205; AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5. Those recommendations are in the Appendix to this Legal Memorandum.
- 87. See, e.g., DAVID CASARETT, STONED: A DOCTOR'S CASE FOR MEDICAL MARIJUANA 182–84, 193, 255 (2015) ("[A]Ithough I'd be the first to admit that the evidence about marijuana and pregnancy isn't entirely convincing, I wouldn't knowingly recommend marijuana to a woman who is pregnant."); LESTER GRINSPOON

& James B. Bakalar, Marijuana: The Forbiden Medicine 137–38, 249–50 (rev. ed. 1997); Hale's Medications and Mothers' Milk 111 (20th ed. Thomas W. Hale & Kaytlin Krutsch eds., 2023) ("In summary, there are increasing concerns about the use of marijuana or other cannabis products, in breastfeeding mothers. Both human and animal studies suggest that early exposure to cannabis may not be benign, and that cannabis exposure in the perinatal period may produce long-term changes in mental and motor development. While this data poses numerous limitations, and does not directly examine the benefits of breast milk versus risks of exposure to marijuana in milk, cannabis use by breastfeeding mothers should be discouraged at this time. Healthcare professionals should encourage alternative treatment options for maternal health conditions requiring the use of marijuana.") (endnotes omitted); Jordyn Stuart et al., *Reproduction and Cannabis: Ups and Downs, Ins and Outs, in* Handbook of Cannabis 256 (Roger Pertwee ed., 2016) ("probably unwise"); cf. Goldstein, supra note 49, at 143 (noting that "most experts recommend avoiding phytocannabinoids during pregnancy," but "[i]n special circumstances, such as cases of extreme nausea that cannot be treated with other medications, low, intermittent doses of cannabis may be recommended"). By contrast, some individual physicians have noted the scientific uncertainties and have not offered an opinion on the subject. See The Pot Book: A Complete Guide to Cannabis—Its Role in Medicine, Politics, Science, and Culture 149 (Julie Holland ed., 2010) (noting only that "[t]he consequences of maternal cannabis use on fetal growth are continuingly being studied, and many remain controversial.").

- 88. Perhaps there would be a different calculus if there were scientific proof that cannabis cures fatal diseases such as cancer. There is no such proof, however, so the issue is a hypothetical one. See Nat'L Acad. Cannabis Report, supra note 1, at 14, 91 ("There is insufficient evidence to support or refute the conclusion that that cannabinoids are an effective treatment for cancers, including glioma."); European Monitoring Cntr. for Drugs and Drug Addiction 15 (Dec. 2018) ("Two observational studies have reported on adverse effects in cancer patients (Bar-Lev Schleider et al., 2018) and elderly patients (Abuhasira et al., 2018) treated in a leading Israeli cancer hospital between January 2015 and October 2017. Adverse events were assessed in a telephone interview conducted 6 months after treatment started. Among cancer patients, 31 % reported an adverse event; these most commonly related to dizziness (8.0 %), dry mouth (7.3 %), increased appetite (3.6 %), sleepiness (3.3 %) and psychoactive effects (2.8 %) (Bar-Lev Schleider et al., 2018). The prevalence and type of adverse events were very similar in older patients treated with cannabis for more varied medical conditions (Abuhasira et al., 2018.").
- 89. See Larkin, Reconsidering Marijuana, supra note 1, at 110–11.
- 90. I will pass over the fact that the chief prosecutors in many large cities have effectively suspended the operation of much of the criminal code by refusing to enforce those laws. That is a subject for another day.
- 91. See, e.g., John Geluardi, Cannabiz: The Explosive Rise of the Medical Marijuana Industry (2010) (describing the birth and growth of state medical cannabis programs).
- 92. See Larkin, Drugged Driving, supra note 1, at 468 (describing the passage of the original state medical cannabis initiative, California's Proposition 215, the Compassionate Use Act of 1996).
