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## Health Matrix: The Journal of Law-Medicine

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Volume 29 | Issue 1

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2019

# High Times Ahead: Products Liability in Medical Marijuana

Steven B. Perlmutter

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# HIGH TIMES AHEAD: PRODUCTS LIABILITY IN MEDICAL MARIJUANA

*Steven B. Perlmutter*<sup>†</sup>

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<sup>†</sup> Steven B. Perlmutter, M.D. (Washington University School of Medicine), J.D. (Sandra Day O’Connor College of Law) is an attorney practicing exclusively in the area of health law in Scottsdale, Arizona. Previously, he practiced as a board-certified ophthalmologist for 25 years in the Phoenix metropolitan area.

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## INTRODUCTION

Medical marijuana is big business. In 2016, Arizonans purchased twenty-nine tons of cannabis products, a fifty-three percent increase from 2015.<sup>1</sup> Nearly 115,000 new patients registered for medical cannabis in Arizona, a thirty percent increase over 2015.<sup>2</sup> The state received \$29.5 million in tax revenue from medical marijuana in 2016.<sup>3</sup> Total marijuana sales in North America exceeded \$6.7 billion in 2016<sup>4</sup> and the estimated impact on the U.S. economy in 2020 could reach \$44 billion.<sup>5</sup> From January 1, 2017 through October 13, 2017, \$1.9 billion of new capital was raised and invested in the cannabis industry.<sup>6</sup>

Big business typically sparks big litigation, but medical marijuana and products liability have been virtual strangers. They will not be for long. While only two cannabis products liability cases have been filed in the United States to date (both in Colorado),<sup>7</sup> it is easy to envision dozens, if not hundreds, of cases being filed in the next decade. This paper considers the basis for potential claims and the actions the industry can take now to increase patient safety and mitigate liability.

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1. Eli McVey, *Arizona Medical Marijuana Patient Count in 2016*, MARIJUANA BUS. DAILY (Feb. 6, 2017), [mjbizdaily.com/chart-arizona-growing-intomedical-marijuana-juggernaut](http://mjbizdaily.com/chart-arizona-growing-intomedical-marijuana-juggernaut).
  2. Eli McVey, *Arizona Growing into Medical Marijuana Juggernaut*, MARIJUANA BUS. DAILY (Feb. 06, 2017), <http://mjbizdaily.com/chart-arizona-growing-into-medical-marijuana-juggernaut>.
  3. Ray Stern, *Arizona Medical Marijuana Sales Hit Record High: We Bought 29 Tons in '16, State Got \$29.5 Million in Taxes*, PHOENIX NEW TIMES (Jan. 24, 2017), <https://www.phoenixnewtimes.com/news/arizona-medical-marijuana-sales-hit-record-high-we-bought-29-tons-in-16-state-got-295-million-in-taxes-9018620>.
  4. Debra Borchardt, *Marijuana Sales Totaled \$6.7 Billion in 2016*, FORBES (Jan. 3, 2017, 9:00 AM), <https://www.forbes.com/sites/debraborchardt/2017/01/03/marijuana00000-sales-totaled-6-7-billion-in-2016/#2ca7610a75e3>.
  5. David Schepp, *Legal Marijuana: A \$44 Billion Business by 2020?*, CBS MONEYWATCH (Mar. 18, 2016, 5:30 AM), <https://www.cbsnews.com/news/legal-marijuana-a-44-billion-business-by-2020/>.
  6. *Cannabis Deal Tracker: Investment and M&A Activity in the Cannabis Industry*, VIRIDIAN CAPITAL ADVISORS, <http://mailchi.mp/viridianca/deal-tracker-2930261> (last visited Sep. 29, 2018).
  7. *See, e.g.* Compl. at 2, *Flores v. Livwell Inc.* (D. Colo. 2015) (No. 2015CV33528); Am. compl. at 7, *Kirk v. Nutritional Elements, Inc.* (D. Colo.) (No. 16CV31310).

