

4-1-2018

## Marijuana Edibles and “Gummy Bears”

Paul J. Larkin Jr.

*The Heritage Foundation*

Follow this and additional works at: <https://digitalcommons.law.buffalo.edu/buffalolawreview>



Part of the [Food and Drug Law Commons](#), and the [Juvenile Law Commons](#)

---

### Recommended Citation

Paul J. Larkin Jr., *Marijuana Edibles and “Gummy Bears”*, 66 Buff. L. Rev. 313 (2018).

Available at: <https://digitalcommons.law.buffalo.edu/buffalolawreview/vol66/iss2/1>

This Article is brought to you for free and open access by the Law Journals at Digital Commons @ University at Buffalo School of Law. It has been accepted for inclusion in Buffalo Law Review by an authorized editor of Digital Commons @ University at Buffalo School of Law. For more information, please contact [lawscholar@buffalo.edu](mailto:lawscholar@buffalo.edu).

# Buffalo Law Review

---

VOLUME 66

APRIL 2018

NUMBER 2

---

## Marijuana Edibles and “Gummy Bears”

PAUL J. LARKIN, JR.†

For most of the last eighty years, state and federal law,<sup>1</sup> along with international agreements to which the United States is a signatory,<sup>2</sup> have outlawed the cultivation, distribution, and possession of marijuana, occasionally punishing such conduct quite severely.<sup>3</sup> Over the last two

---

† Senior Legal Research Fellow, The Heritage Foundation; M.P.P. George Washington University, 2010; J.D., Stanford Law School, 1980; B.A., Washington & Lee University, 1977. The views expressed in this Article are my own and should not be construed as representing any official position of The Heritage Foundation. I thank Lawrence A. Brett, Dr. Robert L. DuPont, David Evans, Calvin Fay, Ed Haislmaier, Mark A.R. Kleiman, Bertha K. Madras, John Malcolm, Kevin Sabet, Charles Stimson, and Amy Swearer for excellent comments on an earlier version of this Article. I also thank Lawrence A. Brett and Claudia Rychlik for outstanding research assistance. Any errors are mine.

1. *See, e.g.*, RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, *THE MARIJUANA CONVICTION: A HISTORY OF MARIJUANA PROHIBITION IN THE UNITED STATES* (Lindesmith Ctr. 1999) (1974).

2. *See* Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, *amended by* 1972 Protocol, Mar. 25, 1972, 26 U.S.T. 1439; Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Dec. 20, 1988, 1582 U.N.T.S. 164; ROBIN ROOM ET AL., *CANNABIS POLICY: MOVING BEYOND STALEMATE* 3, 7–8, 75–76 (2010).

3. *See* *Hutto v. Davis*, 454 U.S. 370, 371, 375 (1982) (rejecting the claim that a forty-year sentence for possessing nine ounces of marijuana with the intent to

decades, however, numerous states have revised their state constitutions or criminal codes to permit marijuana use by adults for medical or recreational purposes.<sup>4</sup> Those developments have led to a variety of novel issues that could not have arisen when marijuana was deemed contraband and was grown and sold in a *sub-rosa* manner.<sup>5</sup> The ongoing

---

distribute it was an unconstitutional cruel and unusual punishment).

4. Since 1996, twenty-nine states and the District of Columbia revised their laws to permit medicinal use of cannabis. *State Medical Marijuana Laws*, NAT'L CONF. ST. LEGISLATURES (Feb. 15, 2018), <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>. There is considerable regulatory variation among those states. *See, e.g.*, Rosalie L. Pacula et al., *Words Can Be Deceiving: A Review of Variation Among Legally Effective Medical Marijuana Laws in the United States*, 7 J. DRUG POL'Y ANALYSIS 1 (2014). The California law is so open-ended and has been so broadly applied that it was tantamount to a recreational-use law. *See* CAL. HEALTH & SAFETY CODE § 11362.5 (West 2014) (authorizing marijuana to be used for treatment of "cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief") (emphasis added); Paul J. Larkin, Jr., *Medical or Recreational Marijuana and Drugged Driving*, 52 AM. CRIM. L. REV. 453, 510–12 (2015) [hereinafter Larkin, *Drugged Driving*]; *cf.* Deepak Cyril D'Souza & Mohini Ranganathan, Editorial, *Medical Marijuana: Is the Cart Before the Horse?*, 313 JAMA 2431, 2431 (2015) (questioning why states authorize medical marijuana for diseases such as psoriasis). Beginning in 2012, eight of those states and the District of Columbia have gone further by legalizing the possession and recreational use of small amounts of marijuana. For example, in the fall of 2016 California voters passed Proposition 64, which legalized the sale, possession, and use of marijuana for recreational purposes and empowered the state to regulate that business. Vermont will join that club on July 1, 2018, when a new state law goes into effect permitting recreational marijuana use, albeit without large-scale commercialization. Magdalena Cerdá et al., *Association of State Recreational Marijuana Laws with Adolescent Marijuana Use*, 171 JAMA PEDIATRICS 142, 143 (2017); Michael R. Blood & Julie Watson, *California Issues 1st Licenses for Legal Pot Market*, U.S. NEWS & WORLD REP. (Dec. 15, 2017, 8:34 AM), <https://www.usnews.com/news/best-states/california/articles/2017-12-15/california-issues-1st-licenses-for-legal-pot-market>; Chantal Da Silva, *Vermont Becomes Ninth State to Legalize Marijuana, But Getting Pot Might Be Tricky*, NEWSWEEK (Jan. 23, 2018), <http://www.newsweek.com/vermont-becomes-ninth-state-legalize-marijuana-heres-where-buy-it-787792>.

5. For a sample of recently published scientific, professional, and popular books and papers discussing those issues (in addition to the literature cited elsewhere in this Article), see NAT'L HIGHWAY SAFETY ADMIN., U.S. DEP'T OF TRANSP., DOT HS 812 440, MARIJUANA-IMPAIRED DRIVING: A REPORT TO CONGRESS (2017); NAT'L ACAD. SCI., ENG'G, & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH (2017) [hereinafter NAT'L ACAD. REP.]; OFF. OF NAT'L DRUG CONTROL

debate over marijuana policy has generated considerable disagreement over a host of issues,<sup>6</sup> particularly over the treatment of marijuana under the state liberalization initiatives as a legitimate article of trade or medicine, even though it remains contraband under federal law.<sup>7</sup>

One point on which everyone has agreed is that marijuana should not be peddled to children.<sup>8</sup> Perhaps that

---

POLICY, MARIJUANA MYTHS AND FACTS: THE TRUTH BEHIND 10 POPULAR MISCONCEPTIONS (2014), [http://www.nationaldec.org/goopages/pages\\_download\\_gallery/download.php?filename=19411.pdf&orig\\_name=418.pdf](http://www.nationaldec.org/goopages/pages_download_gallery/download.php?filename=19411.pdf&orig_name=418.pdf); WILLIAM J. BENNETT & ROBERT A. WHITE, GOING TO POT: WHY THE RUSH TO LEGALIZE MARIJUANA IS HARMING AMERICA (2015); JONATHAN P. CAULKINS ET AL., MARIJUANA LEGALIZATION: WHAT EVERYONE NEEDS TO KNOW (2d ed. 2016) [hereinafter CAULKINS ET AL., MARIJUANA LEGALIZATION]; KEVIN A. SABET, REEFER SANITY: SEVEN GREAT MYTHS ABOUT MARIJUANA (2d ed. 2018); Laura Amato et al., *Systematic Review of Safeness and Therapeutic Efficacy of Cannabis in Patients with Multiple Sclerosis, Neuropathic Pain, and in Oncological Patients Treated with Chemotherapy*, 41 EPIDEMIOLOGY PREV. 279 (2017); Marcus A. Bachhuber et al., *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999–2010*, 174 JAMA INTERNAL MED. 1668 (2014); Alain Braillon, *Low-Risk Cannabis Use Is an Oxymoron*, 107 AM. J. PUB. HEALTH e26 (2017); June H. Kim et al., *State Medical Marijuana Laws and the Prevalence of Opioids Detected Among Fatally Injured Drivers*, 106 AM. J. PUB. HEALTH 2032 (2016); Melvin D. Livingston et al., *Recreational Cannabis Legalization and Opioid-Related Deaths in Colorado, 2000–2015*, 107 AM. J. PUB. HEALTH 1827 (2017); Andrew A. Monte et al., *The Implications of Marijuana Legalization in Colorado*, 313 JAMA 241 (2015); David L. Nathan et al., *The Physicians’ Case for Marijuana Legalization*, 107 AM. J. PUB. HEALTH 1746 (2017).

6. See, e.g., W. Hall & M. Weier, *Assessing the Public Health Impacts of Legalizing Recreational Cannabis Use in the USA*, 97 CLINICAL PHARMACOLOGY 607 (2015); Angela Hawken et al., Editorial, *Quasi-Legal Cannabis in Colorado and Washington: Local and National Implications*, 108 ADDICTION 837 (2013); Todd Subritzky et al., *Issues in the Implementation and Evolution of the Commercial Recreational Cannabis Market in Colorado*, 27 INT’L J. DRUG POL’Y 1 (2016); see generally Paul J. Larkin, Jr., *Introduction to a Debate: “Marijuana: Legalize, Decriminalize, or Leave the Status Quo in Place?”*, 23 BERKELEY J. CRIM. L. (forthcoming 2018) (summarizing the arguments on each side) [hereinafter Larkin, *Marijuana Debate*].

7. See, e.g., *Gonzales v. Raich*, 545 U.S. 1, 32–33 (2005) (upholding Congress’s Commerce Clause authority to prohibit the local cultivation and use of marijuana in compliance with state law); *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 494–95 (2001) (holding that medical necessity is not a defense under federal law to a charge of unlawfully distributing marijuana).

8. See THOMAS BABOR ET AL., DRUG POLICY AND THE PUBLIC GOOD 105 (2010) (“Preventing people from becoming illicit drug users is a broadly shared goal

is because the supporters of marijuana liberalization believe that arguing for marijuana to be treated in the same manner as alcohol—viz., lawfully sold but regulated—is an easier political sell than complete legalization. Perhaps that is because proponents of liberalization know that the political blowback from any proposal that would allow minors free access to marijuana would sink their efforts to legalize adult marijuana use. Or perhaps it is because of something else entirely. Regardless, despite the well-known adage that advocates for any principle tend to push it to the extreme limit of its logic,<sup>9</sup> no one argues today that minors should be free to use marijuana in the same manner as adults. Even states that allow marijuana to be sold to adults for recreational purposes deny minors that privilege.<sup>10</sup>

The problem arises of how to police that judgment with respect to a variety of different commercial food products, colloquially known as “edibles.” They are designed to be eaten and often resemble food products that anyone, including minors, would consume. Edibles allow individuals to obtain the psychoactive benefits of using marijuana

---

among policymakers. When focused on young people, prevention programmes enjoy broad popular support as well.”); *e.g.*, COLO. CONST. art. XVIII, § 16(1)(a), (2)(b), (3), (4) (creating a state constitutional right for only adults to use marijuana for recreational purposes); COLO. REV. STAT. § 18-18-406 (2017); 1 COLO. CODE REGS. § 212-2.402(A) (2017) (“Licensees are prohibited from transferring, giving, or distributing Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product to persons under 21 years of age.”); WASH. REV. CODE § 69.50.360(3) (2017); WASH ADMIN. CODE § 314-55-095(1) (2017). Medical and recreational uses of marijuana raise distinct concerns. *See, e.g.*, COLO. CONST. art. XVIII, § 16(7) (stating that recreational marijuana amendment does not limit the rights of a medical marijuana patient); *id.* art. XVIII, § 14(6) (creating special rules for medical marijuana use by minors). No state that has permitted marijuana to be used recreationally—Alaska, California, Colorado, Maine, Massachusetts, Nevada, Oregon, Vermont, and Washington (along with the District of Columbia)—permits cannabis to be distributed to minors for recreational use. *See* Robert J. MacCoun & Michelle M. Mello, *Half-Baked—The Retail Promotion of Marijuana Edibles*, 372 N. ENG. J. MED. 989, 989–90 (2015).

9. *See* *Hein v. Freedom from Religion Found.*, 551 U.S. 587, 615 (2007) (lead opinion).

10. Cerdá et al., *supra* note 4, at 143.

without inhaling carcinogens.<sup>11</sup> Edibles have two other attractive features as well: they can contain a heavy dose of sugar, making them enticing for people with a sweet tooth, and they avoid the tell-tale aroma of smoked marijuana, making them attractive for minors trying to avoid detection by their parents.

Selling edibles poses the risk that children will find and mistakenly consume a product that injures them and that adolescents will find and intentionally consume the same product. How do we prevent those results? Who should make that decision—the local, state, or federal governments? Will the method selected to prevent those harms infringe on the ability of adults to purchase the same delivery mechanism? If so, does that matter?

This Article will discuss one of those issues: namely, whether the Food and Drug Administration (FDA) should intervene and regulate the sale of edible forms of marijuana to prevent the risk that children who happen upon their parents' "stash" will unwittingly consume it, believing that it is a traditional form of candy, or that adolescents will knowingly consume it, hoping for its psychoactive effects. Part I will discuss the retail distribution of marijuana in edible forms. Part II will identify the potential harms that minors can suffer from the consumption of marijuana, regardless of its form. It also explains the particular harms that can result from distributing food containing cannabinoids, the psychoactive ingredients in marijuana,

---

11. See, e.g., ROBERT L. DUPONT, *THE SELFISH BRAIN: LEARNING FROM ADDICTION* 156 (1997) ("Marijuana smoke contains more tar and cancer-causing chemicals than even cigarette smoke. One marijuana cigarette has as much cancer-causing tar as 17 tobacco cigarettes. Marijuana smoke, like tobacco smoke, causes bronchitis, inflammation of the airways in the lungs, and chronic respiratory illnesses."); GEORGE F. KOOB ET AL., *DRUGS, ADDICTION, AND THE BRAIN* 306 (2014) ("Marijuana smoke may also have the same potential toxicity as cigarette smoke with regard to lung function."); Daniel G. Barrus et al., *Tasty THC: Promises and Challenges of Cannabis Edibles*, RTI PRESS 2, 4 (Nov. 2016) (stating that anecdotal consumer reports attribute interest in edibles to the ability to use them discretely, their more relaxing state of intoxication they provide, and the ability to avoid toxins and health risks).

principally one known by the acronym THC.<sup>12</sup> Part III then discusses the options available to the local, state, and federal governments, particularly to the U.S. Food and Drug Administration, to prevent minors from suffering those harms by prohibiting the distribution of marijuana edibles that could be mistaken for candy or some other treat that a minor could eat.

### I. THE DISTRIBUTION OF MARIJUANA IN EDIBLE FORM

Legalization initiatives have led to the sale of marijuana by private parties from brick-and-mortar buildings called “dispensaries” when marijuana is sold for medical use.<sup>13</sup> Those businesses sell marijuana in the traditional dried plant form of leaves and flowers that can be smoked in cigarettes, cigars, pipes, water pipes, and “blunts” (marijuana wrapped in tobacco leaves), or, using today’s new technology, vaporized and inhaled (or, to use the vernacular, “vaped”). The psychoactive component of marijuana, THC, also comes in the form of oil or concentrates. Another popular medium is commercial food products, known as “edibles.”

Food is rarely used as the delivery system for drugs,

---

12. DU PONT, *supra* note 11, at 154–55; LESLIE L. IVERSEN, *THE SCIENCE OF MARIJUANA* 35 (2d ed. 2008); Harold Kalant, *Effects of Cannabis and Cannabinoids in the Human Nervous System*, in *THE EFFECTS OF DRUG ABUSE ON THE HUMAN NERVOUS SYSTEM* 387, 387 (Bertha Madras & Michael Kuhar eds., 2014). The technical name for THC is  $\Delta^9$ -tetrahydrocannabinol. The chemical structure of THC closely resembles that of anandamide, an endogenously produced cannabinoid, named after the Sanskrit term “ananda,” which means “bliss.” See Bertha Madras, *Drug Use and Its Consequences*, in *THE EFFECTS OF DRUG ABUSE ON THE HUMAN NERVOUS SYSTEM*, *supra*, at 11; Maximilian Peters & Raphael Mechoulam, *The Endocannabinoid System*, in *2 PROFESSIONAL PERSPECTIVES ON ADDICTION MEDICINE* 31, 34–36 (Mark Sanford & Donald Avoy eds., 2009).

13. As of September 2015, there were 385 licensed retail stores, 496 licensed marijuana cultivators, and 141 licensed infused product manufacturers in Colorado. Subritzky et al., *supra* note 6, at 1. One Arizona business has a drive-thru. Marcella Baietto, *Arizona’s First Medical Marijuana Drive-Thru Now Open*, AZ CENTRAL (Oct. 28, 2017), <https://www.azcentral.com/story/news/nation-now/2017/10/28/arizonas-first-medical-marijuana-drive-thru-now-open/809611001/>.

including controlled substances.<sup>14</sup> Edibles, however, serve in that role. Those foods come in different forms, such as cookies, candies, cakes, popcorn products, lozenges, chocolates, butter, popsicles, and liquids,<sup>15</sup> as well as the Alice B. Toklas brownies made popular in the 1960s.<sup>16</sup> As one observer noted, “[e]ssentially, a cannabis culinary professional can infuse just about anything you want to eat with THC . . . .”<sup>17</sup>

Edibles, it seems, are quite popular among marijuana’s consumers.<sup>18</sup> One estimate is that between eleven and twenty-six percent of people who have used marijuana

---

14. Buprenorphine (a drug that avoids the psychoactive effects of opiates and the discomfort of withdrawal) and naloxone (an opiate antagonist) are delivered in sublingual strips, nicotine and aspirin are delivered in gum, and a few other drugs come in a similar form. George S. Wang et al., *Association of Unintentional Pediatric Exposures with Decriminalization of Marijuana in the United States*, 63 ANNALS OF EMERGENCY MED. 684, 688 (2014) [hereinafter Wang et al., *Multistate Study 2005–2011*]. No FDA-approved medication is smoked. Herbert D. Kleber & Robert L. DuPont, *Physicians and Medical Marijuana*, 169 AM. J. PSYCHIATRY 564, 564 (2012).

15. See, e.g., 1 COLO. CODE REGS. § 212-2.103 (2017) (“‘Edible Retail Marijuana Product’ means any Retail Marijuana Product for which the intended use is oral consumption, including but not limited to, any type of food, drink, or pill.”); JOHN HUDAK, MARIJUANA: A SHORT HISTORY 17–18 (2016) (noting that edibles come in “countless forms including cookies, brownies, candies, granola, salad dressing, and even pasta sauce.”); Katherine M. Kosa et al., *Consumer Use and Understanding of Labeling of Information on Edible Marijuana Products Sold for Recreational Use in the States of Colorado and Washington*, 43 INT’L J. DRUG POL’Y 57, 57 (2017); MacCoun & Mello, *supra* note 8, at 989–90; George Sam Wang et al., *Unintentional Pediatric Exposures to Marijuana in Colorado, 2009–2015*, 170 JAMA PEDIATRICS 1, 2 (2016) [hereinafter Wang et al., *Colorado Study 2009–2015*]; Jennifer Maloney & David-George-Cosh, *Big Brewer Makes a Play for Marijuana Beverages*, WALL ST. J. (Oct. 27, 2017), <https://www.wsj.com/articles/big-brewer-makes-a-play-for-marijuana-beverages-1509300002?mod=ktw&mg=prod/accounts-wsj>.

16. Inspired by I LOVE YOU, ALICE B. TOKLAS (Warner Bros.-Seven Arts 1968). Toklas was a real-life writer whose cookbook had a recipe for marijuana brownies.

17. HUDAK, *supra* note 15, at 20; *id.* at 18 (“The variety now available is a real testament to American entrepreneurship and innovation.”).

18. A 2015 estimate was that sixteen to twenty-six percent of patients using medical cannabis consume edible products. Ryan Vandrey, et al., *Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products*, 313 JAMA 2491, 2491 (2015).



medicinally have consumed edibles.<sup>19</sup> Approximately five million units of edible products were sold in Colorado in 2014, the first year of recreational marijuana sales; one company alone produced 40,000 THC-infused candy bars per month.<sup>20</sup> All told, edibles constituted forty-five percent of the \$573 million in revenue generated by legal cannabis sales in Colorado and forty percent—more than 570,000 units—of marijuana sales in Washington.<sup>21</sup>

The pharmacokinetics—the action of the body on a drug, *viz.*, metabolism, distribution, and elimination—of inhalation and ingestion differ materially from each other. Inhaling marijuana quickly distributes THC to the brain by entering the circulatory system in the lungs, providing the user with the hoped-for psychoactive effect without delay. By contrast, ingesting marijuana through an edible takes far longer to achieve that effect because the food must be digested and pass through the liver, which metabolizes much of the THC, before it becomes available to the brain.<sup>22</sup> As a result, someone unfamiliar with the pharmacokinetics of marijuana, such as a minor or first-time user, or someone who travels to a state with liberal marijuana laws for the purpose of trying out cannabis, a so-called “marijuana tourist,” might overconsume the amount of THC-laced food necessary to receive the effect and, instead, wind up with a very unpleasant experience and a trip to the emergency

---

19. Barrus et al., *supra* note 11, at 2.

20. *Id.*; Kosa et al., *supra* note 15, at 57; Subritzky et al., *supra* note 6, at 3; see also Jane A. Allen et al., *New Product Trial, Use of Edibles, and Unexpected Highs Among Marijuana and Hashish Users in Colorado*, 176 *DRUG & ALCOHOL DEPENDENCE* 44, 46 (2017) (noting that in Colorado in 2014, more than seventy percent of a sample of past-year marijuana and hashish users tried a new product and half of them consumed an edible).

21. Barrus et al., *supra* note 11, at 2; Kosa et al., *supra* note 15, at 57; Wang et al., *Colorado Study 2009–2015*, *supra* note 15, at 2.