- 93. The FDCA could regulate the distribution of botanical cannabis in interstate commerce even if Congress were to repeal the CSA. See Larkin, Reflexive Federalism, supra note 1, at 585–86; Sean M. O'Connor & Erika Lietzan, The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling, 68 Am. U. L. Rev. 823 (2019) (explaining that descheduling cannabis transfers regulatory authority to the FDA); Patricia J. Zettler, Pharmaceutical Federalism, 92 InD. L.J. 845, 849 (2017) (noting the consensus that "state jurisdiction is reserved for medical practice—the activities of physicians and other health care professionals—and federal jurisdiction for medical products, including drugs") (emphasis in original; footnote omitted). Whether the FDA would do so is a political question.
- 94. See 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, 499 (2018) [hereafter Larkin, States' Rights] ("We do not...make scientific decisions in the same manner that we elect politicians: by ballot."). On numerous occasions, Congress has reaffirmed that judgment whenever it amended the original FDCA, id. (collecting examples of such statutes), or appropriated funds for the FDA to pursue its mission, id. (citing TVA v. Hill, 437 U.S. 153, 189–91 (1978)).
- 95. Drug companies test the effect of a drug's potency on animals before conducting tests on humans. After obtaining those results, pharmaceutical companies then conduct what is known as Phase 1 of the standard three-phase process for the clinical trial of drugs. The potential toxicity of a drug is an essential feature of the early stages of a drug trial because no drug can be deemed safe if the minimum lethal dose and the potential adverse long-term effects are unknown. For a summary of the testing and approval process that ordinary pharmaceuticals must undergo before the FDA can approve them as safe and effective, see, e.g., Ng, supra Note 72, at 136–206; Sekeres, supra note 72, at 51, 79–80, 91, 96. The FDA also examines the drug proponent's manufacturing practices to ensure that the drug has a consistent quality and the drug's labeling to satisfy itself that the quantity of active and inactive ingredients is accurate and the directions for use are helpful to a patient. See, e.g., 21 U.S.C. §§ 351(a)(2)(B), 352, 352(b), (c)–(f), 355(a), (b) & (d) (2018); 21 C.F.R. Pt. 200 Subpt. A (2018) (General Labeling Provisions); id. Pt. 201 (Labeling); id. Pt. 211 (Current Good Manufacturing Practices for Finished Pharmaceuticals); FDA, Compliance Program Guidance Manual § 7346.832 (2010); Wyeth v. Levine, 555 U.S. 555, 566–68 (2009); Thomas & ElSohly, supra note 72, at 11 ("The quality, safety, and efficacy of starting material are basic prerequisites in the pharmaceutical industry.").
- 96. 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/THGY-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]. See generally Larkin, Reflexive Federalism, supra note 1, at 593–94 & nn.244–46.
- 97. See Larkin. Cannabis Potency. supra note 69.

- 98. "Cannabis 'came of age,' so to speak, in the 1960s as a symbol of an intergenerational protest. The image of someone in his or her 20s or 30s smoking a joint could well serve as a representation of that generation's attitudes toward then-contemporary social and political culture. Users can still smoke cannabis as a 'joint' (botanical marijuana in wrapping paper) or a 'blunt' (botanical marijuana wrapped in tobacco), by using a 'bong' (a pipe or water pipe), or by vaporizing THC via an Electronic Nicotine Delivery Device (ENDD or e-cigarette). Yet, today numerous food products, known as 'edibles,' also contain THC. In addition to the Alice B. Toklas brownies popular in the 1960s, numerous food products—such as coffee, tea, soda, cookies, candies, caramels, lozenges, salad dressing, marinara sauce, and others—contain THC. As one commentator put it, a 'cannabis culinary professional can infuse just about anything you want to eat with THC,' and the variety of available THC-infused food products is 'a real testament to American entrepreneurialism and innovation." Larkin, *Cannabis Capitalism*, *supra* note 17, at 238-39 (footnotes omitted).
- 99. Blaskowsky, in Finn ed., supra note 5, at 407 (emphasis in original).
- 100. See AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 10 ("Pediatricians are in a unique position to counsel women of childbearing age about the potential negative consequences of marijuana use during pregnancy and breastfeeding. Discussing what is known about adverse consequences of marijuana use during pregnancy and breastfeeding at prenatal visits with either the pediatrician or the obstetric provider is an important component of promoting the best health outcomes for both the pregnant woman and the infant. Legalization of marijuana may give the false impression that marijuana is safe."); id. ("Breastfeeding has numerous valuable health benefits for the mother and the infant, particularly the preterm infant. Limited data reveal that THC does transfer into human milk, and there is no evidence for the safety or harm of marijuana use during lactation. Therefore, women also need to be counseled about what is known about the adverse effects of THC on brain development during early infancy, when brain growth and development are rapid.").