Part I discusses basic information about medical marijuana and its supply chain of production. Part II explores current federal and state law. Part III suggests a paradigm for medical marijuana liability. Potential regulation for medical marijuana is explored by comparison to similar products that are subject to varying regulations. Part IV describes our current knowledge of the therapeutic and adverse effects of medical marijuana. It also highlights that more research is needed to fully understand and educate users about the risks and benefits of medical marijuana. Part V considers manufacturing defects as a theory of product liability. Part VI discusses defective design related to the unregulated nature of medical cannabis, while Part VII explores the current system's failure to warn. Finally, Part VIII examines the special problem of youth marketing.

## I. THE BASICS

### A. *Marijuana*

Marijuana is a plant, more specifically a greenish-gray mixture of dried flowers from *Cannabis sativa*.<sup>8</sup> It is referred to by a wide variety of names, including cannabis, weed, herb, pot, grass, bud, ganja, 420, and Mary Jane.<sup>9</sup> Individuals and corporations on the cutting edge of the marijuana industry are called “ganjapreneurs.”<sup>10</sup>

Marijuana is used for both recreational and medical purposes.<sup>11</sup> This article focuses on medical marijuana, particularly in edible form. According to the National Institute on Drug Abuse, a division of National Institutes of Health (NIH), “*medical marijuana* refers to using the whole, unprocessed marijuana plant or its basic extracts to treat symptoms of illness and other conditions.”<sup>12</sup> Web MD defines medical marijuana as “the use of this drug to help treat symptoms like pain, muscle stiffness (spasticity), nausea, and lack of appetite. It may be used by people who have conditions like cancer, AIDS, or multiple

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8. *Marijuana as Medicine*, NIH NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/drugfacts/marijuana-medicine> (last updated June 2018).
  9. *What is Marijuana?*, NIH - NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/research-reports/marijuana/what-marijuana> (last updated June 2018).
  10. Madhura Yale, *Cash in on Marijuana Boom: Become a Ganjapreneur*, JUNGLEWORKS, <https://jungleworks.com/cash-marijuana-boom-become-ganjapreneur> (last visited Dec. 19, 2018).
  11. NAT'L ACAD. SCIENCES, ENG'G, & MED., *THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH*, xvii, 1 (Nat'l Acad. Press eds., 2017), available at <https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state>.
  12. *Marijuana as Medicine*, *supra* note 8.

sclerosis.”<sup>13</sup> The working definition of medical cannabis for the purposes of this article is: the use of one or more components of the *Cannabis sativa* plant, as recommended by a licensed healthcare provider, for the treatment of a disease or its symptoms.

*Cannabis sativa* is a complex substance, containing 545 constituents.<sup>14</sup> The most significant medicinal components are the psychoactive *delta-9-trans-tetrahydrocannabinol* (THC) and the non-psychoactive *cannabidiol* (CBD).<sup>15</sup> Both compounds exert effects on the ubiquitous endocannabinoid system.<sup>16</sup>

The endocannabinoid system is a highly complex, endogenous system in the human body.<sup>17</sup> For the purposes of this article, the two most important cannabinoid receptors are CB1 and CB2. The distribution of these receptors in various tissues accounts for the psychotropic and peripheral effects of THC.<sup>18</sup> CB1 receptors are most abundant in the basal ganglia, cerebellum, hippocampus, and cerebral cortex.<sup>19</sup> CB2 receptors are most commonly found in immune cells and tissues.<sup>20</sup> By activating CB1 receptors, THC affects high-order behavioral activities, such as executive functioning, decision making, sensory responsiveness, motor function, learning, memory, and emotional reactions.<sup>21</sup> Short term effects of THC on the central nervous system (CNS) are dose-dependent and include:<sup>22</sup>