22. IVERSEN, *supra* note 12, at 41–47, 129; Barrus et al., *supra* note 11, at 3–5; NAT'L INST. ON DRUG ABUSE, *MARIJUANA* 2–3 (Aug. 2017) [hereinafter NAT'L INST., *MARIJUANA*].

room.<sup>23</sup>

Inhaled and edible versions of marijuana have another important difference, too. Businesses have developed edibles that resemble the traditional candies attractive to children. Some edibles resemble “Gummy Bears,” while others have been labeled as “Pot Tarts,” “Buddahfinger,” “Munchy Way,” or Keef Kat.”<sup>24</sup> That clever—perhaps too clever—marketing strategy raises a serious medical and public policy issue because THC produces harmful effects in minors that do not occur in adults due to the materially different stages of neurological development for the two groups. This presents state and federal governments with a legal problem that did

---

23. MacCoun & Mello, *supra* note 8, at 989–90. That may be what happened to Maureen Dowd when she ate a THC-laced candy bar in Colorado. Maureen Dowd, *Don't Harsh Our Mellow, Dude*, N.Y. TIMES (June 3, 2014), <https://www.nytimes.com/2014/06/04/opinion/dowd-dont-harsh-our-mellow-dude.html>; *see also* HUDAK, *supra* note 15, at 17 (discussing what has been called the “Maureen Dowd Effect”); Allen et al., *supra* note 20, at 46; Barrus et al., *supra* note 11, at 5 (noting that 65 percent of edible users have an adverse experience and that “[t]he lack of consistency and the delayed intoxication may cause both new and experienced users of cannabis to consume higher than intended amounts of the drug. Edible products are responsible for the majority of health care visits due to cannabis intoxication, which is likely due to the failure of users to appreciate the delayed effects.”).

24. *See* Barrus et al., *supra* note 11, at 6; MacCoun & Mello, *supra* note 8, at 990; Jack Healy, *New Scrutiny on Sweets with Ascent of Marijuana*, N.Y. TIMES, Oct. 30, 2014, at A13. The same fundamental mistake—marketing marijuana products to minors—sank reform efforts in the 1970s. *See* EMILY DUFTON, GRASS ROOTS: THE RISE AND FALL AND RISE OF MARIJUANA IN AMERICA 75 (2017) (“the movement’s peak [in the 1970s] also brought with it the movement’s downfall. Much of the new paraphernalia for sale deliberately riffed on children’s toys, as smokers were offered everything from pot-themed Frisbees and board games to Christmas stockings. Even more troubling, children were quickly becoming the targets of paraphernalia marketing themselves. By 1978, newspapers were reporting that kids had easy access to head shops and were able to purchase pipes, papers, and bongs with no questions asked. The paraphernalia market that sprang up in the wake of decriminalization developed too quickly for government oversight and, with its interest in profits and giving the growing smoking population what it desired, it also chose not to regulate itself. In doing so, it set itself up for its own demise when a new generation of marijuana activists—parents angry at the rising rate of adolescent pot use—emerged in the wake of the paraphernalia boom. Once they made their power felt, it would be decades before decriminalization was spoken of positively in Washington again.”).

not occur before the state legalization efforts began: what to do about the open-and-obvious public commercial distribution of food containing an illegal substance that poses unique harms for minors.

## II. THE PROBLEM OF MARIJUANA USE BY MINORS

Advocates for the liberalization of the marijuana laws argue that, because marijuana is no more harmful than alcohol, the government should treat the two drugs alike, allowing cannabis to be regulated and sold. Treating marijuana like alcohol during Prohibition not only deprives people of its benefits in the medicinal treatment of conditions like chemotherapy-induced nausea, epilepsy-induced seizures, and multiple sclerosis spasticity, but also leads to considerable social harms.<sup>25</sup> A better approach, supporters

---

25. The most commonly cited therapeutic uses of cannabinoids are for the treatment of chemotherapy-induced nausea and emesis, AIDS-induced anorexia and cachexia (HIV/AIDS wasting), and the neuropathic pain and spasticity caused by multiple sclerosis. *See, e.g.*, BRITISH MED'L ASS'N, THERAPEUTIC USES OF CANNABIS 21–49 (1997); NAT'L ACAD. REP., *supra* note 5, at 53–54 (listing conditions for which marijuana is a treatment for which there are varying degrees of scientific support); HUDAK, *supra* note 15, at 15, 22 (noting that cannabidiol, an ingredient of cannabis ingredient, has anticonvulsive and anti-inflammatory properties); JERROLD S. MEYER & LINDA F. QUENZER, PSYCHOPHARMACOLOGY: DRUGS, THE BRAIN, AND BEHAVIOR 410–11 (2d ed. 2018); Alan J. Budney et al., *Cannabis*, in LOWINSON AND RUIZ'S SUBSTANCE ABUSE: A COMPREHENSIVE TEXTBOOK 233 (Pedro Ruiz & Eric Strain eds., 5th ed. 2011); *see also* Marcus A. Bachhuber et al., *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999–2010*, 174 JAMA INTERNAL MED. 1668 (2014) (reporting that there were fewer opioid overdoses in states with medical marijuana laws); Wayne Hall & Louisa Degenhardt, *Adverse Health Effects of Non-Medical Cannabis Use*, 374 LANCET 1383, 1389 (2009) (“The public health burden of cannabis use is probably modest compared with that of alcohol, tobacco, and other illicit drugs.”); 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.”); Philip McGuire et al., *Cannabidiol (CBD) as an Adjunctive Therapy in Schizophrenia: A Multicenter Randomized Controlled Trial*, 175 AM. J. PSYCHIATRY 225 (2018); Madeline H. Meier et al., *Associations between Cannabis Use and Physical Health Problems in Early Midlife: A Longitudinal Comparison of Persistent Cannabis versus Tobacco Users*, 73 JAMA PSYCHIATRY 731 (2016); Theresa H.M. Moore et al., *Cannabis Use and Risk of Psychotic or Affective Mental Health Outcomes: A Systematic Review*, 370 LANCET 319 (2007);

argue, is to legalize and regulate the growth and distribution of marijuana and its products.<sup>26</sup> That regulation would exclude minors from recreational use.<sup>27</sup>

Opponents fundamentally disagree with liberalization's supporters over the relative safety of marijuana. They argue that, at bottom, marijuana is a harmful substance. As Dr. Nora Volkow, Director of the National Institute on Drug

---

Penny F. Whiting et al., *Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis*, 313 J. AM. MED'L ASS'N 2456, 2467 (2015); see generally CAULKINS ET AL., MARIJUANA LEGALIZATION, *supra* note 5, at 67–68, 88–89, 131–57 (collecting arguments and authorities). In that regard, supporters contend that smoking marijuana provides benefits not offered by other THC delivery vehicles (e.g., pills, inhalants, and suppositories) approved by the U.S. Food and Drug Administration (e.g., Dronabinol) or other nations (e.g., Nabiximol), because inhalation works more effectively and more quickly, reaching the brain within seconds. See, e.g., NAT'L ACAD. REP., *supra* note 5, at 54; IVERSEN, *supra* note 12, at 41–47; Sunil K. Aggarwal et al., *Medicinal Use of Cannabis in the United States: Historical Perspectives, Current Trends, and Future Directions*, 5 J. OPIOID MGMT. 153, 163–64 (2009); see generally Larkin, *Marijuana Debate*, *supra* note 6 (manuscript at 2–4, nn.9–21) (summarizing arguments and collecting authorities). The World Health Organization (WHO) Expert Committee on Drug Dependence (ECDD) recently recommended examining the proper classification “[p]reparations containing almost exclusively CBD” because they are not likely to be addictive and can be used for medical purposes, such as calming spasms during epileptic fits. See WORLD HEALTH ORGAN., CANNABIDIOL (COMPOUND OF CANNABIS): ONLINE Q&A (Dec. 2017), <http://www.who.int/features/qa/cannabidiol/en/>; ESSENTIAL MEDICINES AND HEALTH PRODUCTS, WHO RECOMMENDS THE MOST STRINGENT LEVEL OF INTERNATIONAL CONTROL FOR SYNTHETIC OPIOID CARFENTANIL (DEC. 2017), <http://www.who.int/medicines/news/2017/WHO-recommends-most-stringent-level-int-control/en/> (“Recent evidence from animal and human studies shows that [cannabidiol’s] use could have some therapeutic value for seizures due to epilepsy and related conditions. Current evidence also shows that cannabidiol is not likely to be abused or create dependence as for other cannabinoids (such as [THC], for instance). The ECDD therefore concluded that current information does not justify scheduling of cannabidiol and postponed a fuller review of cannabidiol preparations to May 2018, when the committee will undertake a comprehensive review of cannabis and cannabis related substances.”); Letter from Dr. Tedros Ahhanom Ghebreyesus, Director-General, WHO, to Antonio Guterres, Secretary-General of the United Nations (Nov. 27, 2017) (noting that the WHO ECDD recommended a later “critical review” of “[p]reparations containing almost exclusively cannabidiol (CBD)” (emphasis omitted)); *id.* Annex 1, at 7.

26. See, e.g., CAULKINS ET AL., MARIJUANA LEGALIZATION, *supra* note 5, at 131–57.

27. See *id.* at 131.

Abuse, once wrote, “[m]arijuana is not a benign drug. It is illegal and has significant adverse health effects and consequences associated with its use.”<sup>28</sup> Opponents maintain that marijuana use can be harmful to adults,<sup>29</sup> but can cause

---

28. Nora D. Volkow, *Marijuana and Medicine: The Need for a Science-Based Approach*, in Sanford & Avoy, *supra* note 12, at 23, 28; see also NAT'L INST., MARIJUANA, *supra* note 22, at 14 (endnote omitted) (“Marijuana use can lead to the development of problem use, known as a marijuana use disorder, which takes the form of addiction in severe cases. Recent data suggest that 30 percent of those who use marijuana may have some degree of marijuana use disorder.”); NAT'L INST., MARIJUANA, *supra*, at 3 (“[C]ontrary to popular belief, marijuana can be addictive, and its use during adolescence may make other forms of problem use or addiction more likely.”); WAYNE HALL & ROSALIE LICCARDO PACULA, CANNABIS USE AND DEPENDENCE: PUBLIC HEALTH AND PUBLIC POLICY (2003) (“A cannabis dependence syndrome occurs in heavy chronic users of cannabis. Regular cannabis users develop tolerance to THC, some experience withdrawal symptoms on cessation of use, and some report problems controlling their cannabis use. The risk of dependence is about one in ten among those who ever use the drug, between one in five and one in three among those who use cannabis more than a few times, and around one in two among daily users.”); David A. Gorelick et al., *Diagnostic Criteria for Cannabis Withdrawal Syndrome*, 123 DRUG & ALCOHOL DEPENDENCE 141 (2012); Deborah S. Hasin et al., *Prevalence of Marijuana Use Disorders in the United States Between 2001–2002 and 2012–2013*, 72 JAMA PSYCHIATRY 1235 (2015); Sheryl Ryan & Seth D. Ammerman, *Counseling Parents and Teens About Marijuana Use in the Era of Legalization of Marijuana*, 139 PEDIATRICS E2 (2017) [hereinafter Ryan & Ammerman, *Counseling Parents and Teens*]. As if to make a bad situation worse, according to a 2015 publication by the Centers for Disease Control and Prevention, individuals who are addicted to marijuana are three times as likely to become addicted to heroin. See *Today's Heroin Epidemic Infographics*, CTRS. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vitalsigns/heroin/infographic.html> (last updated July 7, 2015).

29. See, e.g., U.S. DEP'T HEALTH & HUM. SERVS., FACING ADDICTION IN AMERICA: THE SURGEON GENERAL'S REPORT ON ALCOHOL, DRUGS, AND HEALTH 65 (Nov. 2016); WORLD HEALTH ORG., THE HEALTH AND SOCIAL EFFECTS OF NONMEDICAL CANNABIS USE 15 (2016) [hereinafter WHO REPORT] (“The daily use of cannabis over years and decades appears to produce persistent impairments in memory and cognition, especially when cannabis use begins in adolescence . . . .”); AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 509–16 (5th ed. 2013) [hereinafter DSM-5] (discussing “Cannabis Use Disorder”); HALL & PACULA, *supra* note 28; MEYER & QUENZER, *supra* note 25, at 416 (“Heavy cannabis use for a long period of time may lead to impaired executive functioning for at least 2 to 3 weeks following cessation of use. . . . However, some of the data suggest that heavy, long-time users may continue to show impairment in decision making, planning, and concept formation.”); *id.* at 420 (ten percent of marijuana users become dependent, while fifty percent of daily users do so); *id.* at 422–25 (discussing potential adverse

---

psychological, neuropsychiatric, and physiological effects from long-term use); *id.* at 424–25 (discussing potential psychosis-causing effect of early-onset, long-term use); ROOM ET AL., *supra* note 2, at 25 (“The risk of dependence is about 9% among persons who have ever used cannabis . . . and about one in six for young people who initiate in adolescence,” although the risk of dependence is greater for nicotine, alcohol, stimulants, cocaine, and heroin); *id.* at 27 (“There are good reasons for believing that cannabis can cause cancers of the lung and aerodigestive tract . . .”); *id.* at 43–44 (summarizing potential harms); Budney et al., in Ruiz & Strain, *supra* note 25, at 214 (“Clearly cannabis misuse and addiction are real and relatively common phenomenon that pose a significant public health issue . . .”); *id.* at 227–28 (“Whether or not cannabis use can induce acute psychosis or contribute to the development of more chronic psychotic disorders (e.g., schizophrenia) also remains controversial, although data supporting such a causal relationship are emerging. . . . Estimates of attributable risk suggest that cannabis may play a role in approximately 1 of 10 cases.”) (endnote omitted); Madras, *supra* note 12, at 16–17, 19–25; Kalant, *supra* note 12, at 387–412; Bertha Madras, *Introduction*, in CELL BIOLOGY OF ADDICTION 1, 8 (Bertha Madras et al. eds., 2006); Peter Allebeck, *Psychopathological Manifestations of Cannabis Use*, in DRUG ABUSE IN THE DECADE OF THE BRAIN 159–65 (Gabriel G. Nahas & Thomas F. Burks eds., 1997); Rabi Abouk & Scott Adams, *Examining the Relationship between Medical Cannabis Laws and Cardiovascular Deaths in the US*, 53 INT’L J. DRUG POL’Y 1, 5 (2018) (“Our study finds evidence suggesting that MCL [*viz.*, medical cannabis legalization] was followed by increased cardiac mortality in states passing such laws compared with those that did not. This effect was concentrated among older individuals, particularly males, and states where there are less restrictions on dispensaries and cardholders.”); Louise Arseneault et al., *Causal Association Between Cannabis and Psychosis: Examination of the Evidence*, 184 BRIT. J. PSYCHIATRY 110, 113 (2004); Amber L. Bahorik et al., *Adverse Impact of Marijuana Use on Clinical Outcomes Among Psychiatry Patients with Depression and Alcohol Use Disorder*, 259 PSYCHIATRY RES. 316, 320–21 (2017); Wilson M. Compton et al., *Marijuana Use and Use Disorder in Adults in the USA, 2002–2014: Analysis of Annual Cross-Sectional Surveys*, 3 LANCET PSYCHIATRY 954, 961 (2016); Marta Di Forti et al., *Proportion of Patients in South London with First-Episode Psychosis Attributable to Use of High Potency Cannabis: A Case-Control Study*, 2 LANCET PSYCHIATRY 233, 236 (2015) (“People who used cannabis or skunk every day were both roughly three times more likely to have a diagnosis of a psychotic disorder than were those who never used cannabis . . .”); Herman Friedman, *Neuroimmunology and Marijuana*, in DRUG ABUSE IN THE DECADE OF THE BRAIN, *supra* note 29, at 145–51; Wayne Hall, *What Has Research over the Past Two Decades Revealed about the Adverse Health Effects of Recreational Cannabis Use?*, 110 ADDICTION 19, 29–30 (2015); Hall & Degenhardt, *supra* note 25; Hannah J. Jones et al., *Association of Combined Patterns of Tobacco and Cannabis Use in Adolescence with Psychotic Experiences*, 75 JAMA PSYCHIATRY 240 (2018); Peter Manza et al., *Subcortical Local Functional Hyperconnectivity in Cannabis Dependence*, 3 BIOLOGICAL PSYCHIATRY: CNNI 285 (2017); Mark Olfson et al., *Cannabis Use and Risk of Prescription Opioid Use Disorder in the United States*, 175 AM. J. PSYCHIATRY 47, 49–50 (2018); Nadia Solowij et al., *Differential Impairments of Selective Attention due to Frequency and Duration of*

even greater injury to minors, especially if it leads to heavy or long-term use.<sup>30</sup> Several respected government and

---

*Cannabis Use*, 37 *BIOLOGICAL PSYCHIATRY* 731, 737 (1995); Marie Stefanie Kejser Starzer et al., *Rates and Predictors of Conversion to Schizophrenia or Bipolar Disorder Following Substance-Induced Psychosis*, 175 *AM. J. PSYCHIATRY* 345 (2017) (“We found that 32.2% of patients with a substance-induced psychosis later converted to either bipolar disorder or schizophrenia. The highest conversion rate (47.4%) was found for cannabis-induced psychosis. Young age was associated with a higher risk of conversion to schizophrenia; the risk was highest for those in the range of 16–25 years. Self-harm after a substance-induced psychosis was significantly linked to a higher risk of converting to both schizophrenia and bipolar disorder.”); Nora D. Volkow et al., *Adverse Health Effects of Marijuana Use*, 370 *NEW ENG. J. MED.* 2219, 2220 (2014). An additional type of harm can result from attempts to extract THC from marijuana in home laboratories. See Monte et al., *supra* note 5, at 241–42 (“The University of Colorado burn center has experienced a substantial increase in the number of marijuana-related burns. In the past 2 years, the burn center has had 31 admissions for marijuana-related burns; some cases involve more than 70% of body surface area and 21 required skin grafting. The majority of these were flash burns that occurred during THC extraction from marijuana plants using butane as a solvent.”).

30. See WHO REPORT, *supra* note 29, at 16 (“Accumulating evidence reveals that regular, heavy cannabis use during adolescence is associated with more severe and persistent negative outcomes than use during adulthood.”); KOOB ET AL., *supra* note 11, at 269, 279–87 (2014); ROOM ET AL., *supra* note 2, at 31–39 (describing studies investigating the risk that adolescent marijuana use could adversely affect learning, result in a greater drop-out rate, be a prelude to other drug use, or lead to schizophrenia or depression); Madras, *supra* note 12, at 14–15; Hall, *supra* note 29, at 24–26; Volkow, *supra* note 29, at 2220 (noting that negative effects in brain development, educational outcome, cognitive impairment, and life satisfaction are “strongly associated with initial marijuana use early in adolescence”); see also Manzar Ashtari et al., *Diffusion Abnormalities in Adolescents and Young Adults with a History of Heavy Cannabis Use*, 43 *J. PSYCHIATRIC RES.* 189, 201–02 (2009); Carlos Blanco et al., *Cannabis Use and Incidence of Psychiatric Disorders: Prospective Evidence from a US National Longitudinal Study*, 73 *JAMA PSYCHIATRY* 388 (2016); Matthijs G. Bossong & Raymond J.M. Niesink, *Adolescent Brain Maturation, the Endogenous Cannabinoid System and the Neurobiology of Cannabis-Induced Schizophrenia*, 92 *PROGRESS NEUROBIOLOGY* 370 (2010); J. S. Brook et al., *Early Adolescent Marijuana Use: Risks for the Transition to Young Adulthood*, 32 *PSYCHOL. MED.* 79 (2002); R. Andrew Chambers et al., *Developmental Neurocircuitry on Motivation in Adolescence: A Critical Period of Addiction Vulnerability*, 160 *AM. J. PSYCHIATRY* 1041 (2003); Michael D. De Bellis et al., *Neural Mechanisms of Risky Decision-Making and Reward Response in Adolescent Onset Cannabis Use Disorder*, 133 *DRUG & ALCOHOL DEPENDENCE* 134 (2013); Donald M. Dougherty et al., *Impulsivity, Attention, Memory, and Decision-Making Among Adolescent Marijuana Users*, 226 *PSYCHOPHARMACOLOGY* 307 (2013); David M. Fergusson & Joseph M. Bolden, *Cannabis Use and Later Life Outcomes*, 103 *ADDICTION* 969,

private organizations—the American Medical Association, the American Psychiatric Association, the American Academy of Pediatrics, the American Cancer Society, the

---

969 (2008); D. M. Fergusson et al., *Cannabis Dependence and Psychotic Symptoms in Young People*, 33 PSYCHOL. MED. 15, 20 (2003); Charles B. Fleming et al., *Examination of the Divergence in Trends for Adolescent Marijuana Use and Marijuana-Specific Risk Factors in Washington State*, 59 J. ADOLESCENT HEALTH 269, 269–70 (2016); Jodi M. Gilman et al., *Cannabis Use Is Quantitatively Associated with Nucleus Accumbens and Amygdala Abnormalities in Young Adult Recreational Users*, 34 J. NEUROSCIENCE 5529, 5537 (2014); Hall, *supra* note 11, at 24–26; Kim Kiser, *Rocky Mountain Reality*, MINN. MED., Apr. 2014, at 12, 12 (interview with Jan Kief, M.D.) (“Seventy-four percent of teens in the Denver area who are in treatment said they used someone else’s medical marijuana on average 50 times.”); Dan I. Lubman et al., *Cannabis and Adolescent Brain Development*, 148 PHARMACOLOGY & THERAPEUTICS 1, 10 (2015); Michael Lynskey & Wayne Hall, *The Effects of Adolescent Cannabis Use on Educational Attainment: A Review*, 95 ADDICTION 1621 (2000); Madeline H. Meier, et al., *Persistent Cannabis Users Show Neuropsychological Decline from Childhood to Midlife*, 109 PROC. NAT’L ACAD. SCI. E2657 (2012); Bridget Onders et al., *Marijuana Exposure Among Children Younger than Six Years in the United States*, 55 CLINICAL PEDIATRICS 428 (2016); Edmund Silins et al., *Young Adult Sequelae of Adolescent Cannabis Use: An Integrative Analysis*, 1 LANCET PSYCHIATRY 286 (2014); Nadia Solowij et al., *Verbal Learning and Memory in Adolescent Cannabis Users, Alcohol Users and Non-Users*, 216 PSYCHOPHARMACOLOGY 131 (2011); Joan E. Zweben & Judith Martin, *Physician Recommendations for Marijuana: Special Populations and Contraindications*, in Sanford & Avoy, *supra* note 12, at 91, 94; Valérie Wolff et al., *Cannabis Use, Ischemic Stroke, and Multifocal Intracranial Vasoconstriction: A Prospective Study in 48 Consecutive Young Patients*, 42 STROKE 1778 (2011); *see generally* Volkow, *supra* note 28, at 2219 (“The regular use of marijuana during adolescence is of particular concern, since use by this age group is associated with an increased likelihood of deleterious consequences . . .” (footnote and citation omitted); *id.* at 2220 (noting that “[a]ltered brain development,” “[p]oor educational outcome,” “cognitive impairment,” and “[d]iminished life satisfaction” are “strongly associated with initial marijuana use early in adolescence”). Recently, an eleven-month old infant died from what physicians surmised (because no other cause was found) was marijuana-induced myocarditis (inflammation of the heart muscle). *See* Thomas M. Nappe & Christopher O. Hoyte, *Pediatric Death Due to Myocarditis After Exposure to Cannabis*, 1 CLINICAL PRAC. & CASES EMERGENCY MED. 166 (2017); *see also* Andrew Blake, *Marijuana Overdose Killed 11-Month-Old Infant, Doctors Claim*, WASH. TIMES (Nov. 16, 2017), <https://www.washingtontimes.com/news/2017/nov/16/marijuana-overdose-killed-11-month-old-infant-doct/>; Ellie Silverman, *The Truth Behind the ‘First Marijuana Overdose Death’ Headlines*, WASH. POST (Nov. 17, 2017), [https://www.washingtonpost.com/news/to-your-health/wp/2017/11/17/the-truth-behind-the-first-marijuana-overdose-death/?hpid=hp\\_hp-more-top-stories\\_marijuana-death-555am%3Ahomepage%2Fstory&utm\\_term=.0a10a86cd9db](https://www.washingtonpost.com/news/to-your-health/wp/2017/11/17/the-truth-behind-the-first-marijuana-overdose-death/?hpid=hp_hp-more-top-stories_marijuana-death-555am%3Ahomepage%2Fstory&utm_term=.0a10a86cd9db).