- 101. See AAP, Marijuana and Pregnancy/Breastfeeding, supra note 5, at 2 ("Mark et al demonstrated in a retrospective cohort study of urban, predominantly African American women that, of patients receiving prenatal care and delivering at their institution, 21.8% initially had positive screen results for marijuana use (by either self-report or urine toxicology), but only 1.9% had positive urine screen results for marijuana at the time of delivery. They attributed their high rate of cessation of marijuana use during pregnancy to be related to opportunities for education about adverse effects of drug use, including tobacco and marijuana, during prenatal visits.") (endnotes omitted) (citing Katrina Mark et al., Marijuana Use and Pregnancy: Prevalence, Associated Characteristics, and Birth Outcomes, 19 Archives Women's Mental Health 105 (2016)).
- 102. See supra (text accompanying notes 30–33).
- 103. *Id.* (citing 1 Co. ADC 212-3:3-1010.C.3.j (2018) (requiring every package sold to contain the following warning: "There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery.") (emphasis in original). The current regulation states that "[t]he label(s) on the Container shall not make any claims regarding health or physical benefits to the consumer." 1 Co. ADC 212-3:3-1020 (2022) (current warning requirement). Businesses, however, must have a sign warning pregnant women not to use cannabis. 1 Co. ADC 212-3:5-120(D) (2022) ("Pregnancy Warning. Medical Marijuana Stores must post, at all times and in a prominent place inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads: [¶] WARNING: Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.") (emphasis in original).
- 104. The current regulation states that "[t]he label(s) on the Container shall not make any claims regarding health or physical benefits to the consumer." 1 Co. ADC 212-3:3-1020 (2022) (current warning requirement).
- 105. See Gonzales v. Carhart, 550 U.S. 124, 157-58 (2007).
- 106. A website that identifies itself as "Cannabis Training University" located in Denver, Colorado, offers advice on "how to apply for weed jobs in Colorado[.]" Cannabis Training Univ. (undated), https://cannabistraininguniversity.com/jobs/apply-weed-jobs-colorado/ (last accessed Nov. 15, 2022). The website states that, "If you want to qualify for a marijuana job, you must... [n]ot be a licensed doctor." *Id.* (punctuation omitted).
- 107. See, e.g., Alexander v. United States, 509 U.S. 544 (1993); Fort Wayne Books, Inc. v. Indiana, 489 U.S. 46 (1989); 18 U.S.C. §§ 1963(a)(1), (2) & 3, 1963(b) (1) & (2) (2018); 720 ILL. Comp. Stat. Ann. 550/12; N.J. Stat. Ann. Ch. 6I, § 24:6i-34.c.
- 108. Fort Wayne, 489 U.S. at 60 ("It may be true that the stiffer RICO penalties will provide an additional deterrent to those who might otherwise sell obscene materials; perhaps this means—as petitioner suggests...—that some cautious booksellers will practice self-censorship and remove First Amendment protected materials from their shelves. But deterrence of the sale of obscene materials is a legitimate end of state antiobscenity laws, and our cases have long recognized the practical reality that any form of criminal obscenity statute applicable to a bookseller will induce some tendency to self-censorship and have some inhibitory effect on the dissemination of material not obscene.... The mere assertion of some possible self-censorship resulting from a statute is not enough to render an antiobscenity law unconstitutional under our precedents.").
- 109. See Alexander, 509 U.S. at 549-52; Fort Wayne, 489 U.S. at 57-60.
- 110. See Alexander, 509 U.S. at 552 ("[A] contrary [rule] would be disastrous from a policy standpoint, enabling racketeers to evade forfeiture by investing the proceeds of their crimes in businesses engaging in expressive activity.").
- 111. Fried, Ottawa Study, supra note 40, at 2165.
- 112. Am. College of Obstetricians & Gynecologists, *supra* note 15, at e205.
- 113. Am. Academy of Pediatrics, *supra* note 5, at 3.