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13. *Medical Marijuana FAQ*, WEBMD, <http://www.webmd.com/mental-health/tc/medical-marijuana-topic-overview#1> (last visited Oct. 11, 2017).
  14. MAHMOUD ELSOHLY & WASEEM GUL, CONSTITUENTS OF *CANNABIS SATIVA* IN HANDBOOK OF CANNABIS, 3 (Roger G. Pertwee ed., 2014).
  15. Carola Rong et al., *Cannabidiol in Medical Marijuana: Research Vistas and Potential Opportunities*, 121 PHARMACOLOGICAL RESEARCH 213, 214 (2017).
  16. *Id.*
  17. *Id.*
  18. See Vincenzo Di Marzo et al., *The Endocannabinoid System and its Therapeutic Exploitation*, 3 NAT'L REV. DRUG DISCOVERY 771, 772 (2004).
  19. See Debra A. Kendall et al., *Cannabinoid Receptors in the Central Nervous System: Their Signaling and Roles in Disease*, 10 FRONTIERS IN CELLULAR NEUROSCIENCE 1, 1(2017).
  20. *Id.* at 3.
  21. Bradley E. Alger, *Getting High on the Endocannabinoid System*, CEREBRUM at 4 (Nov. 1. 2013), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3997295/>.
  22. *Marijuana as Medicine*, *supra* note 8.

- altered senses and perception
- distorted sense of time
- mood fluctuations
- impaired body movement
- disorganized thinking and problem-solving
- diminished memory
- hallucinations
- delusions
- psychosis

The effects of CBD are less well understood. CBD interacts with multiple receptors in the endocannabinoid system, antagonizing CB1 receptors but potentiating CB2 receptors.<sup>23</sup> In contrast to THC, CBD has salutary effects on mood, anxiety, and sleep disturbances.<sup>24</sup>

Cannabis can be smoked, vaporized, brewed, and ingested in foods and drinks.<sup>25</sup> Administration of cannabis produces a blood level of all 545 constituent compounds;<sup>26</sup> however, therapeutic effects and adverse reactions differ based on the method of administration.<sup>27</sup> Ingested components, known as edibles, have variable pharmacodynamics. Their effects and side effects are uncertain.<sup>28</sup> Consequently, the unpredictability of their effects and the resulting enhanced potential for harm suggests that edibles are likely to precipitate the bulk of medical marijuana products liability and litigation. Thus, edibles will be the focus of this article.

Marijuana edibles are food items infused with cannabis or its concentrates. They contain cannabinoids and are popular alternatives

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23. Rong et al., *supra* note 15, at 213-214.

24. Rong et al., *supra* note 15, at 215.

25. NAT'L ACAD. SCIENCES, ENG'G, & MED., *supra* note 11, at 50.

26. Ron R. Flegel, *SAMHSA'S Role: Integrating the Science & Technical Information into Regulated Testing*, AM. SOC. ADDICTION MED. (Oct. 07, 2016), available at <https://www.asam.org/docs/default-source/education-docs/state-of-the-art-2016/session-6-combined.pdf>.

27. NAT'L ACAD. SCIENCES, ENG'G, & MED., *supra* note 11, at 51.

28. Noelle Crombie, *How Potent Are Marijuana Edibles? Lab Tests Yield Surprising Results*, MARIJUANA NEWS (Mar. 06, 2015), [https://www.oregonlive.com/marijuana/index.ssf/2015/03/how\\_potent\\_are\\_marijuana\\_edibl.html](https://www.oregonlive.com/marijuana/index.ssf/2015/03/how_potent_are_marijuana_edibl.html).

to smoking or vaporizing cannabis.<sup>29</sup> Edibles became popular after Alice B. Toklas created and published a recipe for Hashish Fudge in her 1954 cookbook.<sup>30</sup> The recipe was published in the British edition but omitted from the U.S. edition until the second publishing in the early 1960's.<sup>31</sup> The craze was popularized by the movie, *I Love You, Alice B. Toklas*, in which the conservative Peter Sellers was introduced to hash brownies by a hippie.<sup>32</sup> Edibles come in many forms, often reminiscent of products found in a supermarket, candy store, or bakery. Here is a partial list:

- Beverages – soda, tea, coffee, beer, lemonade, smoothies
- Breakfast – rice crispy cereal bars, fruit and nut snacks, breakfast bars, croissants, madeleines, and oat squares
- Brownies
- Candy – gummy worms, gummy bears, caramels, sour drops, dried pineapple, fruit chews, mints, jellies, caramel popcorn, pastilles, coconut almond candy bars, apple rings, lollipops, lozenges, taffy, gourmet fruit slices, lemon drops, and peanut butter bars
- Chocolates – white, milk and dark bars (plain, raisins, nuts, peanut butter, or caramel) and peppermint patties
- Condiments – honey, BBQ sauce, blue cheese dressing, ranch dressing, jelly, maple syrup, and peanut butter
- Cookies – snickerdoodle, ginger snap, chocolate, oatmeal, butterscotch, sugar, mint, coconut, peppermint, molasses, lemon, peanut butter, red velvet, and gluten-free
- Cooking – butter, olive oil, vegetable oil, coconut oil, honey, vinaigrette, marinades

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29. See Daniel Barrus et al., *Tasty THC: Promises and Challenges of Cannabis Edibles*, RTI INT'L (Nov. 2016), <https://www.rti.org/rti-press-publication/tasty-thc>.
30. Dave Chachere, *Alice in Wonderland: The Toklas Brownie*, DOPE MAGAZINE (Nov. 28, 2016), <https://www.dopemagazine.com/alice-wonderland-toklas-brownie/>.
31. Layla Eplett, *Go Ask Alice: The History of Toklas' Legendary Hashish Fudge*, SCI. AM. (Apr. 20, 2015), <https://blogs.scientificamerican.com/food-matters/go-ask-alice-the-history-of-toklas-8217-legendary-hashish-fudge/>.
32. *Id.*

- Snacks – rice crispy treats, bars, crackers, fish crackers, cupcakes, pies, baklava, macaroons, peanut butter cups, and mixed nut clusters.<sup>33</sup>

### B. Supply Chain

According to the online Business Dictionary, a supply chain consists of a network of entities, directly or indirectly interlinked and interdependent, which serve the same consumer or customer.<sup>34</sup> The supply chain includes raw material vendors, manufacturers, warehouses, distribution centers, and retailers. The three basic functions of a supply chain are the: (1) supply of raw materials to a manufacturer; (2) actual manufacturing; and (3) delivery of the finished product via a network of distributors and retailers to the end user.<sup>35</sup>

Regarding medical marijuana, the supply chain can be diagrammatically represented as follows:

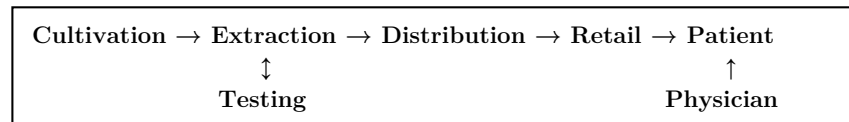


Figure 1. Supply Chain Schematic

Growers plant and harvest the cannabis crop. Buds, or flowers, are separated from the plant and processed.<sup>36</sup> Manufacturers produce cannabis-infused edibles, oils, waxes, and tinctures.<sup>37</sup> Extractions and final products undergo laboratory testing for purity and THC