American Academy of Ophthalmology, the National Institute for Drug Abuse, and others—have noted those harms and agree that minors should not use cannabis.<sup>31</sup>

Of particular concern in the case of minors is the neurophysiological effect that THC has on the juvenile brain. According to one textbook, “[g]rowing evidence suggests that marijuana use during adolescence affects normal physiological maturation processes in the frontal cortex.”<sup>32</sup> Those adverse effects could be a contributory factor to future problems with executive functioning and impulse control, including substance use disorders.<sup>33</sup>

---

31. See, e.g., U.S. FOOD & DRUG ADMIN., FDA AND MARIJUANA (Feb. 28, 2017) (“The FDA has not approved marijuana as a safe and effective drug for any indication.”); NAT’L INST., MARIJUANA, *supra* note 22, at 17; AM. ACAD. OPHTHALMOLOGY, COMPLEMENTARY THERAPY ASSESSMENT: MARIJUANA IN THE TREATMENT OF GLAUCOMA 1 (2014); AM. CANCER SOC’Y, MEDICAL USE OF MARIJUANA: ACS POSITION 3 (2013); AM. MED. ASS’N HOUSE OF DELEGATES, REPORT OF REFERENCE COMMITTEE K 6–7 (2014); AM. PSYCHIATRIC ASS’N, POSITION STATEMENT ON MARIJUANA AS MEDICINE (Dec. 2013); HALL & PACULA, *supra* note 28, at 214–17 (discussing adverse effects to cells and to immunological, reproductive, cardiovascular, respiratory, and gastrointestinal systems, as well as the risk of precipitating psychosis in vulnerable individuals); Ryan & Ammerman, *Counseling Parents and Teens*, *supra* note 28, at e2; Volkow et al., *supra* note 28; cf. AM. EPILEPSY SOC’Y, AES POSITION ON MEDICAL MARIJUANA (Mar. 21, 2016) (“The anecdotal reports of positive effects of the marijuana derivative cannabidiol (CBD) for some individuals with treatment-resistant epilepsy give reason for hope. However, we must remember that anecdotal reports alone are not sufficient to support treatment decisions.”). Infrequent or “experimental” marijuana use, however, generally is a different matter. There might be an exception for use of high-potency THC, low cannabidiol content marijuana, colloquially known as “skunk.” Marijuana with a very high THC:CBD ratio can give rise to psychotic episodes. See Marta Di Forti et al., *supra* note 29, at 236. A novice using such cannabis might have such an episode from his first use. A child, almost certainly.

32. KOOB ET AL., *supra* note 11, at 287. “Executive functioning” means “the ability to organize thoughts and activities, prioritize tasks, manage time, and make decisions.” *Id.* at 286. Marijuana use can also harm children in utero. See, e.g., WHO REPORT, *supra* note 29, at 28 (citations omitted) (“[A]ccumulating evidence suggests that prenatal cannabis exposure may interfere with normal development and maturation of the brain. Children exposed to cannabis in utero demonstrate impaired attention, learning and memory, impulsivity and behavioural problems and a higher likelihood of using cannabis when they mature . . .”).

33. See KOOB ET AL., *supra* note 11, at 287.

Since the 1960s, scientists have discovered that the human brain maturation process extends into a person's mid-twenties as the brain creates neurons while pruning and reorganizing neural pathways for efficient use by adults.<sup>34</sup> The process of ongoing development is particularly important in connection with the prefrontal cortex, the region responsible for higher mental functions such as reasoning, judgment, and decision-making. Given the labile state of the adolescent brain, and depending on the dose and frequency of use, a minor's use of a psychoactive substance like THC is likely to have adverse physical and mental effects that would not occur in an adult or, even if they did, would not be present to the same degree.<sup>35</sup> The result hampers

---

34. See, e.g., Seth Ammerman et al., *The Impact of Marijuana Policies on Youth: Clinical, Research, and Legal Update*, 135 PEDIATRICS E769, E771 (2015) [hereinafter Ammerman et al., *Marijuana Policies*]; Bossong & Niesink, *supra* note 30, at 372–77; Madras, *supra* note 12, at 14–15; Ryan & Ammerman, *Counseling Parents and Teens*, *supra* note 28, at E2. In fact, the prefrontal lobe region is the last area of the adolescent brain to undergo the neuromaturational development resulting from the extension of neurons into new regions and the pruning of unnecessary connections. See, e.g., Ammerman et al., *Marijuana Policies*, *supra*, at E770; Bossong & Niesink, *supra*, at 373.

35. See Kalant, *supra* note 12, at 394 (noting “the possibility that during brain maturation in adolescence, heavy exposure to cannabis might prevent the growth of axons and the establishment of large numbers of synaptic connections that normally accompany experience and learning”) (citations omitted); *id.* (“the results of MRI studies of the brains of late teen-aged males who had used marijuana heavily throughout adolescence” revealed a “smaller brain size and thinner cortex in early heavy users than in age-matched users who did not begin until after 17”); Ammerman et al., *Marijuana Policies*, *supra* note 34, at E770 (noting adverse “effects of marijuana use on hippocampal, prefrontal cortex, and white matter volume” in minors); Sarah D. Lichenstein et al., *Nucleus Accumbens Functional Connectivity at Age 20 Is Associated with Trajectory of Adolescent Cannabis Use and Predicts Psychosocial Functioning in Young Adulthood*, 112 ADDICTION 1961 (2017); Meier et al., *supra* note 30 (noting that the “results of several studies showing executive functioning or verbal IQ deficits among adolescent-onset but not adult-onset chronic cannabis users . . . as well as studies showing impairment of learning, memory, and executive functions in samples of adolescent cannabis users”) (endnotes omitted); Volkow et al., *supra* note 28, at 2220 (“The brain remains in a state of active, experience-guided development from the prenatal period through childhood and adolescence until the age of approximately 21 years. . . . The negative effect of marijuana use on the functional connectivity of the brain is particularly prominent if use starts in adolescence or young adulthood, which may help to explain the finding of an

development of higher-order mental states necessary for mature reasoning and planning.<sup>36</sup>

Those adverse effects can manifest themselves in several ways. As the American Academy of Pediatrics has noted,<sup>37</sup> numerous published studies have established the harmful short- and long-term effects suffered by minors—from infants to adolescents—resulting from unwitting THC consumption or heavy, long-term marijuana use. Aside from intoxication, the range of effects include: decreased concentration, attention span, diminished judgment, reaction time, tracking ability, and problem-solving skills, which hampers driving ability; short-term memory loss; respiratory deficits or arrests; and increased risk of mental

---

association between frequent use of marijuana from adolescence into adulthood and significant declines in IQ. The impairments in brain connectivity associated with exposure to marijuana in adolescence are consistent with preclinical findings that the cannabinoid system plays a prominent role in synapse formation during brain development.”) (footnotes omitted). Heavy or long-term cannabis use appears to be a critical factor. See Madeleine H. Meier, *Associations Between Adolescent Cannabis Use and Neuropsychological Decline: A Longitudinal Co-Twin Control Study*, 113 ADDICTION 257 (2017) (concluding that short-term marijuana use does not appear to cause IQ decline or impair executive function); Wendy Swift et al., *Are Adolescents Who Moderate Their Cannabis Use at Lower Risks of Later Regular and Dependent Cannabis Use?*, 104 ADDICTION 806 (2009) (answering the question posed in title as “Yes”).

36. See KOOB ET AL., *supra* note 11, at 285 (“The adolescent period represents a critical phase of development, characterized by specific progressive neurobiological maturational processes in the prefrontal cortex that includes myelination and synaptic pruning. This period of maturation also involves the rearrangement of key neurotransmitter systems, such as glutamate,  $\gamma$ -aminobutyric acid, dopamine, and Endocannabinoid systems in the frontal cortex. Changes in these systems are believed to support the emergence of adult cognitive processes. Over the course of adolescence and early adulthood, individuals show normative growth in planning, preference for delayed rather than immediate rewards, resistance to peer pressure, and impulse control. Many of the brain regions that are undergoing these developmental changes may be particularly affected by alcohol and marijuana use.”). Of course, the science on this subject is not on a par with Newton’s First Law of Motion; there are studies to the contrary as well. See, e.g., Ileana Pacheco-Colon et al., *Is Cannabis Use Associated with Various Indices of Motivation Among Adolescents?*, 52 SUBST. USE & MISUSE 1 (2017).

37. See Ammerman et al., *Marijuana Policies*, *supra* note 34, at E670; Ryan & Ammerman, *Counseling Parents and Teens*, *supra* note 28, at E2.

health disorders such as psychosis and depression. Adolescent marijuana use is also associated with a lower probability of faring well in school—including a greater likelihood of being suspended or dismissed from school, a higher probability of work dissatisfaction and failure—being fired and collecting welfare, later marijuana dependence, use of other illegal drugs, and suicide attempts.<sup>38</sup> Finally, someone who begins long-term use during adolescence is likely to suffer negative effects on executive functioning that do not recover upon reaching the age of majority, even if use is later discontinued.<sup>39</sup> The number of minors affected multiplies the societal implications of those individual harms. The associated harms are troubling too. As two commentators noted, “the availability of child-friendly edibles could increase the probability of initiation to marijuana use, reduce the average age of initiation, and increase the frequency and intensity of use among users of all ages.”<sup>40</sup>

---

38. See, e.g., Budney et al., in Ruiz & Strain, *supra* note 25, at 227 (“Cross-sectional and longitudinal studies have reported a clear association between chronic cannabis use and impaired psychological functioning. In particular, cannabis has been associated with poorer life satisfaction, increased mental health treatment and hospitalization, higher rates of depression, anxiety disorders, suicide attempts, and conduct disorder.”) (endnote omitted); Brook et al., *supra* note 29, at 87–88; Silins et al., *supra* note 29, at 286. Other harms, such as comas, are also possible but are rare. See, e.g., WHO REPORT, *supra* note 29, at 48–50.

39. See, e.g., NAT’L ACAD. OF SCI., ENG’G, & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 18 (2017); Madeline H. Meier et al., *Persistent Cannabis Users Show Neuropsychological Decline from Childhood to Midlife*, 109 PROC. NAT’L ACAD. SCI. E2657 (2012); Henrietta Szutorisz & Yasmin L. Hurd, *High Times for Cannabis: Epigenetic Imprint and Its Legacy on Brain and Behavior*, 85 NEUROSCIENCE & BIOBEHAVIORAL REVS. 93, 98–99 (2018) (“The relationship between cannabis use and neuropsychiatric vulnerability is clearly complex, but the limited data accrued to date in this fast growing field already documents that early exposure during one’s lifetime leaves a long-term epigenetic memory mark which sets a legacy even onto future generations.”).

40. MacCoun & Mello, *supra* note 8, at 990. Cf. ROOM ET AL., *supra* note 2, at 15 (“The health and psychological effects of regular cannabis use are not as well understood as those of alcohol and tobacco, but epidemiological research over the past decade has provided evidence that it can have adverse effects on some users,

States that have liberalized their marijuana laws have attempted to avoid those dangers by, *inter alia*, limiting recreational sales to adults.<sup>41</sup> Unfortunately, experience has taught that such legal restrictions do not prevent children—to say nothing of adolescents—from finding the drug in their parents' supply or obtaining it elsewhere and mistakenly consuming it, or being deliberately tempted to do so.<sup>42</sup> According to Sgt. Jim Gerhardt of the Colorado Drug Investigators Association, “[y]ou have little kids that accidentally get into this stuff; they don’t know any better.”<sup>43</sup> He also said that others, such as a neighbor, a friend, a schoolmate, a babysitter, or another family member, could unwittingly give a child candy not realizing what it is. “Those

---

particularly those who initiate use in adolescence and use more than weekly for years during young adulthood.”). That is troublesome because “[c]annabis use in the USA typically begins in the mid to late teens, and is most prevalent in the early 20s” and because “about 10% of those who ever use cannabis become daily users,” with “another 20% to 30% use cannabis weekly . . .” *Id.* at 4–5. “Among those who begin to use in their early teens, the risk of developing problem use may be as high as one in six . . .” *Id.* at 5.

Two other points are worth noting. First, adolescents who drive after using marijuana are at greater risk of being in a motor vehicle accident, particularly if, as is often the case, they also consume alcohol. *See, e.g.,* KOOB ET AL., *supra* note 11, at 283–84; ROOM ET AL., *supra* note 2, at 15, 17–19; Larkin, *Drugged Driving*, *supra* note 4, at 473–80 & nn.87–109. Second, juveniles who begin heavy, long-term marijuana use can become addicted to it. *See* Peters & Mechoulam, *supra* note 12, in Stanford & Avoy, *supra* note 12, at 38–39 (describing the neurobiology of addiction); Volkow et al., *supra* note 28, at 2220 (“[E]arly and regular marijuana use predicts an increased risk of marijuana addiction, which in turn predicts and increased risk of the use of other illicit drugs. As compared with persons who begin to use marijuana in adulthood, those who begin to use in adolescence are approximately 2 to 4 times as likely to have symptoms of cannabis dependence within 2 years after first use.”) (footnotes omitted).

41. MacCoun & Mello, *supra* note 8, at 989. Minors can use marijuana medically only with physician approval and parental consent. *See, e.g.,* COLO. CONST. art. XVII, § 14(6).

42. *See* Barrus et al., *supra* note 11, at 4 (“Not unexpectedly, ingestion was the most common route of exposure resulting in most of these [pediatric] emergency room visits.”).

43. Jeff Rossen & Jovanna Billington, *Rossen Reports Update: Edible Marijuana that Looks Like Candy Is Sending Kids to the ER*, TODAY (Sep. 16, 2017, 7:41 AM), <https://www.today.com/parents/edible-marijuana-looks-candy-sending-kids-er-t94486>.

accidental issues are on the rise, and it's a big problem.”<sup>44</sup> In the words of Dr. Robert Glatter, a New York City emergency room physician, “[t]his is extremely dangerous.”<sup>45</sup>

---

44. *Id.*

45. *Id.*; see, e.g., Kosa et al., *supra* note 15, at 58 (noting that a 2016 study found that “annual Regional Poison Center pediatric marijuana cases increased more than fivefold from 2009 to 2015, and edibles were responsible for 52% of the exposures.”); MacCoun & Mello, *supra* note 8, at 990 (“Whether through deliberate acquisition or unknowing consumption, these child-friendly edibles increase minors’ risk of exposure to and experimentation with marijuana.”); Derek Murray et al., *When the Grass Isn’t Greener: A Case Series of Young Children with Accidental Marijuana Ingestion*, 18 CAN. J. EMERG. MED. 480 (2016); Nathan et al., *supra* note 5, at 1746 (“[C]annabis prohibition for adults does not prevent underage use. For decades, preventive education reduced the rates of alcohol and tobacco use by minors, whereas underage marijuana use has fluctuated despite its prohibition for adults. Since the 1970s, 80% to 90% of those aged 18 years have consistently reported easy access to the drug.”) (footnote omitted); Wang et al., *Colorado Study 2009–2015*, *supra* note 15; Wang et al., *Multistate Study 2005–2011*, *supra* note 14, at 686 (noting an increase in the rate of pediatric exposure to marijuana from 2005 to 2011 in states that had passed marijuana legislation); George Sam Wang et al., *Pediatric Marijuana Exposures in a Medical Marijuana State*, 167 JAMA PEDIATRICS 630 (2013); 3 *Warren Middle Schoolers Hospitalized After Eating Marijuana-Laced Cookie Crisp*, CBS DETROIT (Nov. 15, 2017), <http://detroit.cbslocal.com/2017/11/15/students-eat-marijuana-edibles/> (“Warren Police Commissioner Bill Dwyer said officers were called to the Michigan Math and Science Academy on Dequindre Road, Wednesday morning, after three young girls had eaten Cookie Crisp cereal coated in marijuana oil. . . . ‘When our officers arrived, the principal and parents advised the officers that three 8th grade female students had been transported to St. John Oakland Hospital after complaints of feelings dizzy and light-headed,’ . . . .”); 11 *Teens Ill After Eating Drug-Laced Gummy Bears*, ABC NEWS (July 7, 2017), <http://abc7chicago.com/news/11-teens-ill-after-eating-drug-laced-gummy-bears/2192901/>; *Alaska High School Students’ Parents Turn Them in for Selling Pot Gummy Bears*, ASSOCIATED PRESS (Dec. 8, 2017), <http://www.thecannabist.co/2017/12/08/alaska-high-school-students-marijuana-gummy-bears/94235/>; Dan Atkinson, *THC-Laced Sweets Causing Concern*, BOSTON HERALD (Oct. 31, 2017), [http://www.bostonherald.com/news/local\\_coverage/2017/10/thc\\_laced\\_sweets\\_causing\\_concern](http://www.bostonherald.com/news/local_coverage/2017/10/thc_laced_sweets_causing_concern); Peter Burke, *2 Teens Treated after Ingesting Marijuana-Laced Gummy Candies at School*, ABC NEWS (Mar. 30, 2017), <https://www.local10.com/education/2-teens-ingest-marijuana-laced-gummy-candies-at-school>; Bill Bird, *Teens Charged in Pot-Laced Gummy Bear Incident at Naperville North*, CHI. TRIBUNE (Feb. 9, 2017), <http://www.chicagotribune.com/suburbs/naperville-sun/crime/ct-nvs-naperville-more-gummy-arrests-st-0212-20170210-story.html>; Jessica Chen, *One Arrested after Marijuana Gummy Bears Sicken Chula Vista Students*, ABC NEWS (Apr. 27, 2017), <https://www.10news.com/news/one-arrested-after-marijuana-gummy-bears-sickens-chula-vista-students>; K.J. Dell ‘Antonia, *When Marijuana Looks Like Candy, Not Drugs*, N.Y. TIMES (Feb. 11,

---

2014), <https://parenting.blogs.nytimes.com/2014/02/11/when-marijuana-looks-like-candy-not-drugs/>; Keith Farner, *GCPS Investigating Edible Medical Marijuana Incident at Middle School*, Jan. 20, 2017, GWINNETT DAILY POST (Jan. 20, 2017), [http://www.gwinnettdaily.com/local/gcps-investigating-edible-medical-marijuana-incident-at-middle-school/article\\_14237fd4-fca8-577e-9b59-50b52ddaebd5.html](http://www.gwinnettdaily.com/local/gcps-investigating-edible-medical-marijuana-incident-at-middle-school/article_14237fd4-fca8-577e-9b59-50b52ddaebd5.html); Carla Field, *Students Eat THC-Laced Gummy Bears; 1 Taken to Hospital, Another Arrested*, WYFF GREENVILLE (Mar. 21, 2017) <http://www.wyff4.com/article/students-eat-thc-laced-gummy-bears-1-taken-to-hospital-another-arrested/9163208>; *Gummy Candy Found at Florida High School Was Laced with THC*, JUST BELIEVE RECOVERY CTR., <https://justbelieverecover.com/gummy-candy-thc/> (last accessed Dec. 9, 2017); Sheena Jones & Madison Park, *Sickened Students Suspect Marijuana-Laced Gummy Bears*, CNN (Dec. 8, 2016), <http://www.cnn.com/2016/12/07/us/students-sick-gummy-bears/index.html> (“Several [14, in fact] high school students were taken to a local hospital after eating gummy bears some said may have been laced with marijuana.”); Dal Kalsi, *Police: Hillcrest High Student Hospitalized, Another Arrested After Eating Marijuana-Laced Gummy Bears*, FOX CAROLINA (Apr. 18, 2017), <http://www.foxcarolina.com/story/34964042/police-hillcrest-high-student-arrested-after-distributing-marijuana-laced-gummy-bears-at-school>; Seth Klamann, *Parents Ask Casper School Officials to Consider Drug Testing*, CASPER STAR TRIBUNE (Mar. 8, 2017), [http://trib.com/news/local/education/parents-ask-casper-school-officials-to-consider-drug-testing/article\\_3195b84f-5820-5dae-a1c5-570010591694.html](http://trib.com/news/local/education/parents-ask-casper-school-officials-to-consider-drug-testing/article_3195b84f-5820-5dae-a1c5-570010591694.html) (“Natrona County High School students eating marijuana-laced gummy bears on a school bus prompted a group of parents to approach school board members about implementing a drug testing policy in the district.”); Lance Knobel, *Two Berkeley High Students Hospitalized after Eating Marijuana Edibles*, BERKELEYSIDE (Dec. 2, 2016), <http://www.berkeleyside.com/2016/12/02/two-berkeley-high-students-hospitalized-after-eating-marijuana-edibles/> (“[Berkeley High School Principal Sam Pasarow] said parents should remind students to never accept food from other students without knowing their origin. ‘Edible products are particularly dangerous as they can include a range of substances and unclear dosages and drug potency,’ he wrote.”); Abby Phillip, *More and More Little Kids are Finding Mom and Dad’s (Legal) Marijuana Stash*, WASH. POST (June 9, 2015), [https://www.washingtonpost.com/news/wonk/wp/2015/06/09/more-and-more-little-kids-are-finding-mom-and-dads-legal-marijuana-stash/?noredirect=on&utm\\_term=.a0d87a0044cf](https://www.washingtonpost.com/news/wonk/wp/2015/06/09/more-and-more-little-kids-are-finding-mom-and-dads-legal-marijuana-stash/?noredirect=on&utm_term=.a0d87a0044cf) (“In the places where marijuana is legal, more and more children are being accidentally exposed to their parents’ drugs, a new study found. . . . [B]etween 2006 and 2013, the rate of exposure increased by 147.5 percent. . . . Accidental ingestions, which account for a whopping 75 percent of cases, are much more likely with the growing availability of marijuana edibles. Most of these kids are probably ingesting marijuana accidentally—on account of their natural curiosity and the fact that the products themselves can taste like treats, researchers said. A majority of the children exposed to marijuana were 3 years old or younger, according to the study.”); Kristine Phillip, *A Fifth Grader Thought She Brought Gummy Bears to School. They Were Laced with Marijuana*, WASH. POST (Jan. 21, 2018) (on file with author) (“A 9-year-old student in New Mexico gave fellow students gummies—only to realize later they were not ordinary candies. The candies had apparently been laced with [THC] the chemical responsible for how marijuana

Proof can be seen in the increase in calls to poison control centers. From 2005 through 2011, there was no increase in the call rate to poison control centers in states where marijuana use was illegal, but there was a thirty percent increase in the number of calls in states that had decriminalized marijuana use.<sup>46</sup> The rate of exposure is also increasing. There was no change in the rate between 2000 and 2006, but the rate increased by 147.5% from 2006 through 2013.<sup>47</sup> The number of reports is also significant: 1,969 children under six years old were reported for marijuana exposure to poison control centers from 2000 through 2013.<sup>48</sup> More than seventy-five percent of the children exposed to marijuana were under three years old.<sup>49</sup> One study noted that “[s]tates that decriminalized medical marijuana have shown an increase in emergency department (ED) visits and regional poison center (RPC) cases for unintentional pediatric marijuana exposures.”<sup>50</sup> Colorado, in particular, saw a thirty-four percent increase in marijuana exposure cases between 2009 and 2015—an amount greater

---

affects the brain and were being used by the student’s parents as medical marijuana.”); Shira Schoenberg, “From Gummy Bears to Open Doors, Inspections Identify Problems at Massachusetts Medical Marijuana Dispensaries,” MASSLIVE.COM (Jan. 19, 2018), [http://www.masslive.com/politics/index.ssf/2018/01/from\\_gummy\\_bears\\_to\\_open\\_doors.html](http://www.masslive.com/politics/index.ssf/2018/01/from_gummy_bears_to_open_doors.html)); Rick Wilking, Reuters, *Bad Munchies: Boy Sent to Hospital after Eating Pot-Laced Gummy Bears on School Bus*, RT QUESTION MORE (Jan. 13, 2017) <https://www.rt.com/usa/373363-marijuana-gummy-bears-schoolbus/>; Lyndsay Winkley, *Eighth-Grader Sold Pot-Laced Gummy Bears to Fellow Students, Authorities Say*, L.A. TIMES (Apr. 27, 2017), <http://www.latimes.com/local/lanow/la-me-ln-marijuana-gummy-bears-20170427-story.html>. Even adults can accidentally consume THC-infused food. See Barrus et al., *supra* note 11, at 7 (“Reports of inadvertent ingestion of cannabis edibles by adults are widespread. For example, a group of preschool teachers in California experienced nausea, dizziness, headache, and other symptoms after consuming brownies containing cannabis. One of the teachers had purchased the brownies from a sidewalk vendor and placed them in the breakroom . . .”).

46. Wang et al., *Multistate Study 2005–2011*, *supra* note 14, at 686.

47. Onders, *supra* note 30, at 430.

48. *Id.*

49. *Id.* at 430, 432.

50. Wang et al., *Colorado Study 2009–2015*, *supra* note 15, at 2.



than what occurred in any other state.<sup>51</sup> The vast majority of exposures were edibles; they accounted for seventy-five percent of the exposures.<sup>52</sup> That result is particularly likely when edibles are shaped and colored to mimic candies already familiar to children or infants who are not yet intellectually capable of understanding the risks of consuming edibles or parental warnings about the harms of marijuana use.<sup>53</sup>

Of course, children are not the only minors who can consume marijuana. Marijuana, including cannabis obtained for medical purposes, has been diverted to adolescents, who may use edibles to disguise their marijuana use.<sup>54</sup> Smoking marijuana leaves a signature aroma; ingesting marijuana does not. The result is that adolescents may use edibles,

---

51. See *id.* at 4; see also John Ingold, *Children's Hospital Sees Surge in Kids Accidentally Eating Marijuana*, DENVER POST (Oct. 2, 2016, 4:01 PM), <http://www.denverpost.com/2014/05/21/childrens-hospital-sees-surge-in-kids-accidentally-eating-marijuana/> (“The number of children coming into Colorado’s largest pediatric emergency department after accidentally eating marijuana is on pace to more than double last year’s total. . . . Most of the children admitted are between 3 and 7 years old . . .”).

52. See Monte et al., *supra* note 5, at 242 (“The most concerning health effects have been among children. The number of children evaluated in the ED for unintentional marijuana ingestion at the Children’s Hospital of Colorado increased from 0 in the 5 years preceding liberalization to 14 in the 2 years after medical liberalization. This number has increased further since legalization; as of September 2014, 14 children had been admitted to the hospital this year, and 7 of these were admitted to the intensive care unit. The vast majority of intensive care admissions were related to ingestion of edible THC products.”); Onders, *supra* note 30, at 430, 432; Wang et al., *Multistate Study 2005–2011*, *supra* note 14, at 684.

53. Wang et al., *Multistate Study 2005–2011*, *supra* note 14, at 688 (“These edible products are often indistinguishable from non-marijuana-containing food products, are highly attractive and palatable to children, and can contain very high amounts of [THC.]”) (footnote omitted).

54. Wang et al., *Multistate Study 2005–2011*, *supra* note 14, at 684. Kris Kirschner, “Weed Candy” Just One Way Teenagers Hide Marijuana Use, WTHR (Apr. 14, 2016, 10:30 PM), <https://www.wthr.com/article/weed-candy-just-one-way-teenagers-hide-marijuana-use> (“Across the country, police agencies are reporting evidence of a new way to disguise illegal drugs, by wrapping them in familiar and innocent looking covers. ‘Weed candy’ is marijuana cooked into hard candy—and it’s beginning to make its way into Indiana.”).

particularly ones disguised as anodyne candies, to start down a path that could lead to the harms resulting from prolonged use.

There are additional risks associated with use of marijuana by teenagers. They may be aware that they are consuming marijuana, but unaware of the considerable delay between ingestion and the psychoactive effect that THC produces or of the amount of THC that they can consume in a single edible. The result is that they may overconsume the amount of marijuana necessary to produce the hoped-for euphoria and, instead, have an adverse reaction.<sup>55</sup>

Keep in mind that the marijuana grown and sold today is not your granddaddy's ganja. Current products have a greater THC content than what was used from the 1960s through the 1980s, perhaps due to the effect of competition.<sup>56</sup>

---

55. Cf. BRUCE BARCOTT, WEED THE PEOPLE: THE FUTURE OF LEGAL MARIJUANA IN AMERICA 272 (2015) ("It [viz., overconsumption] was a problem because industry and state officials miscalculated their dosing rules. A single package of recreational edibles in Colorado could contain no more than 100 milligrams of THC. That meant one cookie in its own package might max out at 100 milligrams. But the state considered a 'serving size' to be 10 milligrams. So a single cookie might constitute 10 servings. Who looks at a single cookie and thinks, *Ten servings? Nobody, that's who.*") (emphasis in original).

56. See, e.g., Budney et al., *in* Ruiz & Strain, *supra* note 25, at 216 (the potency of marijuana increased by sixty percent over 2000–2010); ROOM ET AL., *supra* note 2, at 6 (noting that some varieties of marijuana (Sinsemilla, also known as skunk and Netherweed) may have THC content as high as 20 percent, that hashish (dried cannabis resin and crushed plants) has a THC content in the range of 2–20 percent, and that hash oil (an oil-based extract of hashish) has a THC content of 15–50 percent); *id.* at 39–40; Wayne Hall & Louisa Degenhardt, *High Potency Cannabis: A Risk Factor for Dependence, Poor Psychosocial Outcomes, and Psychosis*, 350 BR. MED. J. 1205 (2015); Eric L. Sevigny et al., *The Effects of Medical Marijuana Laws on Potency*, 25 INT'L J. DRUG POL'Y 308, 309 (2014) ("Although direct empirical evidence is limited, insider and journalistic accounts suggest that [medical marijuana laws]—and the medical marijuana industry built up around them—have greatly enhanced the development and diffusion of high-potency cannabis cultivars and sophisticated techniques of production."); Volkow et al., *supra* note 29, at 2222 ("The THC content, or potency, of marijuana, as detected in confiscated samples, has been steadily increasing from about 3% in the 1980s to 12% in 2012. . . . This increase in THC content raises concerns that the consequences of marijuana use may be worse now than in the past and may account for the significant increases in emergency

One study estimates that the potency nearly tripled between 1990 and 2010 from 3.4% to 9.6%,<sup>57</sup> although other studies put the number even higher, up to 20%.<sup>58</sup> Cannabis oil extracts can be as high as 80%.<sup>59</sup> The THC content of edibles can be especially high.<sup>60</sup> In fact, the marijuana industry has developed a synthetic crystalline form of THC that is 99.9% pure.<sup>61</sup> The increase in potency over time persuaded NIDA Director Dr. Volkow to question “the current relevance of the findings in older studies on the effects of marijuana use, especially studies that assessed long-term outcomes.”<sup>62</sup>

---

department visits by persons reporting marijuana use . . . and the increases in fatal motor-vehicle accidents.”) (footnotes omitted). It is also important to note that the relatively low ratio of THC to cannabidiol (CBD) in the native plant may have protected earlier generations of users from severe adverse effects. Research shows that THC administered alone can have a dramatic adverse effect on critical brain biology. The theory is that CBD attenuates the effects of THC in brain tissue. See ROOM ET AL., *supra* note 2, at 15; Di Forti et al., *supra* note 29, at 236; M.A. El Sohly et al., *Changes in Cannabis Potency Over the Last Two Decades (1995–2014): Analysis of Current Data in the United States*, 79 BIOLOGICAL PSYCHIATRY 613, 617 (2016). Even if adults can titrate the amount of high-content THC they consume, see ROOM ET AL., *supra* note 2, at 40, children cannot.

57. Sevigny et al., *supra* note 56, at 308, 315 (noting that marijuana potency “significantly increases by about one percentage point over time” in states with medical marijuana laws).

58. See DSM-5, *supra* note 28, at 511 (marijuana potency ranges from 1–15 percent, hashish from 10–20 percent; “During the past two decades, a steady increase in the potency of seized cannabis has been observed.”); HUDAK, *supra* note 15, at 17–18; IVERSEN, *supra* note 12, at 10 (estimating potency at 10–20 percent); Kleber & DuPont, *supra* note 14, at 565 (estimating up to 20 percent).

59. See Beau Kilmer & Rosalie Liccardo Pacula, *Understanding and Learning from the Diversification of Cannabis Supply Laws*, 112 ADDICTION 1128, 1131 (2016).

60. Onders et al., *supra* note 30, at 432.

61. See Anna Wilcox, *THC-A Crystalline: The World’s Strongest Hash with 99.99% THC*, HERB (Mar. 29, 2017), <https://herb.co/2017/03/29/thc-a-crystalline/>. A 99% standard is used in Dronabinol, marketed as Marinol, an FDA-approved pill-form drug with an isolated THC cannabinoid that is approved for chemotherapy-induced nausea. See *Dronabinol: Pharmacology and Biochemistry*, NAT’L CTR. BIOTECHNOLOGY INFO., <https://pubchem.ncbi.nlm.nih.gov/compound/Dronabinol#section=Pharmacology-and-Biochemistry> (last visited Mar. 21, 2018).

62. Volkow et al., *supra* note 28, at 2222. Another consideration is the inconsistency in the THC concentration within some products, which can lead

Those problems are not isolated or transient ones. On the contrary, at least 60% of new drug initiates are younger than eighteen years old, the age of onset is declining, daily use of marijuana by juveniles is at its highest level in thirty years, marijuana use exceeds nicotine use, and 44.5% of twelfth-graders report having used cannabis, with 6% reporting daily use during the preceding thirty days.<sup>63</sup> Juvenile consumption of THC is a serious public health and policy issue.

### III. THE NEED FOR THE FDA TO PROTECT MINORS FROM MARIJUANA EDIBLES

#### A. *State Regulatory Efforts*

States authorizing recreational marijuana use, such as Colorado, have sought to prevent those problems from occurring by regulating the manufacture, packaging, and distribution of edible marijuana.<sup>64</sup> For example, four states currently have operational recreational marijuana programs. Each one forbids the manufacture and packaging of products that could appeal to children and requires that edibles be sold in child-resistant packaging.<sup>65</sup> The level of

---

some users to overconsume a suggested service portion. *See, e.g.*, Kosa et al., *supra* note 15, at 58.

63. *See* BABOR ET AL., *supra*, note 8, at 105 (“[A]dolescence is the period of life in which drug use is most likely to begin.”); Budney et al., *in* Ruiz & Strain, *supra* note 25, at 216 (rates of use and incidence of cannabis use disorder increased during 1995–2010; marijuana use also initiating at a younger age); Lichenstein et al., *supra* note 35, at 1961; Madras, *supra* note 12, at 12–13.

64. *See* Barrus et al., *supra* note 11, at 9–10; Jacob T. Borodovsky & Alan J. Budney, *Legal Cannabis Laws, Home Cultivation, and Use of Edible Cannabis Products: A Growing Relationship*, 50 INT’L J. DRUG POL’Y 102, 103 (2017); Camille Gourdet et al., *How Four U.S. States Are Regulating Recreational Marijuana Edibles*, 43 INT’L J. DRUG POL’Y 83, 84–89 (2017); Kosa et al., *supra* note 15, at 58–64. In 2016, California, Maine, Massachusetts, and Nevada also legalized recreational marijuana use, but, other than California, those programs have not yet become operational as of the date of this Article. *See* Gourdet et al., *supra*, at 83.

65. *See, e.g.*, COLO. CODE REGS. § 212-1-1001.5(C) (2017) (prohibiting medical marijuana businesses from packaging items “in a manner that specifically

---

targets individuals under the age of 21, including but not limited to, cartoon characters or similar images.”); *id.* § 212-1-1001.5(H) (forbidding the use of the word “candy” or “candies” on medical marijuana products); *id.* §§ 212-1-1004.5(A), 212-1-1006(A), 212-1-1007(A) (requiring medical marijuana centers to package their products in child-resistant containers); *id.* §§ 212-2-1001 to 212-2-1007.5 (requiring the same packaging and labeling requirements for retail or recreational marijuana); WASH. ADMIN. CODE § 314-55-105(7) (2017) (“Marijuana-infused products and marijuana concentrates meant to be eaten, swallowed, or inhaled, must be packaged in child resistant packaging in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act or use standards specified in this subsection. Marijuana-infused product in solid or liquid form may be packaged in plastic four mil or greater in thickness and be heat sealed with no easy-open tab, dimple, corner, or flap as to make it difficult for a child to open and as a tamperproof measure. Marijuana-infused product in liquid form may also be sealed using a metal crown cork style bottle cap. Marijuana-infused solid edible products. If there is more than one serving in the package, each serving must be packaged individually in childproof packaging (see WAC 314-55-105(7)) and placed in the outer package. Marijuana-infused liquid edible products. If there is more than one serving in the package, a measuring device must be included in the package with the product. Hash marks on the bottle do not qualify as a measuring device. A measuring cap or dropper must be included in the package with the marijuana-infused liquid edible product.”); *id.* § 314-55-105(11) (“All marijuana and marijuana products when sold at retail must include accompanying material that is attached to the package or is given separately to the consumer containing the following warnings: (a) ‘Warning: This product has intoxicating effects and may be habit forming. Smoking is hazardous to your health’; (b) ‘There may be health risks associated with consumption of this product’; (c) ‘Should not be used by women that are pregnant or breast feeding’; (d) ‘For use only by adults twenty-one and older. Keep out of reach of children’; (e) ‘Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug’; (f) Statement that discloses all pesticides applied to the marijuana plants and growing medium during production and processing.”); *id.* § 314-55-105(13) (“In addition to requirements in subsection (10) of this section, labels affixed to the container or package containing usable marijuana, or packaged marijuana mix sold at retail must include: (a) Concentration of THC (total THC and activated THC-A) and CBD (total CBD and activated CBD-A); (b) Date of harvest.”); *id.* § 314-55-105(14) (“In addition to requirements in subsection (10) of this section, labels affixed to the container or package containing marijuana-infused products meant to be eaten or swallowed sold at retail must include: (a) Date manufactured; (b) Best by date; (c) Serving size and the number of servings contained within the unit; (d) Total milligrams of active THC, or Delta 9 and total milligrams of active CBD; (e) List of all ingredients and major food allergens as defined in the Food Allergen Labeling and Consumer Protection Act of 2004; (f) ‘Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by two or more hours.’”); *id.* § 314-55-106(1) (“Marijuana-infused products meant to be eaten or swallowed sold at retail must be labeled on the principal display panel or front of the product package with the ‘not for kids’ warning symbol created and made available in digital form to licensees without cost by the Washington poison

success those states have had in keeping marijuana out of the hands of minors, according to one study, “remains an open, and somewhat controversial, question.”<sup>66</sup>

Additional steps could be taken to prevent access by minors.<sup>67</sup> Colorado recently took one such step by forbidding the sale of any edible product in a form that resembles an animate creature.<sup>68</sup> Of course, there are numerous other shapes that children easily recognize, such as a train, a car, a flower, or a classic cuboidal shaped candy bar. The new Colorado regulation, therefore, is an incomplete remedy.<sup>69</sup> A

---

center (WPC). The warning symbol may be found on the WPC’s web site. (a) The warning symbol must be of a size so as to be legible, readily visible by the consumer, and effective to alert consumers and children that the product is not for kids, but must not be smaller than three-quarters of an inch in height by one-half of an inch in width; and (b) The warning symbol must not be altered or cropped in any way other than to adjust the sizing for placement on the principal display panel or front of the product package, except that a licensee must use a black border around the edges of the white background of the warning symbol image when the label or packaging is also white to ensure visibility of the warning symbol.”); Barrus et al., *supra* note 11, at 10; Gourdet et al., *supra* note 64, at 87–88.

66. Gourdet et al., *supra* note 64, at 87; Ben Tsutaoka et al., *Edible Marijuana Labeling and Packaging*, 57 CLINICAL PEDIATRICS 227, 227–230 (2018) (“Compliance of edible marijuana products to California label and packaging requirements, set forth in AB-266, was poor. Ninety percent of the products were labeled and in a tamper evident package; however, only one was in child-resistant packaging. Colorado medical and retail marijuana statutes have provisions for child-resistant packaging that conform to federal consumer product safety regulations, that products are in opaque packaging so the product cannot be seen and that the package is resealable if not single use; still pediatric exposures to marijuana increased 5-fold from 2009 to 2015.”) (footnote omitted).

67. See MacCoun & Mello, *supra* note 8, at 990–91 (offering suggestions).

68. See COLO. CODE REGS. § 212-2-402(P) (forbidding edibles shaped as, or containing characteristics of, humans, animals, or fruit); COLO. REV. STAT. § 12-43.3-202(1)(b)(I) (2017) (authorizing the state marijuana licensing authority to promulgate rules “as necessary for the proper regulation and control of the cultivation, manufacture, distribution, and sale of medical marijuana and for the enforcement of this article”).

69. See Kosa et al., *supra* note 15, at 58–59; *Colorado Marijuana Bill: Banning Weed-Infused Gummy Bears*, WEEDLEX (July 4, 2016), <http://weedlex.com/colorado-marijuana-bill-banning-weed-infused-gummy-bears> (“While sweet edibles in the shape of bears and fish will be illegal to produce, cannabis stars, leaves, and many other shapes that should have also fallen within the purview of the law are not banned. This conveys that the House Bill 1436 is

state could rely on state tort law to supplement regulations. One theory would be that an edible resembling a traditional form of candy would qualify as an “attractive nuisance,” which would enable minors to recover damages from the manufacturer and seller of the edible.<sup>70</sup> Yet, insofar as the blame lies with the parents for failing to prevent a minor from accessing their “stash,” allowing, let alone encouraging, minors to recover damages from their parents is hardly an attractive way to encourage the latter to be careful.