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33. LEAFLY, <https://www.leafly.com/products/edibles> (last visited Sept. 30, 2018).
34. BUSINESS DICTIONARY, <http://www.businessdictionary.com/> (last visited Sept. 27, 2018).
35. See *Cannabis Supply Chain Traceability*, GITHUB (Mar. 23, 2016), <https://github.com/CannabisReports/Cannabis-Supply-Chain-Traceability/blob/master/cannabis-supply-chain-traceability.md>; *Supply Chain Definitions*, CANADIAN SUPPLY CHAIN SECTOR COUNCIL, <http://www.supplychaincanada.org/en/supply-chain> (last visited Sept. 23, 2018).
36. See *Arizona Cannabis Society Grower Job Description*, OAKSTERDAM UNIVERSITY, <https://oaksterdamuniversity.com/wp-content/uploads/2017/10/Arizona-Cannabis-Society-Grower-Job-Description.pdf> (last visited Sept. 30, 2018); See Max Anderson, *Best Tips For Harvesting Cannabis*, PROD. GROWER (March 11, 2018), <https://productiongrower.com/blogs/how-to-grow-weed/harvesting>; See *Your Guide to Drying and Curing Cannabis Buds*, LEAFLY (Aug. 8, 2016), <https://productiongrower.com/blogs/how-to-grow-weed/harvesting>.
37. *Market Opportunity*, BUDLIFE, <https://www.budlife.net/medical-marijuana-1/> (last visited Sept. 27, 2018).



concentration.<sup>38</sup> Physicians evaluate patients for medical marijuana program qualifying characteristics.<sup>39</sup> Qualifying patients receive certifications and are directed to retail dispensaries that sell the finished products.<sup>40</sup>

## II. FEDERAL AND STATE MEDICAL MARIJUANA LAW

### A. *Federal Marijuana Law*

Marijuana is currently illegal under federal law.<sup>41</sup> The U.S. Drug Enforcement Agency (DEA) classifies cannabis as a Schedule I drug.<sup>42</sup> “Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.”<sup>43</sup> Other Schedule I drugs include heroin, lysergic acid diethylamide (LSD), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone (Quaalude), and peyote.<sup>44</sup> Further, the DEA claims there is “a lack of accepted safety for use of the drug or other substance under medical supervision.”<sup>45</sup>

On July 19, 2016, the DEA denied a petition to initiate rulemaking proceedings to reschedule marijuana to a classification where it could be used medicinally.<sup>46</sup> Their conclusion was based on their consistent findings that marijuana: (1) “has a high potential for abuse;” (2) “has no currently accepted medical use in treatment in the United States;” and (3) “lacks accepted safety for use under medical supervision.”<sup>47</sup>

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38. *See What You Need to Know About Cannabis Testing, Lab Setup and Training*, GENIE SCI., <https://www.geniescientific.com/what-you-need-to-know-about-cannabis-testing-lab-setup-and-training> (last visited Sept. 27, 2018).
  39. *Qualifying Conditions for a Medical Marijuana Card by State*, LEAFLY (Oct. 30, 2017), <https://www.leafly.com/news/health/qualifying-conditions-for-medical-marijuana-by-state>.
  40. Jeremiah Wilhelm, *Understanding Medical vs. Adult-Use Cannabis Dispensaries*, LEAFLY (Jan. 30, 2017, 1:58 PM), <https://www.leafly.com/news/cannabis-101/what-is-a-marijuana-dispensary/print/>.
  41. 21 U.S.C. § 812(b)(1) (2012).
  42. *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., <https://www.dea.gov/druginfo/ds.shtml> (last visited Oct. 11, 2017).
  43. *Id.*
  44. *Id.*
  45. U.S. DRUG ENF'T ADMIN., DRUGS OF ABUSE: A DEA RESOURCE GUIDE (2017), available at <https://www.dea.gov/documents/2017/06/15/drugs-abuse>.
  46. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 18 Fed. Reg. 53767 (Aug. 12, 2016).
  47. *Id.*