### B. *Potential Federal Regulatory Efforts*

The interesting questions are whether the federal government can and should intervene to supplement the states’ efforts to protect minors. To date, most of the debate has focused on the issue of whether the Department of Justice should prosecute marijuana dispensaries for violating the federal drug laws. Those statutes do not contain a medical or personal use exception,<sup>71</sup> and, under the Supremacy Clause, federal law trumps state law whenever the two conflict.<sup>72</sup> The result is that state marijuana liberalization initiatives do not shield anyone from federal

---

a completely political action.”).

70. See MacCoun & Mello, *supra* note 8, at 989; see generally RESTATEMENT (SECOND) OF TORTS § 339 (AM. LAW INST. 1965); PROSSER & KEETON ON TORTS § 59, 399-402 (W. Page Keeton et al. eds., 5th ed. 1984).

71. See, e.g., *Gonzales v. Raich*, 545 U.S. 1 (2005) (summarized *supra* note 7); *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 494–95 (2001).

72. See U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding.”). The conflict occurs not because the states are obligated to prohibit marijuana use. They are not required to adopt any particular criminal law; what they must do is notify the public what they do make a crime. See Paul J. Larkin, Jr., *The Lost Due Process Doctrines*, 66 CATH. U. L. REV. 293, 307–08 (2016). The conflict arises because the state legalization provisions allow an activity prohibited by federal law.

criminal liability.<sup>73</sup>

The Justice Department, however, has not aggressively prosecuted individuals or businesses in states with liberalized marijuana laws. In part, that approach reflects a policy judgment regarding the proper allocation of law enforcement resources—a decision that, as explained below, Attorney General Jeff Sessions has revisited once and could revisit again.<sup>74</sup> In part, the Justice Department’s policy reflects a limitation imposed by a series of congressional appropriations riders that prohibit the department from using federal funds to bring to a halt state medical marijuana programs.<sup>75</sup> The Fiscal Year 2018 appropriations bill carried

---

73. See, e.g., *United States v. Rosenthal*, 454 F.3d 943, 948 (9th Cir. 2006) (ruling that the City of Oakland cannot “deputize” someone to distribute marijuana under state law and render him immune from prosecution under federal law); *United States v. Stacy*, 734 F. Supp. 2d 1074, 1080 (S.D. Cal. 2010) (holding that state medical marijuana laws do not grant a person immunity from prosecution under federal law); *People v. Crouse*, 388 P.3d 39 (Colo. 2017) (ruling that the federal Controlled Substances Act preempts state constitutional provisions requiring the return to an acquitted defendant of any marijuana seized from him).

74. During the Clinton and Bush Administrations, the Justice Department threatened physicians who prescribed marijuana with the loss of their federal license to prescribe controlled substances and said that it aggressively prosecutes marijuana distribution businesses. The Justice Department did not prosecute individual patients, but it did pursue large-scale companies. During the Obama Administration, the Justice Department publicly stated that it would not strictly enforce federal law against patients and caregivers but would prosecute parties and businesses that operated a marijuana dispensary as a sham for drug trafficking or allied crimes, such as money laundering. See *Larkin, Drugged Driving*, *supra* note 4, at 469–70, 470 n.75. In January 2018, Attorney General Sessions repealed the Obama Administration’s Justice Department policies and instructed the U.S. Attorneys to make changing decisions based on their own assessment of the harms from marijuana trafficking in their respective districts. See *infra* notes 97–99 and accompanying text.

75. See Consolidated and Further Continuing Appropriations Act of 2015, Pub. L. No. 113-235, § 538, 128 Stat. 2130, 2217 (2014) (“None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, and Wisconsin,



that provision forward, but it does not apply to recreational marijuana programs or to other federal agencies.

There is an additional issue, however: can and should the FDA address the distribution of edible cannabis on the ground that THC-infused edibles are an “adulterated” food and therefore cannot be distributed through interstate commerce? The federal government ordinarily relies on the Controlled Substances Act to address drug trafficking because of the severity of its penalties, which, in some cases, can result in life imprisonment.<sup>76</sup> But that statute is not the

---

to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”); Larkin, *Drugged Driving*, *supra* note 4, at 464. Congress has carried forward that provision in subsequent appropriations acts. *See* Continuing Appropriations Act, 2016, Pub. L. No. 114-53, § 104, 129 Stat. 502, 506 (2015); Further Continuing Appropriations Act, 2016, Pub. L. No. 114-96, 129 Stat. 2193 (2015); Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 542, 129 Stat. 2242, 2332–33 (2015); Continuing Appropriations Act, 2017, Div. C of the Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations and Zika Response and Preparedness Act, Pub. L. No. 114-223, 130 Stat. 857, 908-20 (2016); Further Continuing and Security Assistance Appropriations Act, 2017, Pub. L. No. 114-254, § 101, 130 Stat. 1005, 1006 (2016); H.R.J. Res. No. 99, Pub. L. No. 115-30, 131 Stat. 134 (2017); Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017); Continuing Appropriations Act, 2018 and Supplemental Appropriations for Disaster Relief Requirements Act 2017, Div. D, Pub. L. No. 115-56, §§ 103–04, 131 Stat. 1129, 1139–47 (2018); H.R.J. Res. No. 123, Further Continuing Appropriations Act, 2018, Div. A, Pub. L. No. 115-90, § 101, 131 Stat. 1280 (2017); H.R. Res. 1370, 115th Cong. (2017) (enacted); Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 538 (Mar. 23, 2018). The appropriations rider was originally named the Rohrabacher-Farr Amendment after the two congressmen—Dana Rohrabacher and Sam Farr—who originally introduced it. Now, it is known as the Rohrabacher-Blumenauer-Leahy Amendment. *See* Dana Rohrabacher, *My Fellow Conservatives Should Protect Medical Marijuana from the Government*, WASH. POST (Sept. 5, 2017), [https://www.washingtonpost.com/opinions/my-fellow-conservatives-should-protect-medical-marijuana-from-the-government/2017/09/05/73b60b0a-91aa-11e7-8754-d478688d23b4\\_story.html?utm\\_term=.d31ac2ce3daa](https://www.washingtonpost.com/opinions/my-fellow-conservatives-should-protect-medical-marijuana-from-the-government/2017/09/05/73b60b0a-91aa-11e7-8754-d478688d23b4_story.html?utm_term=.d31ac2ce3daa); Press Release, Congressman Dana Rohrabacher, *Rohrabacher Applauds Senate Panel for Adopting ‘Rohrabacher-Farr Amendment’* (July 28, 2017), <https://rohrabacher.house.gov/media-center/press-releases/rohrabacher-applauds-senate-panel-for-adopting-rohrabacher-farr>. For convenience, I will refer to the amendment as the Rohrabacher Amendment.

76. *See* Paul J. Larkin, Jr., *Crack Cocaine, Congressional Inaction, and Equal Protection*, 37 HARV. J. L. & PUB. POL’Y 241, 241–42 (2014) (discussing the penalty structure of the Controlled Substances Act).

only tool available to the government. The Federal Food, Drug, and Cosmetic Act (FDCA) bans the introduction of “adulterated” food into interstate commerce in order to ensure the purity of the nation’s food supply.<sup>77</sup> The question, therefore, is whether the FDCA offers the government an additional option it can use against the potential harms posed by marijuana edibles.

It appears that the FDCA can be used in that manner. The FDCA authorizes criminal prosecution, civil remedies, and injunctive relief for a violation of its terms, including the seizure of any adulterated foods.<sup>78</sup> Under the FDCA, a “food”

---

77. 21 U.S.C. § 331(a)–(c) (2012) (“The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. (b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce. (c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.”). Misbranding of edibles can occur in (at least) two ways: They can contain an inaccurate statement of their treatment value for different medical conditions. *See infra* notes 128–37 and accompanying text. Or they can mistakenly advertise the amount of THC in a product. *See Vandrey et al., supra* note 18, at 2491 (“Edible cannabis products from 3 major metropolitan areas, though unregulated, failed to meet basic label accuracy standards for pharmaceuticals. Greater than 50% of products evaluated had significantly less cannabinoid content than labeled, with some products containing negligible amounts of THC. Such products may not produce the desired medical benefit. Other products contained significantly more THC than labeled, placing patients at risk of experiencing adverse effects. Because medical cannabis is recommended for specific health conditions, regulation and quality assurance are needed.”) (footnotes omitted).

78. 21 U.S.C. § 332 (2012) (authorizing injunctive relief); *id.* § 333 (authorizing criminal and civil penalties); *id.* § 334(a)(1) (authorizing judicial seizure); *id.* § 334(g)–(h) (authorizing administrative detention of adulterated and misbranded food and tobacco products); *id.* § 335b (authorizing civil penalties); *see generally* 21 C.F.R. § 1.378 (2017) (authorizing administrative detention of adulterated foods). The FDCA also authorizes the Commissioner of Food, Drugs, and Cosmetics, as the designee of the Secretary of Health and Human Services, 21 U.S.C. § 371(a); 21 C.F.R. § 5.10 (2017), to promulgate food quality standards. 21 U.S.C. § 341 (“Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of

is defined to include “articles used for food or drink for man” and “articles used for components of any such article.”<sup>79</sup> A food is adulterated if it contains any added “poisonous or deleterious substance which may render it injurious to health”;<sup>80</sup> marijuana edibles qualify. Aside from pesticides, fungi, and other toxins,<sup>81</sup> edibles contain THC, a potentially

---

container. . . . In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.”).

79. 21 U.S.C. § 321(f) (2012).

80. *Id.* § 342(a)(1) (“A food shall be deemed to be adulterated . . . [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . .”); *id.* § 346 (“Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title . . . .”); *cf.* COLO. CODE REGS. § 212-2.103 (2017) (“‘Additive’ means any substance added to Retail Marijuana Product that is not a common baking or cooking item.”).

81. The presence of harmful substances in marijuana products aggravates the problem of edibles. Agricultural marijuana is not a standardized product. It can vary by region, manner of cultivation, and potential contaminants. *See, e.g.,* CAULKINS ET AL., MARIJUANA LEGALIZATION, *supra* note 5, at 34 (“One reason for the lack of consensus is that marijuana is not a standardized good . . . .”); *id.* at 68 (“So asking about, or trying to study, the benefits (or harms) of marijuana generically is a little bit like asking what wine tastes like, as if merlot and champagne were interchangeable.”); *see generally* IVERSEN, *supra* note 12, at 5, 115–86. Various reports have also indicated that, despite efforts to avoid contamination, marijuana sold in states such as Colorado and California have been found to contain bacteria, mold, fungi, pesticides, heavy metals, and solvents such as butane and propane. *See, e.g.,* Franziska Busse et al., *Lead Poisoning Due to Adulterated Marijuana*, 358 NEW ENGLAND J. MED. 1641 (2008); Tista Ghosh et al., *The Public Health Framework of Legalized Marijuana in Colorado*, 106 AM. J. PUB. HEALTH 21, 23 (2016) (“The medical literature reports that marijuana can be contaminated by bacteria, mold, chemicals such as pesticides, lead, ammonia, and formaldehyde.”) (footnotes omitted); Gourdet et al., *supra* note 64, at 88; Subritzky et al., *supra* note 6, at 6 (“[T]he presence of fungus and residues remains problematic in Colorado”); *Contaminated Medical Marijuana Believed to Have Killed Cancer Patient*, CBS NEWS (Feb. 7, 2017, 11:08 AM), <https://www.cbsnews.com/news/contaminated-medical-marijuana-pot-believed-to-have-killed-cancer-patient/>; Brian Handwerk, *Modern Marijuana Is Often Laced With Heavy Metals and Fungus*, SMITHSONIAN (Mar. 23, 2015), <https://www.smithsonianmag.com/science-nature/modern-marijuana-more-potent-often-laced-heavy-metals-and-fungus-180954696/> (“Concentrates and edibles (think brownies) make up perhaps half of the current Colorado market . . . some manufacturers employ potentially harmful compounds like butane to strip the

harmful substance, as explained above. A “food additive” is “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food” unless that substance is generally recognized by experts “to be safe under the conditions of its intended use.”<sup>82</sup> THC certainly satisfies

---

plant of most everything but THC. Tests also show that marijuana plants can draw in heavy metals from the soil in which they are grown, and concentrating THC can increase the amounts of heavy metals, pesticides or other substances that end up in a product. ‘People use all kinds of different methods to produce concentrates,’ [Andy] LaFrate [founder of a laboratory certified to test cannabis] says. ‘They allow people to use rubbing alcohol and heptane. But what grade of solvents are they using? Are they buying heptane on eBay, and if so, what exactly is in there? There are a whole bunch of issues to figure out, and right now there are not enough resources and really no watchdog.’”); Brian Melley, *Burners Beware: California Pot Sold Jan. 1 Could be Tainted*, ABC NEWS (Dec. 17, 2017), <http://abcnews.go.com/Technology/wireStory/burners-beware-california-pot-sold-jan-tainted-51846148> (“Any marijuana sold when recreational sales become legal Jan. 1 in the nation’s most populous state will have been grown without regulatory controls that will eventually be in place. Pot could contain pesticides, molds and other contaminants. ‘Buyer beware,’ cautioned Donald Land, a University of California, Davis, chemistry professor who is the chief scientific consultant at Steep Hill Labs Inc., which tests marijuana in several states. Earlier this year, Land oversaw testing that found 93 percent of samples collected by KNBC-TV from 15 dispensaries in four Southern California counties tested positive for pesticides. That may come as a surprise for consumers who tend to trust what’s on store shelves because of federal regulations by the U.S. Agriculture Department or the U.S. Food and Drug Administration. ‘Unfortunately, that’s not true of cannabis,’ Land said. ‘They wrongly assume it’s been tested for safety.’”); Lynne Peeples, *Marijuana Pesticide Contamination Becomes Health Concern as Legalization Spreads*, HUFFINGTON POST (May 24, 2013; 7:44 AM), [https://www.huffingtonpost.com/2013/05/24/marijuana-pesticides-contamination\\_n\\_3328122.html](https://www.huffingtonpost.com/2013/05/24/marijuana-pesticides-contamination_n_3328122.html).

82. 21 U.S.C. § 321(s) (“The term ‘food additive’ means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—(1) a

those requirements. It is intended to become, and in fact becomes, a component of an edible, and it has not been proven to be safe. On the contrary, the FDA has concluded that marijuana is not safe for use in any capacity. In fact, Congress resolved that issue as a matter of law when it placed marijuana in Schedule I of the Controlled Substances Act, the category for drugs that, *inter alia*, pose a danger to human health.<sup>83</sup> That conclusion effectively ends the inquiry. A state recreational marijuana law offers no shield against enforcement of federal law, and the appropriations rider noted above does not apply to recreational marijuana programs or to the FDA. Accordingly, the FDCA empowers the FDA to intervene against the sale of edibles.

However unusual it may seem, prohibiting edibles alone—that is, without also prosecuting the sale of marijuana to be smoked—is not an irrational choice, given the marijuana regulatory regime we have today. Because marijuana is contraband under federal law, the FDA and Justice Department could seize any ingestible or inhalable marijuana products that may be sold under state law, as well as shut down the dispensary itself. To date, the FDA and the Justice Department have not pursued that strategy, preferring to focus on sham distribution schemes and sales to minors. If the government decides to continue with that approach, it could readily pursue administrative, civil, and criminal actions against the sale of edibles, given the certainty that, as a practical matter, edibles will wind up in the hands of minors. The result would be that the government could shut down the distribution of THC-infused foods, while allowing marijuana to be sold in non-edible

---

pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C.A. § 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C.A. § 601 et seq.]; (5) a new animal drug; or (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.”).

83. Larkin, *Drugged Driving*, *supra* note 4, at 460 & n.27.

forms, as a way to lessen the risk that minors, particularly children, will consume attractive, innocent-looking brownies, candies, and the like.<sup>84</sup>

To be sure, this two-pronged approach is an odd way to approach this problem. Stopping the commercial production of edibles would drive some people to make their own—where there is no quality control—and some others to smoke marijuana—which creates its own set of problems. As long as the concentrated form of marijuana is available, some people will make their own edibles. (That is particularly true if, as seems likely, the price of concentrate will fall, due to a decreased demand, if edibles are banned.) The result will be a lack of statewide quality control, which increases the risk of an unintentional overdose, particularly by minors who are amateur chefs—and amateur chemists—as well as a greater risk of consuming a product contaminated with various toxins. If people switch to smoking marijuana, there are other risks. No other drug is smoked because smoking does not guarantee that a predetermined amount of a medicine will be delivered to the body—for example, there is no uniform number of “puffs” or depth of an individual puff—and smoking marijuana carries with it many of the harms of smoking tobacco—for example, it irritates the lung tissues. Nonetheless, like all compromise solutions, this one is not perfect, but it does address one fear that society has.

Why then has the FDA not taken any step to halt the distribution of edibles since California enacted the first medical marijuana law in 1996? Three explanations come to mind.

One is that the FDA decided to leave the entire subject of marijuana to the federal law enforcement agencies because the Controlled Substances Act deems marijuana contraband.<sup>85</sup> That is, the FDA saw no reason to regulate the

---

84. A narrower option would be to stop the interstate distribution of *sweetened* edibles, given that a high sugar content may attract children.

85. The Controlled Substances Act was enacted as Title II of the

sale of a drug that cannot be lawfully sold.<sup>86</sup> That explanation makes sense on its face, but is ultimately flawed in the case of edibles. A rule prohibiting a particular substance from being added to food is a form of regulation, but it does not imply that all other substances are permissible additives. In other words, the directive, “you may not add *A* to food,” does not imply that *B*, *C*, and the other letters in the alphabet can be included in a food product sold to the public. To eliminate any doubt, the FDA could make that point in the same rule banning the sale of edibles.<sup>87</sup>

The second reason may be that the agency chose to avoid becoming involved in the battles over the proper federal

---

Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236. Under that act, a “controlled substance” is “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title,” except for “distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.” 21 U.S.C. § 802(6) (2012). The Controlled Substances Act incorporates the definition of a “drug” from the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 201 (g)(1) (2017). Congress placed marijuana in Schedule I when it enacted the Controlled Substances Act. *See Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 n.1 (D.C. Cir. 1991). Marijuana (and its salts, isomers, and synthetic equivalents) remains on that list today. 21 C.F.R. § 1308.11(d)(31) (2017). Drugs placed on Schedule I drugs are one found to have no accepted medical use and pose a serious danger of harm and addiction. Physicians cannot prescribe Schedule I drugs. Larkin, *Drugged Driving*, *supra* note 4, at 460 & nn.26–27.

86. MacCoun & Mello, *supra* note 8, at 990.

87. The FDA could say something like this:

Section 1: Because THC and other ingredients in marijuana can have adverse effects on people, food products, commonly known as ‘edibles,’ cannot be distributed in interstate commerce if they contain THC or other cannabinoids found in marijuana. Section 2: The ban in Section 1 on the use of THC or other cannabinoids in food is not a license or approval to distribute those substances in interstate commerce in any other manner.

An agency generally has the last word on the meaning of its own regulations unless its reading is inconsistent with the text of the rule. Under settled law, when an agency’s interpretation of its own regulation is at stake, “the ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.” *See Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *accord, e.g., Auer v. Robbins*, 519 U.S. 452, 461 (1997) (reaffirming the *Seminole Rock* standard).

response to state marijuana legalization. Current legalization proposals focus on the recreational use of marijuana, but the initial proposals sought only to permit marijuana to be used as a “treatment” for various afflictions. Supporters of medical marijuana argued that it could help alleviate the suffering of the dying or grievously impaired, particularly when smoked.<sup>88</sup> They pointed to individuals disabled by chemotherapy-induced nausea and vomiting, the weight loss associated with HIV/AIDS, the neuropathic pain and spasticity afflicting victims of multiple sclerosis, the chronic pain in adults that over-the-counter analgesics cannot assuage, and the sleep disturbances that are consequent upon several different diseases.<sup>89</sup> Supporters also argued that it is irrational to be worried about long-term health problems for someone who is in the end stages of a terminal disease or is presently suffering from the type of intractable pain, nausea, and vomiting that would make anyone wish that death were near.<sup>90</sup> The FDA may have decided that Presidents Clinton, Bush, and Obama were unwilling to endure the political blowback that would result from armed federal agents seizing marijuana from hospices and homes that would be displayed all-day across television screens. The FDA may have feared that intervening in this fray would lead to irreparable damage to its authority and image from being chastened by the media and corralled by the president, and perhaps, Congress. The FDA may have

---

88. Smoked plant-form marijuana, supporters contend, is superior to other, synthetic THC delivery vehicles (*e.g.*, pills, inhalants, and suppositories) approved by the U.S. Food and Drug Administration (*e.g.*, Dronabinol) or other nations (*e.g.*, Nabiximol) because inhalation works more effectively and more quickly, reaching the brain within seconds. *See, e.g.*, NAT'L ACAD. REP., *supra* note 5, at 54; IVERSEN, *supra* note 12, at 45–47.

89. *See, e.g.*, NAT'L ACAD. REP., *supra* note 5, at 128 (listing conditions for which marijuana is a treatment for which there are varying degrees of scientific support); IVERSEN, *supra* note 12, at 131, 140–48, 162; Volkow et al., *supra* note 28, at 2224 (listing clinical conditions with symptoms marijuana may alleviate); *supra* note 28.

90. *See, e.g.*, Jerome P. Kassirer, *Federal Foolishness and Marijuana*, 336 NEW ENG. J. MED. 366, 366 (1997).



decided to wait until it was sure that the political branches would support its intervention.