Although cannabis is illegal under federal law, enforcement of those laws was guided by the 2013 Cole Memorandum entitled, “Guidance Regarding Marijuana Enforcement.”<sup>48</sup> This memorandum shifted governmental priorities from tough enforcement of federal cannabis law towards a more hands-off approach in those “jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale and possession of marijuana.”<sup>49</sup> Further, the Cole Memorandum declared that:

a robust system may affirmatively address [federal] priorities by, for example, implementing effective measures to prevent diversion of marijuana outside the regulated system and to other states, prohibiting access to marijuana by minors, and replacing an illicit marijuana trade that funds criminal enterprises with a tightly regulated market in which revenues are tracked and accounted for.<sup>50</sup>

The relaxed attitude of the Obama Administration did not survive past the first year of the Trump presidency. On January 4, 2018, Attorney General Jefferson B. Sessions, III drafted a memorandum to all U.S. Attorneys rescinding the Cole Memorandum and other federal guidelines that circumscribed the prosecution of individuals and entities following state law in the use and sale of marijuana.<sup>51</sup> Federal prosecutors have been instructed to decide which cases to prosecute based on “federal law enforcement priorities set by the Attorney General, the seriousness of the crime, the deterrent effect of the criminal prosecution, and the cumulative impact of particular crimes of the community.”<sup>52</sup>

#### *B. State Marijuana Law*

According to the National Conference of State Legislatures, as of 2018, thirty-three states plus the District of Columbia, Guam, and Puerto Rico have enacted laws permitting the medical use of

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48. DEPUTY ATT’Y GEN. JAMES M. COLE, MEMORANDUM FOR ALL UNITED STATES ATTORNEYS: GUIDANCE REGARDING MARIJUANA ENFORCEMENT, Aug. 29, 2013), *available at* <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

marijuana.<sup>53</sup> States that have legalized medical marijuana are predominantly in the west, southwest, northeast, and northwest.<sup>54</sup>

The Arizona Medical Marijuana Act (AMMA), captioned as A.R.S. §§ 36-2801 to -2819, was passed as Proposition 203 in 2010.<sup>55</sup> The law permits the certification of individuals with a “debilitating medical condition” for medical marijuana use.<sup>56</sup> Debilitating conditions include the following:

- (a) Cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis, crohn’s disease, agitation of alzheimer’s disease or the treatment of these conditions.<sup>57</sup>
- (b) A chronic or debilitating disease or medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe and chronic pain; severe nausea; seizures, including those characteristic of epilepsy; or severe and persistent muscle spasms, including those characteristic of multiple sclerosis.
- (c) Any other medical condition or its treatment added by the department pursuant to section 36-2801.01.<sup>58</sup>

Qualifying patients are certified for medical use of marijuana by actively licensed allopathic, osteopathic, naturopathic, or homeopathic physicians in Arizona.<sup>59</sup> Physicians do not “prescribe” marijuana because that would violate federal law.<sup>60</sup> Instead, physicians

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- 53. Jeremy Berke & Skye Gould, *This Map Shows Every US State Where Pot is Legal*, BUS. INSIDER (Jan. 4, 2019), <https://www.businessinsider.com/legal-marijuana-states-2018-1>.
  - 54. *See Marijuana DeepDive*, NAT’L CONF. ST. LEGIS., <http://www.ncsl.org/bookstore/state-legislatures-magazine/marijuana-deep-dive.aspx> (last visited Jan. 27, 2018).
  - 55. Ariz. Rev. Stat. Ann. § 36-2801(18) (2010).
  - 56. *Id.*
  - 57. The Arizona legislature left out the capital letters of the diseases characterized by and named after Alois Alzheimer, M.D. and Burrill Crohn, M.D. Ariz. Rev. Stat. Ann. § 36-2801(3) (2010).
  - 58. Debilitating conditions are subject to change annually via petition to the state health department. *Id.*; *See e.g., Petition to Add a Debilitating Condition*, COLO. DEP’T PUB. HEALTH & ENV’T, <https://www.colorado.gov/pacific/cdphe/petition-to-add-debilitating-condition> (last visited Dec. 18, 2018).
  - 59. Ariz. Rev. Stat. Ann. §§ 36-2801(12), (13) (2018).
  - 60. TODD GARVEY ET AL., CONG. RESEARCH SERV., R43435, MARIJUANA: MEDICAL AND RETAIL – SELECTED LEGAL ISSUES at 4 (2015).