That wait may not yet be over. The federal political branches have yet to decide on the appropriate federal response to state marijuana legalization. Congress has largely stayed out of the debate. With the one exception adumbrated above and discussed below regarding the Justice Department's prosecution policies, Congress has studiously avoided any serious debate over the legality of medical or recreational marijuana. As far as the executive branch goes, the administrations of former Presidents Bill Clinton, George W. Bush, and Barack Obama did not come to a settled position. From 1996, when California adopted the first medical marijuana initiative, through the end of the Obama Administration, the Justice Department has gone back and forth on the issue of whether it should prosecute the sale of marijuana in states with medical and recreational marijuana régimes. In fact, the initial response, set forth early in 1997, only three months after California passed its medical marijuana initiative, by Barry McCaffrey, the high-profile Director of the Office of National Drug Control Policy in the Clinton Administration, was to threaten any physician who prescribed marijuana for a patient with the loss of his license to prescribe controlled substances.<sup>91</sup> The Clinton and Bush Administrations also signaled that they would ignore the state liberalization measures and prosecute businesses distributing cannabis.<sup>92</sup> By contrast, the Obama Administration adopted a policy of largely declining to enforce federal law against patients, caregivers, and recreational users and of focusing on businesses engaged in

---

91. McCaffrey made that point in no uncertain terms. See Administration Response to Arizona Proposition 200 and California Proposition 215, 62 Fed. Reg. 6164, 6164 (Feb. 11, 1997) (warning that the "DEA will seek to revoke the DEA registrations of physicians who recommend or prescribe Schedule I controlled substances").

92. Larkin, *Drugged Driving*, *supra* note 4, at 469.

large-scale trafficking in cannabis or the sale to minors.<sup>93</sup> Indeed, the growth in states' medical marijuana programs coincides with the release in October 2009 of a memorandum signed by Deputy Attorney General David Ogden—known as the Ogden Memorandum—announcing a policy that was seen as a hands-off approach toward the sale of medical marijuana in compliance with state law, while the growth in recreational marijuana laws resulted from the 2013 Cole Memorandum, which signaled that the Justice Department would take the same approach toward state recreational marijuana programs as long as they were applied in accordance with state law.<sup>94</sup> The Justice Department represented the FDA in federal court,<sup>95</sup> so it may have made little sense to the agency to adopt a position treating edibles as adulterated under the FDCA if the Justice Department would not defend that position in court.

It is unclear what will happen now. In 2017, Attorney

---

93. See Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Justice, for United States Attorneys on Guidance Regarding Marijuana Enforcement (Aug. 29, 2013); Memorandum from David W. Ogden, Deputy Att'y Gen., U.S. Dep't of Justice, for Selected United States Attorneys on Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana (Oct. 19, 2009); see also Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Justice, for United States Attorneys on Guidance Regarding Marijuana Related Financial Crimes (Feb. 14, 2014); Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Justice, for United States Attorneys on Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use (June 30, 2011); BARCOTT, *supra* note 55, at 65.

94. See Monte et al., *supra* note 5, at 241 ("Few patients used medical marijuana until October 2009, when the US Attorney General distributed guidelines for federal prosecution of the possession and use of marijuana, ceding jurisdiction of marijuana law enforcement to state governments. The combination of permissive local law and the federal policy change effectively liberalized the sale and use of medical marijuana in Colorado. Anyone with one of the conditions outlined by Colorado law could be issued a medical marijuana license with no expiration date. The number of licenses increased from 4819 on December 30, 2008, to 116 287 on September 30, 2014."); Onders, *supra* note 30, at 433; Wang et al., *Multistate Study 2005–2011*, *supra* note 14, at 688.

95. See 28 U.S.C. §§ 503, 506, 509–519 (2006) (authorizing the Attorney General to supervise all federal litigation); FDA ENFORCEMENT MANUAL ¶ 1220 (2015).

General Jeff Sessions said that the widespread sale of marijuana was harmful for the nation, which indicated a willingness to reconsider the enforcement positions of his predecessors.<sup>96</sup> On January 4, 2018, he decided to revisit the Justice Department's policy and both the Cole and Ogden Memoranda.<sup>97</sup> The Sessions Memorandum stated that U.S. Attorneys should make charging decisions based on the seriousness of marijuana trafficking in their respective jurisdictions.<sup>98</sup>

The 2018 Sessions Memorandum does not indicate that it will be the only change in marijuana policy that we may see in the Trump Administration. Sessions may not attempt to fully return the department to the position that it held prior to the post-1996 state marijuana reform efforts, but there is additional room for him to expand the department's efforts to suppress large-scale commercial marijuana operations. If he does, he may decide to enlist the FDA's support, and, if he does, that would prevent the FDA from standing on the sidelines. A formal declaration by Attorney General Sessions that the executive branch will aggressively pursue civil and criminal enforcement actions against the distribution of marijuana edibles under the Controlled Substances Act and FDCA would force the FDA to take a position on one side or the other regarding its enforcement authority and priorities. That might lead President Trump and Congress to enter the fray as well.

Regardless of what executive branch officials decide to do, marijuana legalization's supporters will pressure

---

96. See, e.g., Tom Angell, *Jeff Sessions Slams Marijuana Legalization (Again)*, FORBES (Sept. 27, 2017), <https://www.forbes.com/sites/tomangell/2017/09/20/jeff-sessions-slams-marijuana-legalization-again/#3afea92a27d1>.

97. Press Release, U.S. Dep't of Justice, Marijuana Enforcement (Aug. 29, 2013) (on file with author), <https://www.justice.gov/opa/press-release/file/1022196/download>; see Charlie Savage & Jack Healy, *Trump Administration Takes Step That Could Threaten Marijuana Legalization Movement*, N.Y. TIMES (Jan. 4, 2018), <https://www.nytimes.com/2018/01/04/us/politics/marijuana-legalization-justice-department-prosecutions.html>.

98. See Press Release, U.S. Dep't of Justice, *supra* note 97.

Congress to halt any aggressive use of federal law to stem the sale of edibles. Marijuana legalization is potentially a huge business for private parties and a new source of revenue for states. Estimates are that marijuana legalization will generate thousands of jobs, along with billions of dollars in revenues for private parties and state governments over the next few years.<sup>99</sup> People who stand to make or lose that

---

99. See, e.g., Debra Borchart, *Marijuana Industry Projected to Create More Jobs than Manufacturing by 2020*, FORBES (Feb. 22, 2017), <https://www.forbes.com/sites/debraborchart/2017/02/22/marijuana-industry-projected-to-create-more-jobs-than-manufacturing-by-2020/> (“A new report from New Frontier Data projects that by 2020 the legal cannabis market will create more than a quarter of a million jobs. This is more than the expected jobs from manufacturing, utilities or even government jobs, according to the Bureau of Labor Statistics. The BLS says that by 2024 manufacturing jobs are expected to decline by 814,000, utilities will lose 47,000 jobs and government jobs will decline by 383,000. This dovetails with data that suggests the fastest-growing industries are all healthcare related. The legal cannabis market was worth an estimated \$7.2 billion in 2016 and is projected to grow at a compound annual rate of 17%. Medical marijuana sales are projected to grow from \$4.7 billion in 2016 to \$13.3 billion in 2020. Adult recreational sales are estimated to jump from \$2.6 billion in 2016 to \$11.2 billion by 2020.”); Rory Campbell, *Hippy Dream Now a Billion-Dollar Industry with California Set to Legalize Cannabis*, GUARDIAN (Dec. 30, 2017), <https://amp.theguardian.com/us-news/2017/dec/30/california-legalise-cannabis-hippy-dream-billion-dollar-industry> (“The Salinas Valley, an agricultural zone south of San Francisco nicknamed America’s salad bowl, has already earned a new moniker: America’s cannabis bucket. Silicon Valley investors and other moneyed folk are hoping to mint fortunes by developing technology to cultivate, transport, store and sell weed. Entrepreneurs are devising pot-related products and services. Financiers are exploring ways to fold the revenue – estimated at \$7bn per annum by 2020—into corporate banking.”); Chris Morris, *Legal Marijuana Sales Are Expected to Hit \$10 Billion This Year*, FORTUNE (Dec. 6, 2017), <http://fortune.com/2017/12/06/legal-marijuana-sales-10-billion/>; Aaron Smith, *Market for Legal Pot Could Pass \$20 Billion*, CNN MONEY (Nov. 11, 2017, 7:08 AM), <http://money.cnn.com/2016/11/09/news/economy/marijuana-legalization-sales/index.html> (“Voters in four states approved legal recreational pot on Tuesday. Four more states expanded access to medical marijuana. All told, it could expand the national market to \$21 billion by 2020, according to New Frontier Data, which partnered with the marijuana industry organization Arcview Group. That is up from \$5.7 billion last year and an expected \$7.9 billion this year.”); Aaron Smith, *Colorado Passes a Milestone for Pot Revenue*, CNN MONEY (July 19, 2017, 2:52 PM), <http://money.cnn.com/2017/07/19/news/colorado-marijuana-tax-revenue/index.html> (“VS Strategies, a pro-legalization research company in Denver, says that the state has pulled in \$506 million since retail revenues began in January 2014. . . . Revenue from taxes and fees has increased each year, from \$76 million in 2014 to \$200 million last year, and the

much money are not likely to watch idly as elected federal officials decide what to do. If they are not already making their voices heard in Congress—especially to members of the California delegation—they will.<sup>100</sup>

The third reason why the FDA may have chosen to stand on the sidelines is that the federal government may have broadly read an appropriations rider restricting the Justice Department from nullifying state medical marijuana programs. As explained above, in 2014, Congress added a provision to the Consolidated and Further Continuing Appropriations Act of 2015, prohibiting the Department of Justice from using federal funds to “prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”<sup>101</sup> The U.S. Court of Appeals for the Ninth Circuit construed that provision in 2016 in a case involving large-scale traffickers, *United States v. McIntosh*.<sup>102</sup> The

---

state is on track to beat that this year, according to VS Strategies, which used state revenue data in its report Wednesday.”).

100. See Morris, *supra* note 99 (“California’s medical marijuana market is already as big as the total markets in Colorado, Washington, and Oregon combined, according to BDS Analytics’ GreenEdge point-of-sale tracking service. Given the boost from that state and others that could change their laws (including New Jersey), Arcview says that it expects the legal cannabis market to reach sales of \$24.5 billion by 2021.”).

101. See Consolidated and Further Continuing Appropriations Act of 2015, *supra* note 75.

102. 833 F.3d 1163 (9th Cir. 2016). The facts were the following:

In *McIntosh*, five codefendants allegedly ran four marijuana stores in the Los Angeles area known as Hollywood Compassionate Care (HCC) and Happy Days, and nine indoor marijuana grow sites in the San Francisco and Los Angeles areas. These codefendants were indicted for conspiracy to manufacture, to possess with intent to distribute, and to distribute more than 1000 marijuana plants in violation of 21 U.S.C. §§ 846, 841(a)(1), 841(b)(1)(A). The government sought forfeiture derived from such violations under 21 U.S.C. § 853. In *Lovan*, the U.S. Drug Enforcement Agency and Fresno County Sheriff’s Office executed a federal search warrant on 60 acres of land located on North Zedicker Road in Sanger, California. Officials allegedly located more than 30,000 marijuana plants on this property. Four codefendants were indicted for manufacturing 1000 or more marijuana plants and for conspiracy to

defendants argued that the rider barred the government from prosecuting them for any marijuana-related offense because they were licensed under California and Washington state law to grow and distribute marijuana. *McIntosh* held that the appropriations rider bars the federal government from prosecuting someone who fully complies with the medical marijuana laws in his state. The court reasoned that, “[i]f the federal government prosecutes such individuals, it has prevented the state from giving practical effect to its law providing for non-prosecution of individuals who engage in the permitted conduct.”<sup>103</sup> During the Obama Administration, the Justice Department might have concluded that the *McIntosh* case was correctly decided. If so, the department read that case too broadly.

The Ninth Circuit concluded that the California and Washington laws sought to immunize parties from a federal prosecution if they complied with state law. The relevant issue in *McIntosh*, however, was whether the criminal prosecution brought in *McIntosh* would “prevent” those states from “implementing” their medical marijuana program. It is difficult to see how any one prosecution would “prevent” a state from “implementing” such a program as long as other uncharged parties can grow and distribute

---

manufacture 1000 or more marijuana plants in violation of 21 U.S.C. §§ 841(a)(1), 846. In *Kynaston*, five codefendants face charges that arose out of the execution of a Washington State search warrant related to an investigation into violations of Washington’s Controlled Substances Act. Allegedly, a total of 562 ‘growing marijuana plants,’ along with another 677 pots, some of which appeared to have the root structures of suspected harvested marijuana plants, were found. The codefendants were indicted for conspiring to manufacture 1000 or more marijuana plants, manufacturing 1000 or more marijuana plants, possessing with intent to distribute 100 or more marijuana plants, possessing a firearm in furtherance of a Title 21 offense, maintaining a drug-involved premise, and being felons in possession of a firearm in violation of 18 U.S.C. §§ 922(g)(1), 924(c)(1)(A)(i) and 21 U.S.C. §§ 841, 856(a)(1).

*Id.* at 1169.

103. *Id.* at 1177.

marijuana.<sup>104</sup> In any event, the purpose of the rider is to keep the Justice Department from bringing a criminal prosecution against someone involved in the distribution of medical marijuana, not recreational marijuana. The omission of the latter is significant because Congress certainly knows about the difference and, by declining to keep the Justice Department from charging people or businesses involved in recreational marijuana sales, did not intend to prevent the Justice Department from prosecuting the latter.

Legalization's supporters will argue that, although the Rohrabacher Amendment does not specifically refer to the FDA, the Justice Department is the FDA's lawyer, and the amendment limits the department's ability to represent its client. That is, the argument will be that the amendment should not be limited to keeping the Justice Department from bringing criminal prosecutions or asset-forfeiture proceedings, but should also be read to bar the department's

---

104. There is an additional factor to consider—namely, the appropriations rider cannot be read broadly. A government official who violates an appropriations law limitation can be criminally prosecuted for his actions under the Antideficiency Act. *See* 31 U.S.C. § 1341(a)(1)(A) (2012) (“An officer or employee of the United States Government or of the District of Columbia government may not . . . make or authorize an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation . . . .”); 31 U.S.C. § 1350 (“An officer or employee of the United States Government or of the District of Columbia government knowingly and willfully violating section 1341(a) or 1342 of this title shall be fined not more than \$5,000, imprisoned for not more than 2 years, or both.”). The appropriations rider has the effect of a criminal law, which means it cannot be read broadly and any doubt as to its meaning must be resolved by application of the Rule of Lenity. *See, e.g.,* *United States v. Santos*, 553 U.S. 507, 514 (2008) (plurality opinion); Paul J. Larkin, Jr., *Chevron and Federal Criminal Law*, 33 J. L. & POL. 211, 228–29 (2017). That is significant because the term “prevent” can be read narrowly, as meaning to “avert” or “keep [something] from occurring,” or broadly, as including an action that “hinders” someone from acting. *See* Dictionary.com (“prevent”: “verb (used with object) 1. to keep from occurring; avert; hinder: He intervened to prevent bloodshed. 2. to hinder or stop from doing something: There is nothing to prevent us from going. 3. Archaic. to act ahead of; forestall. 4. Archaic. to precede. 5. Archaic. to anticipate.”). *Prevent*, DICTIONARY.COM, <http://www.dictionary.com/browse/prevent?s=t> (last visited Feb. 17, 2018). Because the Antideficiency Act is a criminal statute, the term “prevent” should be narrowly read to mean “halt,” not broadly to include “hinder.”

lawyers from representing the FDA in any action that would have the effect of shutting down a state's medical marijuana regime. The purpose of the Rohrabacher Amendment is to allow states to decide whether to operate medical marijuana programs without fear that the Justice Department will use its litigating authority to shut down any such operation. Accordingly, the amendment should be construed broadly so that it prohibits Justice Department lawyers from representing the FDA if it were to bring an enforcement action against a business on the ground that it sold marijuana edibles that were adulterated or misbranded.

That argument is inventive, but ultimately is unpersuasive.

Start with the fact that the Rohrabacher Amendment does not repeal or revise the FDCA, nor does it limit what the FDA can do with its appropriated funds. The amendment therefore does not affect the ability of the FDA to pursue whatever steps it can independently take to prevent the distribution of adulterated foods in interstate commerce. Given that Congress has not forbidden the FDA from taking action under the FDCA against adulterated or misbranded food products, it is unreasonable to construe the Rohrabacher Amendment as limiting the FDA's authority to protect the public health. After all, it is the FDA's mission to prevent adulterated or misbranded food products from entering the stream of commerce. The Justice Department is merely the agency's lawyer.

That distinction is an important one. It was not the fear of actions potentially undertaken by the FDA to prevent the distribution of adulterated or misbranded food or drugs that lead Representative Dana Rohrabacher to propose, and Congress to adopt the Rohrabacher Amendment; nor was it the Justice Department's role as the FDA's in-court counsel that saw to the amendment's passage. It was the fear of armed federal agents arresting seriously ill medical patients and removing them from their homes, nursing facilities, or



hospices.<sup>105</sup> In some instances, that was more than a mere “fear.” In 2002, Drug Enforcement Administration agents entered the home of a medical marijuana patient and seized six marijuana plants. As one commentator put it:

---

105. See Rohrabacher, *supra* note 75 (“I wrote an amendment to spending bills that prohibits the federal government from prosecuting medical marijuana cases in states where voters have legalized such treatment.”); Alex Kreit, *Beyond the Prohibition Debate: Thoughts on Federal Drug Laws in an Age of State Reforms*, 13 CHAPMAN L. REV. 555, 569–70 (2010) (“Between them, [*Gonzales v. Raich*, 545 U.S. 1 (2005) and *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 494–95 (2001)] left little doubt that federal officials could constitutionally prosecute medical marijuana growers, providers, and even patients themselves. And, throughout the past decade, the federal government enthusiastically exercised this authority, at least in California. It has raided at least 190 medical marijuana collectives and brought criminal charges against medical marijuana growers and collective operators, many of whom were operating in strict compliance with California’s law. In one high profile prosecution, for example, the federal government obtained a conviction against Charlie Lynch, who operated a medical marijuana collective in Morro Bay, California. Lynch had the backing of town officials and even held a ribbon-cutting ceremony attended by the mayor and members of the city council when he opened up shop. At his sentencing, District Court Judge George H. Wu indicated some displeasure with having to impose a one-year jail sentence for Lynch. The New York Times reported that Wu ‘talked at length about what he said were Mr. Lynch’s many efforts to follow California’s laws on marijuana dispensaries’ before concluding: ‘I find I cannot get around the one-year sentence . . . .’ The DEA has even gone after landlords who have knowingly rented their property to medical marijuana collective operators and growers through asset forfeiture proceedings.”) (footnotes omitted); Zach Harris, *A Brief History of Rohrabacher-Farr: The Federal Amendment Protecting Medical Marijuana*, MERRY JANE (Dec. 19, 2017), <https://merryjane.com/news/a-brief-history-of-rohrabacher-farr-the-federal-amendment-protecting-medical-marijuana> (“[T]he Rohrabacher-Farr amendment . . . prevents the Department of Justice from spending federal funds to prosecute cannabis-related activities if they are permitted under state-specific medical marijuana laws.”); Michael M. O’Hear, *Federalism and Drug Control*, 57 VAND. L. REV. 783, 840 n.322 (2004) (“Federal agents have raided medical marijuana distribution organizations in West Hollywood, San Francisco, Oakland, and Sebastopol.”); Maria Alicia Gaura, *Santa Cruz Officials Fume over Medical Pot Club Bust/DEA Arrests Founders, Confiscates Plants*, S.F. CHRON. (Sept. 6, 2002), <http://www.sfgate.com/bayarea/article/Santa-Cruz-officials-fume-over-medical-pot-club-2773777.php>; Charlie LeDuff & Adam Liptak, *Defiant California City Hands Out Marijuana*, N.Y. TIMES (Sept. 18, 2002), <http://www.nytimes.com/2002/09/18/us/defiant-california-city-hands-out-marijuana.html>; cf. *Gonzales v. Raich*, 545 U.S. 1 (2005) (lawsuit brought against the attorney general and the DEA to enjoin the enforcement of the federal controlled substances laws against the use of home-grown marijuana for medical purposes); *supra* notes 7, 69 & 71.

When thirty federal Drug Enforcement Administration (DEA) agents armed with M-16s burst into a medical marijuana hospice in Santa Cruz, California, on September 5, 2002, arresting the two owners and a wheelchair-bound patient disabled by polio, they propelled an already contentious debate between the federal government and state leaders to new heights.<sup>106</sup>

Those events in a California town could not have been lost on Dana Rohrabacher, a Congressman from California, when he offered his amendment. That fear still resonates today.<sup>107</sup>

---

106. Alex Kreit, Comment, *The Future of Medical Marijuana: Should the States Grow Their Own?*, 151 U. PA. L. REV. 1787, 1787 (2003) (footnotes omitted); see also, e.g., HUDAK, *supra* note 15, at 141 (“[T]he Clinton and George W. Bush administrations tried to enforce federal law, authorizing the DEA and the FBI to work with local law enforcement to raid medical marijuana operations across the American West. Grow operations and processors were shut down. Co-op participants were handcuffed and assets were seized. Anecdotes abound of terminally ill patients being treated like street criminals for being caught tending their plants when federal agents arrived”). That incident sparked considerable political protest in California. Kreit, *supra*, at 1787–88 (“In response, Santa Cruz officials, who had ‘cooperated closely’ with the hospice for six years, ‘issued a provocative public challenge’ to the DEA by organizing an event to distribute medical marijuana on the steps of City Hall. Mayor Christopher Krohn, who attended the event alongside city council members, said that ‘[c]learly, state law and federal law are on a collision course’ and vowed to stand by the hospice until federal law changed. Vice-Mayor Emily Reilly went even further, calling it ‘absolutely loathsome . . . that federal money, energy and staff time would be used to harass people like this. . . . The outrage spread quickly from Santa Cruz to other parts of California. Patients organized protests across the state, and ‘State Attorney General Bill Lockyer protested and demanded a meeting with [U.S. Attorney General John] Ashcroft.’ Just a few weeks after the Santa Cruz City Hall event, San José Police Chief William Lansdowne removed his officers from the DEA’s High Intensity Drug Trafficking Area task force in protest. Officials in other California cities followed San José’s lead and asked their police officers to ‘stop cooperating with federal agents.’”) (footnotes omitted); Christopher Krohn, Opinion, *Why I’m Fighting Federal Drug Laws from City Hall*, N.Y. TIMES, Sept. 21, 2002, at A15 (“How did I, a mayor of a small town in California, wind up in a tug of war with the Drug Enforcement Agency? This week, I stood in front of Santa Cruz’s city hall as a local group that provides medical marijuana went about its weekly task of distributing the drug to the sick and dying. . . . My story begins on the morning of Sept. 5 when approximately 30 men, dressed in military fatigues and carrying automatic weapons, descended on a small cooperative farm run by the Wo/Men’s Alliance for Medical Marijuana in northern Santa Cruz County, about 65 miles south of San Francisco.”).

107. See, e.g., Robin Abcarian, *Drug War Overkill: A Post Bust against Legal Growers in Yolo County Seems to Go Too Far*, L.A. TIMES (Jan. 6, 2017), <http://www.latimes.com/local/abcarian/la-me-abcarian-pot-bust-20170106->

It is important to remember that protecting the public against adulterated food is one of the FDA's historic missions. This task originated in the Pure Food and Drug Act of 1906.<sup>108</sup> Signed into law by President Theodore Roosevelt on the same day that he signed the companion bill, Federal Meat Inspection Act of 1906,<sup>109</sup> the Pure Food and Drug Act was a response to "extensive evidence of product adulteration and industrial fraud," as described in Upton Sinclair's novel

---

story.html ("I sat with Hicks and Mears on Wednesday in the office of their Sacramento attorney, Mark Reichel, and both grew tearful as they recalled the terror they felt when dozens of gun-wielding officers pounded on their front doors the morning of Sept. 14. 'I told my 2-year-old son to stay upstairs,' said Mears, 35. 'When I opened the security door, there were 15 cops with assault rifles drawn, pointed, with their fingers on the trigger, in vests, ski masks. They grabbed me and pulled me out front, put me in handcuffs. There were 20 to 30 officers. My son walked downstairs and my wife had to grab him. They had guns pulled on them. It was real painful. Easily, it was the worst day of my life,' said Hicks, 43. 'Every gun you can imagine was pointed at me. I was like, 'Why is this happening?' To add icing to the cake, it was my son's fourth birthday.'"); Thomas Fuller, *Medical Marijuana Is Legal in California. Except When It's Not*, N.Y. TIMES (Nov. 21, 2016), <https://www.nytimes.com/2016/11/22/us/medical-marijuana-is-legal-in-california-except-when-its-not.html> ("CannaCraft produces medical marijuana products, which have been legal in the state for two decades, but operated in a kind of Wild West, unregulated market. In June, the company's newly opened headquarters was raided by federal and local law enforcement officers, who said the process it used to make marijuana products was dangerous and illegal. . . . In May, the company hosted nearly 50 state lawmakers and regulators from Sacramento, the state capital, to demonstrate the process it uses to produce the soft-gel capsules and other cannabis-based products that do not involve smoking. . . . But two weeks after the visit . . . around 100 officers and agents wearing tactical gear, and representing multiple law enforcement agencies, raided the company's headquarters and four other facilities."); Angelique Moss, *Collision of Federal and State Laws about Medical Marijuana Threatens to Make Patients, Legal 'Casualties'*, POLICY (May 15, 2016), <https://thepolicy.us/collision-of-federal-and-state-laws-about-medical-marijuana-threatens-to-make-patients-legal-483a0865e738> ("The growth, manufacture, and distribution of medical marijuana have all been legalized in 24 U.S. states, but current federal laws which prohibit their use are placing well-meaning medical marijuana patients and doctors in legal jeopardy. As the Department of Justice, politicians, and lawyers on both sides wrestle with the reconciliation and resolution of the application of two contradicting laws in one location, the friendly neighbor down the street who grows his own cannabis in order to treat his child's epileptic illness can face arrest, prosecution, and possible imprisonment.").

108. Act of June 30, 1906, ch. 3915, Pub. L. No. 59-348, 34 Stat. 786 (1906).

109. Act of March 4, 1907, ch. 2907, Pub. L. No. 59-242, 34 Stat. 1256 (1906).

*The Jungle* and other then-contemporary publications.<sup>110</sup> With respect to food, the act provided that “an article shall be deemed to be adulterated” if it contained “any added poisonous or other added deleterious ingredient which may render such article injurious to health,”<sup>111</sup> while a food would be deemed “misbranded” if it were “labeled or branded so as to deceive or mislead the purchaser.”<sup>112</sup> To enforce that section, the act assigned to the U.S. Department of Agriculture’s Bureau of Chemistry, which ultimately became the FDA, the responsibility to prevent the shipment of adulterated or misbranded foods in interstate commerce by inspecting food and drug products and referring violators for prosecution.<sup>113</sup> The Pure Food and Drug Act “prohibited the addition of any ingredients that . . . [would] pose a health hazard.”<sup>114</sup> When the FDA replaced the Pure Food and Drug Act in 1938 with the FDCA, Congress directed the FDA to continue the food protection responsibilities of its predecessor agency.<sup>115</sup> The FDA has carried out that

---

110. Ilyse D. Barkan, *Industry Invites Regulation, The Passage of the Pure Food and Drug Act of 1906*, 75 AM. J. PUB. HEALTH 18, 21 (1985) (footnotes omitted); see also INST. MED & NAT’L RESEARCH COUNCIL, *Ensuring Safe Food from Production to Consumption* 21–22, 26–27 (1998); Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors and Forces that Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act*, 69 FOOD & DRUG L. J. 315 (2014).

111. Pure Food and Drug Act § 7, 34 Stat. at 769–70 (1906).

112. *Id.* § 8, 34 Stat. at 770. Interestingly, Congress also provided that a food was misbranded if it did not “bear a statement on the label of the quantity or proportion of” several components that would today be labeled controlled substances, including “cannabis indica.” *Id.*

113. *Id.* §§ 4–5, 34 Stat. at 769.

114. See *The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/EvolvingPowers/ucm054819.htm> (last updated Feb. 1, 2018).

115. See Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 321, 331 (2018); *1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/EvolvingPowers/ucm054826.htm> (last updated Feb. 1, 2018); *Drugs and Foods Under the 1938 Act and Its Amendments*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/EvolvingPowers/ucm055118.htm> (last updated Feb. 1, 2018). Since then, Congress has also enacted the Food Safety Modernization

mandate by issuing regulations or guidance documents and by taking enforcement action when necessary.<sup>116</sup>

That history is particularly important here because the appropriations rider does not state or suggest that Congress intended to restrict the FDA's authority to protect the public against an unsafe food product. The FDCA and the Controlled Substances Act are two entirely separate laws; the latter does not refer to the former, let alone expressly repeal any portion of it. Accordingly, the appropriations rider could limit the FDA's authority only if it repealed by implication the relevant provisions of the FDCA dealing with food products. That, however, would be a difficult hurdle to overcome. A settled rule of statutory interpretation is that two acts of Congress should be construed in a manner that harmonizes their operation, rather than conflict with each other. The Supreme Court has noted that the "rarity" of

---

Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011), to enhance the FDA's ability to protect the food supply.

116. For example, the FDA has recognized that lead can contaminate candies eaten by children and has set limits as to the maximum amount permitted (1 part per million). *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: LEAD IN CANDY LIKELY TO BE CONSUMED FREQUENTLY BY SMALL CHILDREN (2006); U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., SUPPORTING DOCUMENT FOR RECOMMENDED MAXIMUM LEVEL FOR LEAD IN CANDY LIKELY TO BE CONSUMED FREQUENTLY BY SMALL CHILDREN (2006); U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: LETTER TO MANUFACTURERS, IMPORTERS, AND DISTRIBUTORS OF IMPORTED CANDY AND CANDY WRAPPERS (1995); *see also* U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., FOOD DEFENSE GUIDANCE DOCUMENTS & REGULATORY INFORMATION (2017) (collecting memoranda and information); U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION: WHAT YOU NEED TO KNOW ABOUT THE FDA REGULATION: GUIDANCE FOR INDUSTRY SMALL ENTITY COMPLIANCE GUIDE (2017); U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., CNTR. FOR DRUG EVALUATION AND RESEARCH, CNTR. FOR BIOLOGICS EVALUATION AND RESEARCH, GUIDANCE FOR INDUSTRY, WARNINGS AND PRECAUTIONS, CONTRAINDICATIONS, AND BOXED WARNING SECTIONS OF LABELING FOR HUMAN PRESCRIPTION PRODUCTS AND BIOLOGICAL PRODUCTS—CONTENT AND FORMAT (2011). If the FDA were to find that THC-infused food products are "adulterated" or "misbranded" under the FDCA, the FDA could take action against edibles. Or if the FDA found that there is a public health risk that accidentally ingested edibles would harm minors, the FDA could act to protect minors from those products.

instances in which it has found one federal statute to repeal another by implication “is due to the relatively stringent standard” for reaching that conclusion—namely, that there is “an irreconcilable conflict” or “positive repugnancy” between the two laws.<sup>117</sup> That is not the case here. As a result, “when two statutes are capable of coexistence,” as these two are, “it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.”<sup>118</sup>

Broadly construing the Rohrabacher rider would lead to results that Congress clearly did not intend. There is scant evidence that Congress wanted to disable the FDA from preventing the public from being injured by a large batch of edibles that became adulterated from a toxin or other hazardous substance, whether due to the intentional misconduct of an officer or employee of the firm that manufactured the items, or due to the reckless or even negligence conduct of employees on the “assembly line” so to speak. Yet, a broad interpretation of the rider would deny the FDA the ability to use its legal authority to prevent undeniable harm to the consuming public. Congress did not intend that anomalous result, and the rider does not demand that the FDA stand aside and allow it to occur. For that reason, it would make no sense to construe the rider to prevent the FDA, even with the Justice Department’s assistance, from halting the distribution and consumption of food products to which someone had intentionally or mistakenly added a hazardous substance simply because the edibles *also* contained THC. If so, the result should be no different if the FDA deems THC itself to be an adulterant, given its potentially harmful effects on adults and minors.

---

117. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 142–43 (2001).

118. *Id.* at 143–44; *see also* *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014).

#### IV. THE OPTIONS OPEN TO THE FDA AND JUSTICE DEPARTMENT

The FDA and Justice Department have the power to halt or regulate the distribution of marijuana edibles. They also have a range of options to pursue. What should they do? The next subsections discuss those possibilities.

##### A. *An Aggressive Approach*

One option is for the FDA and Justice Department to aggressively enforce federal law in every fashion that the federal code allows. The agencies could undertake a full-bore attack on the sale of medical and recreational marijuana, including edibles, in states where they have been legalized. Federal law enforcement officers could seize any and all marijuana sold by brick-and-mortar dispensaries or online, along with whatever cannabis is grown for commercial sale, as well as arrest the parties who played a material role in a distribution program. The Justice Department could bring criminal charges against individuals for growing marijuana, for manufacturing cannabis products, and for distributing both. The department could prosecute the distribution businesses in states like California and Colorado under the federal controlled substances laws, as well as pursue the full range of ancillary offenses that large-scale marijuana distribution businesses might commit, such as racketeering and money laundering.<sup>119</sup> The FDA could complement the work of the Justice Department by initiating the administrative seizure of marijuana edibles on the ground that they are adulterated and misbranded foods. Together, the Justice Department and the FDA could close businesses engaged in the commercial distribution of cannabis, deter

---

119. Money Laundering Control Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207 (1986) (codified at 18 U.S.C. 1956–1957 (2012)); Racketeer Influenced and Corrupt Organizations Act, enacted as § 901(a) of the Organized Crime Control Act of 1970, Pub. L. No. 91-452, 84 Stat. 922 (codified at 18 U.S.C. §§ 1961–1968 (2012)).

other entrepreneurs from opening new operations, and effectively dissuade investors from seeking to underwrite this business.

Those agencies might be willing to go forward with that approach if three conditions were true: (1) they believed that it is legally authorized, (2) they believed that it is a sensible use of federal resources, and (3) they could count on the support of the White House and Congress.<sup>120</sup> It is unlikely that the Justice Department and FDA will select that option, however, for several reasons.

A full-frontal assault on the state liberalization schemes would likely ignite a challenging political battle between the states and members of Congress on one side and the Executive Branch on the other. At present, more than forty states and the District of Columbia allow marijuana itself or one of its constituents to be used for medical purposes.<sup>121</sup> States could enlist the support of a large majority of the Senate along with the representatives from the relevant states, one of which is California, which alone has fifty-three members of the House. For public and media support, those states and the members of Congress would showcase the patients who use some form of marijuana to alleviate their suffering as they cross the River Styx, as well as the children—and their parents—who use marijuana to deal with seizures.<sup>122</sup> Indeed, the pictures of patients being

---

120. Cf. Cully Stimson, *How Trump's DOJ Can Start Enforcing Federal Marijuana Law*, DAILY SIGNAL (Feb. 27, 2017), <http://dailysignal.com/2017/02/27/how-trumps-doj-can-start-enforcing-federal-marijuana-law/>.

121. NAT'L ACAD. REP., *supra* note 5, at 68 & Fig. 3-1, 74; Kosa et al., *supra* note 15, at 57.

122. See, e.g., *Colorado Girl Sues Jeff Sessions to Legalize Medical Marijuana Nationwide*, FOX NEWS (Nov. 12, 2017), <http://www.foxnews.com/us/2017/11/12/colorado-girl-sues-jeff-sessions-to-legalize-medical-marijuana-nationwide.html>. (“A Colorado girl [Alexis Bortell] who suffers from seizures joined a lawsuit to sue U.S. Attorney General Jeff Sessions in a bid to legalize medical marijuana nationwide. Alexis Bortell, 12, told FOX31 Denver she was diagnosed with epilepsy and traditional medicine wasn't helping her seizures. Her doctors in Texas recommended an invasive brain surgery, but a pediatrician suggested medical marijuana. . . . Bortell found that taking a drop of Haleigh's Hope, a



replayed on television over and over would probably carry more weight in the court of public opinion than what the members of Congress can bring to bear.

Attorney General Sessions may be willing to trigger a large-scale controversy, but it is not clear that President Trump is. In fact, the president has been noticeably quiet about marijuana legalization since being sworn into office. Moreover, the Trump Administration does not yet have in office a Director of the Office of National Drug Control Policy—the person who is responsible for developing, coordinating, and articulating the nation’s response to drug problems. Trying to move forward on this issue without an appointee in that office would be like trying to move the ball downfield without a quarterback.

There is an odd feature of our current marijuana regulatory scheme resulting from the federalist nature of our system of government. States, like Colorado, have established state bureaus to regulate the distribution of medical and recreational marijuana, which includes approving businesses that may sell cannabis products.<sup>123</sup> Federal law enforcement officials might be willing to shut down the private retail sale of marijuana, but they would be quite reluctant to prosecute state officials for implementing a program required by state law.<sup>124</sup> Charging state

---

strain of cannabis oil, twice a day prevented the seizures from coming back. She’s been seizure-free for nearly three years, but she can’t return to Texas because marijuana is illegal there. Colorado is one of several states that legalized marijuana for medicinal and recreational use.”).

123. In Colorado, the Marijuana Enforcement Division of the Colorado Department of Revenue is responsible for regulating medical and retail marijuana. *See* COLO. CODE REGS. § 212-1 (2017) (medical marijuana rules); *id.* § 212-2 (retail marijuana rules); COLO. DEPT’ REVENUE, ENFORCEMENT DIV., MARIJUANA (2017), <https://www.colorado.gov/pacific/enforcement/marijuana> enforcement. In Washington, the Liquor and Cannabis Board has that responsibility. *See* WASH. REV. CODE § 66.08.012 (2017); WASH. ADMIN. CODE § 314-55 (2017).

124. State and local law enforcement personnel are exempt from federal criminal liability if they are “lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.” 21 U.S.C. § 885(d) (2012).

regulators would raise novel questions of “causation” in the criminal law that the courts might decide against the department.<sup>125</sup> In any event, doing so would quite naturally chill the relationship between federal law enforcement officers and their state or local counterparts. Neither the Justice Department nor the Department of Homeland Security, nor their constituent agencies—such as the Federal Bureau of Investigation, the Drug Enforcement Administration, and the U.S. Secret Service—want to see that happen. Federal law enforcement officers—especially the Secret Service—partner with state and local departments in a host of different matters, such as offering security for the president whenever he leaves the White House. If, in response to federal prosecution of state officials, states and localities were to decline to assist federal law enforcement agencies, the latter would be severely hampered in their effectiveness to enforce federal law. Accordingly, the federal government might not want to prosecute state

---

That provision appears directed at the situation in which state or local officers take possession of a controlled substance during a search or seizure undertaken to enforce state criminal law. Efforts to ensure the distribution of marijuana under a state medical or recreational program would not qualify under that exemption. *See United States v. Rosenthal*, 266 F. Supp. 2d 1068, 1079 (N.D. Cal. 2003) (“[L]awfully engaged” in “enforcing a law related to controlled substances” must mean engaged in enforcing, that is, compelling compliance with, a law related to controlled substances which is consistent . . . or at least not inconsistent . . . with the Controlled Substances Act. Section 885(d) cannot reasonably be read to cover acting pursuant to a law which itself is in conflict with the Act.”), *aff’d* 454 F.3d 943, 948 (9th Cir. 2006) (“We agree with the district court that cultivating marijuana for medical use does not constitute ‘enforcement’ within the meaning of § 885.”).

125. *See* 18 U.S.C. § 2 (2012) (someone who causes someone else to commit a crime is responsible for that crime). Aside from raising proximate cause issues that would exceed the ones discussed in *Palsgraf v. L.I.R.R. Co.*, 162 N.E. 99 (N.Y. 1928), the prosecution of state officials, not for the *commercial distribution* of marijuana, but for *regulating* that activity, might be the push that the Supreme Court needs to finally adopt a mistake of law defense. *See, e.g.*, Paul J. Larkin, Jr., *The Folly of Requiring Complete Knowledge of the Criminal Law*, 12 LIBERTY U. L. REV. (forthcoming 2018); Edwin Meese III & Paul J. Larkin, Jr., *Reconsidering the Mistake of Law Defense*, 102 J. CRIM. L. & CRIMINOLOGY 725 (2012).

officials for doing their jobs.<sup>126</sup>

Focusing on recreational marijuana use is also likely to be more socially valuable because recreational use programs present a greater risk of encouraging teenagers to try marijuana. Limiting marijuana use to terminally ill patients or people suffering from painful, disabling diseases does not necessarily weaken the stigma associated with marijuana use or undermine the message that marijuana is a harmful drug; the message sent by a medical use program can readily be seen as one of compassion.<sup>127</sup> By contrast, a recreational

---

126. Of course, if the Justice Department were not to bring charges against state parties, the private defendants in marijuana cases would doubtless claim that the federal government had irrationally discriminated against them by not granting them the same leniency that state officials received. The litigation over those claims would take years to resolve. The result is that, if the Justice Department seeks to end both state medical and recreational marijuana programs, the Justice Department cannot make a decision that does not have a serious downside to it.

127. The Substance Abuse and Mental Health Administration, an arm of the U.S. Department of Health and Human Services, has found that teenage marijuana use has increased in Colorado but not in Washington from 2011–2015. See U.S. DEPT OF HEALTH & HUMAN SERVS., SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HHS Publication No. SMA–17–Baro–16–States–CO (2017) (“In Colorado, an annual average of about 46,000 adolescents aged 12–17 (11.1% of all adolescents) in 2014–2015 used marijuana in the past month. The annual average percentage in 2014–2015 was not significantly different from the annual average percentage in 2011–2012.”); U.S. DEPT OF HEALTH & HUMAN SERVS., SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HHS Publication No. SMA–17–Baro–16–States–WA (2017) (“In Washington, an annual average of about 49,000 adolescents aged 12–17 (9.2% of all adolescents) in 2014–2015 used marijuana in the past month. The annual average percentage in 2014–2015 was not significantly different from the annual average percentage in 2011–2012.”). Other studies have differed as to whether recreational marijuana laws lead to increased marijuana use, particularly by minors. Most have found no such effect. See, e.g., CAULKINS ET AL., MARIJUANA LEGALIZATION, *supra* note 5, at 213; Esther K. Choo et al., *The Impact of State Medical Marijuana Legislation on Adolescent Marijuana Use*, 55 J. ADOLESCENT HEALTH 160 (2014); Sam Harper et al., *Do Medical Marijuana Laws Increase Marijuana Use? Replication Study and Extension*, 22 ANNALS EPIDEMIOLOGY 207 (2012); Deborah S. Hasin et al., *Medical Marijuana Laws and Adolescent Marijuana Use in the USA from 1991 to 2014: Results from Annual, Repeated Cross-Sectional Surveys*, 2 LANCET PSYCHIATRY 601, 601 (2015); Julie Johnson et al., *The Design of Medical Marijuana Laws and Adolescent Use and Heavy Use of Marijuana: Analysis of 45 States from 1991 to 2011*, 170 DRUG & ALCOHOL DEPENDENCE 1, 6–7 (2017) (all concluding that state

use program sends the message to minors that marijuana is the same as alcohol, something reserved for adults and not harmful when used in moderation. Studies also differ on the question of whether medical marijuana programs encourage teen use of cannabis; some say “yes,” others “no.” Yet, studies of medical marijuana programs “cannot be generalized to laws on recreational use,” according to the American Medical Association, because recreational-use laws “may have much broader effects through such factors as pricing, advertising, availability, and/or implicit messages to teens that marijuana use is acceptable or nonrisky.”<sup>128</sup>

A 2017 study published in the *Journal of the American Medical Association Pediatrics*, however, found empirical

---

medical marijuana laws did not cause an increase in youth marijuana use); D. Mark Anderson et al., *Medical Marijuana Laws and Teen Marijuana Use* 19–20 (Nat’l Bureau Econ. Research, Working Paper No. 20332). A few have found an effect. See, e.g., Lisa Stolzenberg et al., *The Effect of Medical Cannabis Laws on Juvenile Cannabis Use*, 27 INT’L J. DRUG POL’Y 82, 82 (2016) (surmising that state medical marijuana laws spur increased marijuana use by juveniles by reducing the social stigma from its use); Melanie M. Wall et al., *Adolescent Marijuana Use from 2002 to 2008: Higher in States with Medical Marijuana Laws, Cause Still Unclear*, 21 ANN. EPIDEMIOLOGY 714, 715–16 (2011) (noting increase but not attributing a cause); cf. Katherine M. Keyes et al., *How Does State Marijuana Policy Affect US Youth? Medical Marijuana Laws, Marijuana Use and Perceived Harmfulness: 1991–2014*, 111 ADDICTION 2187, 2192 (2016) (concluding that the passage of state medical marijuana laws is associated with “increases in perceived harmfulness amount youth and that marijuana use has decreased among youth with that view”); Rosalie L. Pacula et al., *Assessing the Effects of Medical Marijuana Laws on Marijuana Use: The Devil Is in the Details*, 34 J. POL’Y ANALYSIS & MGT. 7, 29 (2015) (concluding that states with marijuana dispensaries protected by state law may see an increase in marijuana use by adults and minors); see generally CAULKINS ET AL., MARIJUANA LEGALIZATION, *supra* note 5, at 212 (“There are now enough contradictory published findings that advocates on any side can weave whatever story they will to tell.”). But see JT Borodovsky et al., *U.S. Cannabis Legalization and Use of Vaping and Edible Products Among Youth*, 177 DRUG & ALCOHOL DEPENDENCE 299, 305 (2017) (the effect of marijuana legalization on use by minors may vary according to the statute at issue); Wayne Hall & Michael Lynskey, *Why It Is Probably Too Soon to Assess the Public Health Effects of Legislation of Recreational Cannabis Use in the USA*, 3 LANCET PSYCHIATRY 900, 900, 904 (2016) (concluding that the current short-term studies of recreational cannabis use may not predict the long-term results given several identified but unanswered questions).

128. Cerdá et al., *supra* note 4, at 143.

support for the belief that recreational marijuana laws can encourage minors to use marijuana.<sup>129</sup> The study found that Washington State had seen a rise in recreational marijuana use by minors after adults were permitted to use marijuana recreationally in 2012.<sup>130</sup> Colorado did not see the same increase in minors' use of cannabis once its recreational program went into effect, the study found,<sup>131</sup> but it concluded that recreational marijuana laws, however, may pose a greater risk in that regard.<sup>132</sup> The upshot is that

---

129. *See id.* at 148.

130. The study noted:

The post-RML increase in adolescent marijuana use in Washington could have several explanations. First, our findings suggest that legalization of recreational marijuana use in 2012 reduced stigma and perception of risk associated with marijuana use. A shift in social norms regarding marijuana use may have, in turn, increased marijuana use among adolescents in Washington. Second, legalization may have increased availability, increasing adolescent access to marijuana indirectly through third-party purchases. Third, legalization could have decreased the price of marijuana in the black market, particularly after the first grower licenses in Washington were issued in March 2014 and the first stores opened in July 2014. . . . Fourth, the increase in marijuana use observed in Washington could be due to other changes occurring at the same time as RML rather than to RML itself.

*Id.* at 146–47 (footnotes omitted).

131. *See id.* at 147–48.

132. The study noted:

This difference may be related to the different degree of commercialization prior to [recreational] legalization in Washington and Colorado. Colorado had a very developed medical marijuana dispensary system prior to legalization, with substantial advertising, to which youth were already exposed. Washington, on the other hand, did not provide legal protection to medical marijuana stores. Therefore, the degree of commercialization and advertising of these collectives was substantially lower than in Colorado. In addition, rates of perceived harmfulness in Colorado were already lower than rates in Washington and non-RML [recreational marijuana law] states prior to legalization. Preexisting low levels of perceived harmfulness and high levels of use may have constrained further short-term increases following RML enactment. The longer-term effect of RML implementation on adolescent marijuana use in Colorado is still to be determined.

*Id.* at 147–48 (footnotes omitted).

recreational-use laws may lead to greater marijuana use by adults and minors both by not only diminishing—or eliminating—the stigma associated with marijuana use, but also reducing the price of cannabis by increasing its supply.<sup>133</sup>

There are, however, less aggressive steps that the FDA and Justice Department can take.

### B. *A Cautious Approach*

If the federal government concludes that challenging medical use of marijuana would generate overwhelming political opposition, there are smaller steps that the Justice Department could take. To start with, it could focus on the state laws authorizing the recreational use of marijuana. To narrow its focus even further, the government could also address the risk that marijuana sold for recreational use could wind up being used by minors, to their detriment. That would particularly be true in the case of any edible that closely resembles—or could be mistaken by a minor to be—candy. The government, therefore, could seek to prevent the distribution of all edibles or only the ones that could readily be mistaken for ordinary candy or a similar item. Finally, rather than bring a criminal prosecution against individuals or businesses for the sale of edibles, at least as a first step, the Justice Department could enlist the support of the FDA and seize adulterated edibles.

If the department decides to proceed in this manner, the scenario could play out in two steps. Step one would be for the FDA to declare that the addition of THC to any edible renders the product “adulterated” under the FDCA. Step two would be to initiate the seizure of any edible products offered for retail sale.<sup>134</sup> Given the popularity of edibles, those steps

---

133. *Id.* at 146–47; see also Wayne Hall & Michael Lynskey, *Evaluating the Public Health Impacts of Legalizing Recreational Cannabis Use in the United States*, 111 ADDICTION 1764, 1766 (2016).

134. See 21 U.S.C. § 334(g), (h) (authorizing the temporary administrative

would have the short-run effect of reducing the supply of THC, halving the profits from the sale of medical and recreational marijuana, increasing the price of the smoked form of marijuana, and driving people, adults and minors, toward the comparatively more dangerous practice of smoking cannabis.<sup>135</sup> Or, the FDA could take two smaller steps: (1) forbidding the sale of edibles that a reasonable person could confuse with a legitimate baked good, candy, or anything similar; and (2) requiring the packaging and sale of any other edible to satisfy a list of requirements deemed necessary to reduce the risk that children will accidentally ingest that product. Those requirements could include the demands that the states already place on the sale of marijuana—such as the limitation to designated retail outlets of distribution rights, the use of child-proof packaging, and the imposition of labeling dictates that clearly display the contents on the package and warn against the potential consequences of use.<sup>136</sup>

There is precedent for the FDA to intervene in the sale of marijuana products. On October 31, 2017, as part of its “ongoing efforts to protect consumers from health fraud,” the FDA issued a warning letter to four large companies selling for the treatment of various diseases self-labeled dietary supplements products containing cannabidiol, a non-

---

detention of adulterated foods without a hearing); *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950) (rejecting a Due Process Clause challenge to the FDA’s authority to seize adulterated or misbranded food before a judicial hearing on the FDA’s claim is held).

135. *See supra* note 11.

136. A more aggressive position would be to require states that want to sell edibles to do so only from state owned and operated facilities. Some states have that requirement for the sale of distilled spirits, so the concept is not a new one. *See, e.g.*, VA. CODE ANN. § 4.1-100 (2017) (defining “Alcohol,” “Alcoholic beverages,” “Beer,” “Spirits,” and “Wine”); *id.* § 4.1-101 (creating the Virginia Alcoholic Beverage Control Authority); *id.* § 4.1-103 (empowering the Board of Directors of the Virginia Alcoholic Beverage Control Authority to sell distilled spirits). No state currently follows that option so they would need to enact new laws to govern the sale of edibles. Whether the federal government should exercise its prosecutorial discretion to force the states to choose that option and whether states should independently adopt it are beyond the scope of this Article.

psychoactive substance found in marijuana that the FDA has not approved for use in any drug for any purpose.<sup>137</sup> In each case, the FDA found that the company marketed a new drug without prior FDA approval, as required by the FDCA, and misbranded the drugs by claiming that they can be used for the treatment of disease. The FDA took this action, as FDA Commissioner Scott Gottlieb explained in an accompanying press release, to protect cancer patients against companies “that deliberately prey on sick people with baseless claims that their substance can shrink or cure cancer.”<sup>138</sup>

---

137. See FDA Warning Letter from Maridalia Torres-Irizarry, San Juan Dist. Dir., FDA, to Laura Fuentes, Green Roads of Florida LLC (Oct. 31, 2017), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583188.htm>; FDA Warning Letter from Darla Bracy, L.A. Dist. Dir., FDA, to Will Claren, CEO, Natural Alchemist (Oct. 31, 2017), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583205.htm>; FDA Warning Letter from CDR Steven E. Porter, Jr., L.A. Dist. Dir., FDA, to Joel Stanley, CEO, Stanley Brothers Social Enterprises, LLC (Oct. 31, 2017), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583192.htm> [hereinafter Stanley Bros. FDA Letter]; FDA Warning Letter from CDR Steven E. Porter, Jr., L.A. Dist. Dir., FDA, to Tisha T. Casida, That’s Natural! Marketing and Consulting (Oct. 31, 2017), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583197.htm>.

138. The FDA said in a 2017 press release:

‘Substances that contain components of marijuana will be treated like any other products that make unproven claims to shrink cancer tumors. We don’t let companies market products that deliberately prey on sick people with baseless claims that their substance can shrink or cure cancer and we’re not going to look the other way on enforcing these principles when it comes to marijuana-containing products,’ said FDA Commissioner Scott Gottlieb, M.D. ‘There are a growing number of effective therapies for many cancers. When people are allowed to illegally market agents that deliver no established benefit they may steer patients away from products that have proven, anti-tumor effects that could extend lives. . . . We have an obligation to provide caregivers and patients with the confidence that drugs making cancer treatment claims have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they’re on the market,’ Commissioner Gottlieb added. ‘We recognize that there’s interest in developing therapies from marijuana and its components, but the safest way for this to occur is through the drug approval process—not through unsubstantiated claims made on a website. We support sound, scientifically-based research using components derived from marijuana, and we’ll continue to work with product developers who are interested



A Colorado company, for example, used an Internet website to sell products that it claimed can be used in the treatment of cancer, Alzheimer's, diabetes, Chronic Traumatic Encephalopathy, and other diseases, as well as for pain relief.<sup>139</sup> The FDA concluded that the products are "drugs" for purposes of the FDCA because they are used "in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure of any function in the body."<sup>140</sup> The products also did not fit within the exception for dietary supplements because that exception is unavailable when there are authorized clinical investigations underway for the product, and two such investigations are in progress for drugs containing cannabidiol.<sup>141</sup> The products, according to the FDA, are also not generally recognized as safe and effective and therefore are "new drugs" for purposes of the FDCA, which cannot be introduced into interstate commerce without prior FDA approval.<sup>142</sup>

Moreover, the FDA also concluded that the products were "misbranded" under the FDCA. The FDCA deems a drug misbranded unless there are adequate directions for its

---

in bringing safe, effective, and quality products to market.'

Press Release, FDA, FDA Warns Companies Marketing Unproven Products, Derived from Marijuana, that Claim to Cure or Treat Cancer (Nov. 1, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583295.htm>; see also, e.g., Anna Edney & Jenifer Kaplan, *FDA Cracks Down on Marijuana Cancer Treatment Claims*, BLOOMBERG TECH. (Nov. 1, 2017), <https://www.bloomberg.com/news/articles/2017-11-01/fda-cracks-down-on-medical-marijuana-cancer-treatment-claims>; Sheila Kaplan, *F.D.A Warns Companies Against Claims that Marijuana Cures Diseases*, N.Y. TIMES (Nov. 1, 2017), <https://www.nytimes.com/2017/11/01/health/fda-marijuana-false-claims.html>; Mina Zhang, *FDA Targets Country's Largest Cannabidiol Producer in Warning over Cancer Claims*, FORBES (Nov. 1, 2017), <https://www.forbes.com/sites/monazhang/2017/11/01/the-fda-targets-countrys-largest-cbd-producer-in-warning-over-cancer-claims/#3fff46493fb7>.

139. See Stanley Bros. FDA Letter, *supra* note 137.

140. *Id.*

141. *Id.*

142. *Id.* (citing 21 U.S.C. § 321(p)).

intended use—that is, directions a layperson can understand to use a drug safely and effectively.<sup>143</sup> In the case of a prescription drug, the FDA has concluded that it can be used safely only at the direction and under the supervision of a licensed physician.<sup>144</sup> The diseases at issue are ones that cannot be diagnosed or treated without the supervision of a licensed physician, which an Internet purchase does not require. Moreover, it is legally impossible for a layperson to write adequate directions for someone to use the company's drugs safely and effectively to treat those diseases.<sup>145</sup> The FDA therefore directed the company to correct the violations or face legal action, which could include seizure of the relevant products and an injunction against further distributions.<sup>146</sup>

Ordinarily, it might make sense for the federal government to leave to the states the freedom to experiment with various regulatory regimes. States can then experiment with different solutions to the problems discussed in this Article. Insofar as those problems are due to use of edibles by “marijuana tourists,” publicity might be a more efficient way to prevent misuse. The states have regulations for edibles, although they vary widely.<sup>147</sup> Those factors argue in favor of deferring a uniform, federal solution for any problems until more evidence is in. At the same time, what those regulations cover and how seriously they are applied might be open questions, or at least subject to dispute. Some states might be acting responsibly.<sup>148</sup> Some states, however, have created

---

143. *Id.* (citing 21 U.S.C. §§ 352(f)(1) and 21 C.F.R. § 201.5 (2017)). Recommendations by a “barista” at the local cannabis store would not qualify.

144. *Id.* (citing 21 U.S.C. § 353(b)(1)(A)).

145. *Id.*

146. *Id.*

147. Barrus et al., *supra* note 11, at 9 (“[C]urrently, the rules governing the manufacturing and labeling of edibles varies dramatically from state to state.”); *see also, e.g., id.* at 9–10.

148. *See* CAULKINS ET AL., MARIJUANA LEGALIZATION, *supra* note 5, at 204 (“So as a gross generalization, medical-marijuana regimes created by state legislatures

medical marijuana programs that are effectively recreational marijuana programs under a different name.<sup>149</sup>

What ultimately militates in favor of the FDA's intervention is this: Congress chartered the FDA to protect the nation's food supply by intervening where necessary to prevent the distribution of adulterated foods. If the FDA concludes that the addition of THC to a food product renders it adulterated, there is no reason why the FDA should defer to whatever answer the states offer on that subject. Accordingly, if the Justice Department agrees to defend the FDA's legal position in court, there is no sound reason for the FDA to forego enforcing the FDCA against marijuana edibles. Federalism principles do not require the FDA to stand aside and watch as adulterated edibles are sold.

Moreover, three related statutes are instructive here. The first one is the Cigarette Labeling and Advertising Act

---

east of the Mississippi generally appear to be good-faith efforts to provide compassionate access to people with well-defined conditions, while regimes originally created by voter propositions farther west are extremely permissive and easy to manipulate.”).

149. See *id.* at 511 nn.275, 277 & 279; Larkin, *supra* note 4, at 511–12 (“There is considerable proof that many state medical marijuana programs are simply a sham for the decriminalization of that substance. Consider the following: according to a 2013 study, in Arizona merely seven of 11,186 applications for medical marijuana had been denied. Only 2,000 patients registered for Colorado’s medical marijuana program before the Justice Department announced in 2009 that it would not enforce the federal marijuana laws against individual patients and caregivers. Colorado residents apparently listened because by March 2011, there were more than 127,000 Colorado registrants. In Colorado, fewer than fifteen physicians wrote more than seventy percent of all medical marijuana recommendations, with the reason being severe or chronic pain in ninety-four percent of the reported conditions. Michigan had fifty-five physicians certify approximately 45,000 patients. California does not require patients to register to receive marijuana for medical use, so the number of patients is a matter of speculation. Estimates, however, are that the number increased from 30,000 in 2002 to more than 300,000 in 2009 and 400,000 in 2010. The California statute permits a patient or caregiver to possess six plants, but it allows counties to amend state guidelines. Humboldt County, which lies in the heart of the Northern California marijuana farming, allows resident to grow up to ninety-nine plants on behalf of a patient. Not surprisingly, there is also considerable evidence that significant quantities of marijuana grown or sold for medical uses have been diverted for recreational use.”) (footnotes omitted).

(CLAA).<sup>150</sup> The act states that it is federal policy “to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health.”<sup>151</sup> The goals are to ensure that “the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes” and to prevent “diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health” from impeding the national economy.<sup>152</sup> To reach those goals, the act empowers the Secretary of Health and Human Services (HHS) to promulgate advertising requirements for cigarette packaging.<sup>153</sup> The second law is the Nutrition Labeling and Education Act of 1990 (NLEA).<sup>154</sup> It empowers the HHS Secretary to promulgate nutritional labeling requirements for commercial food products.<sup>155</sup> The third statute is the Poison Prevention Packaging Act of 1970 (PPPA).<sup>156</sup> It requires use of child-resistant packaging for prescription drugs, over-the-counter drugs, household chemicals, and other hazardous materials potentially dangerous to children. The statute empowers the Consumer Product Safety Commission (CPSC) to establish “technically feasible,

---

150. Pub. L. No. 88-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1333–41 (2012)).

151. Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 (2012).

152. *Id.* § 1331(1)–(2).

153. *See id.* § 1333. The CLAA also leaves in place the Federal Trade Commission’s authority to take action against unfair or deceptive acts or practices regarding cigarette advertising. *Id.* § 1336.

154. Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. §§ 321, 337, 343, 343-1, 345, 371 (2012)). The NLEA amended the FDCA. *See* § 1(b), 104 Stat. at 2353.

155. *See* § 2, 104 Stat. at 2353–57 (codified as amended at 21 U.S.C. § 343(q) (2012)).

156. Pub. L. No. 91-601, 84 Stat. 1670 (codified as amended at 15 U.S.C. §§ 1471–77 (2012)).

practicable, and appropriate” packaging standards for “any household substance” if it found that doing so was necessary “to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting” that substance.<sup>157</sup> In particular, the CPSC can prohibit the use of packages “which it determines are unnecessarily attractive to children.”<sup>158</sup> The PPPA defines a “household substance” to include “any substance” that is “customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is . . . a food as defined in” the FDCA.<sup>159</sup> That definition would include marijuana edibles.

Rather than leave the matter to the states, Congress enacted those laws to empower the federal government to establish national packaging and labeling standards for items such as food, cigarettes, and household cleaning products to inform adult consumers what they were voluntarily or accidentally ingesting and to prevent minors from mistakenly consuming such products. In each case, Congress also directed a federal agency to develop the nationwide rules.<sup>160</sup> The statutes therefore evince the judgment that it is a national responsibility to protect the public against the knowing or mistaken ingestion of potentially harmful substances. Those policy choices are

---

157. Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1472(a)(1)–(2) (2012).

158. *Id.* § 1472(d).

159. *Id.* § 1471(2)(B).

160. A Memorandum of Understanding (MOU) between the FDA and the CPSC recognized that the CPSC has the primary responsibility for regulating food containers, but reserves the FDA’s right to regulate containers insofar as there is a migration of particles from the container into the food or the container is composed, in whole or in part, of a poisonous or deleterious substance that might injure someone’s health. *See* U.S. FOOD & DRUG ADMIN., MOU 225-76-2003, MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. CONSUMER PRODUCT SAFETY COMMISSION AND THE U.S. FOOD AND DRUG ADMINISTRATION (1976). The MOU recognizes that the FDA and CPSC share responsibility for making sure that food containers do not injure a consumer’s health. The FDA and CPSC could negotiate a similar agreement over the proper regulation of the packaging of edibles.

entitled to respect.

#### CONCLUSION

Contemporary American society has decided that, whatever may be the benefits and harms of liberalizing marijuana use by adults, we should continue to outlaw the sale of recreational-use marijuana to children and adolescents. Even the states that permit recreational marijuana use under state law draw the line between adults and minors. Unfortunately, some companies pay only lip service to that line. The ability to develop products that closely resemble cookies, brownies, candies, and other substances that are attractive to children and adolescents—albeit, for different reasons—poses the risk that minors—some accidentally, some intentionally—will consume marijuana edibles found around the home or elsewhere. Any use of marijuana by children and long-term use of marijuana by adolescents poses health risks avoidable through federal prohibition or regulation of edibles.

To avoid the danger to their health and safety, the Justice Department and the FDA should take steps to prevent adulterated and mislabeled edibles from harming the public. Even if the Justice Department decides not to challenge the state medical or recreational use programs, the FDA should consider treating such edibles as adulterated foods under the FDCA—taking whatever steps are available to prevent the sale of any such products altogether—or to allow sales to go forward only under strictly regulated conditions. Doing so would help to reduce the danger that edibles pose to the health and safety of children and adolescents without materially interfering in state decisions on how to regulate the distribution of medical-use marijuana or the recreational use of that drug by adults.

## APPENDIX

FIGURE 1. A first Marijuana Edible example.<sup>161</sup>FIGURE 2. A second Marijuana Edible example.<sup>162</sup>

---

161. *Colorado Marijuana Bill: Banning Weed-Infused Gummy Bears*, WEEDLEX (July 4, 2016, 9:20 AM), <http://weedlex.com/colorado-marijuana-bill-banning-weed-infused-gummy-bears>.

162. Robert J. MacCoun & Michelle M. Mello, *Half-Baked—The Retail Production of Marijuana Edibles*, 372 N. ENG. J. MED. 989, 990 (2015).

FIGURE 3. A third Marijuana Edible example.<sup>163</sup>



---

163. Veronika Bondarenko, *This 59-year-old Mother of 2 is Making Millions Selling Legal Marijuana Gummies*, BUS. INSIDER (July 31, 2017, 3:00 PM), <http://www.businessinsider.com/wana-brands-nancy-whiteman-colorado-legal-marijuana-industry-edibles-entrepreneur-2017-7>.