“recommend” marijuana and certify in writing that they believe the patient is likely to “receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient’s debilitating medical condition or symptoms associated with the debilitating condition.”<sup>61</sup> The physician’s right to recommend marijuana has been held to be protected by the First Amendment.<sup>62</sup>

### III. MEDICAL MARIJUANA AS A “PHARMA-PSEUDICAL”

States considering the legalization of medical marijuana must consider the paradigm under which it will be regulated. This is complicated by the fact that, in many ways, medical marijuana is a unique product because it is used for both recreation and medical purposes. Medical cannabis is “recommended” by doctors, but never prescribed. It is rarely dispensed by a pharmacist, but rather by a retailer with no mandatory training or certification.<sup>63</sup> Thus, medical cannabis has some characteristics in common with alcohol, tobacco, nutritional supplements, and pharmaceuticals. Medical marijuana most closely resembles a pharmaceutical; though important differences exist. For that reason, the term, “pharma-pseudical,” shall be used to indicate medical marijuana is akin to a pseudo-pharmaceutical.

#### A. Alcohol

Although there are similarities, there are three reasons why alcohol is not a useful heuristic for marijuana regulation. First, while alcohol and marijuana have intoxicating effects with oral or intravenous administration, there is no currently recognized medical indication for the internal use of alcohol.<sup>64</sup> Once used internally as an anesthetic and

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61. Ariz. Rev. Stat. Ann. § 36-2801(12).

62. *Conant v. Walters*, 309 F.3d 629, 638-39 (9th Cir. 2002) (affirming district court’s permanent injunction enjoining federal government from revoking DEA registration or investigating physician in a manner that might lead to revocation where the government’s action based solely on physician’s recommendation of medical marijuana. Doctor’s speech to patient protected under First Amendment).

63. *State Medical Marijuana Legislation and the Pharmacist’s Role*, NAT’L CMTY. PHARMACISTS ASS’N, <http://www.ncpa.co/pdf/medical-marijuana-one-pager-aug-2017.pdf> (last visited Dec. 18, 2018).

64. *Alcohol, If You Drink it, Keep it Moderate*, MAYO CLINIC, <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/alcohol/art-20044551> (last updated Nov. 6, 2018); Resveratrol, a component of the skins of red grapes has a limited antioxidant and anti-inflammatory effect. Evidence of its benefits is minimal. Chandra K. Sing, et al., *Resveratrol, in its Natural Combination in Whole Grape, for Health Promotion and Disease Management*, 1348 ANNALS N.Y. ACAD. SCI. 150, 151 (2015).

as a tocolytic in the mid-twentieth century,<sup>65</sup> alcohol is currently indicated only externally as an antiseptic and disinfectant.<sup>66</sup>

Second, ethyl alcohol is regulated by a complex network of federal, state, and municipal statutes and rules.<sup>67</sup> Medical marijuana is regulated by state law<sup>68</sup> and issues of zoning are municipal.<sup>69</sup> Third, because the dangers of alcohol are readily apparent and universally known, manufacturers of alcoholic beverages have a very limited duty to warn consumers.<sup>70</sup> Beverages containing more than 0.5% of alcohol by volume are required to have only two warnings: “(1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption

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65. Tocolytic drugs are used to stop preterm labor. The current drug of choice is terbutaline. J.D. Whitby, *Alcohol in Anaesthesia and Surgical Resuscitation*, 35 ANAESTHESIA 502, 502 (1980); Marc J.N.C. Keirse, *The History of Tocolysis*, 110 BRITISH J. OBSTETRICS AND GYNAECOLOGY 94, 95 (2003).
66. Ethyl alcohol has been taken internally; isopropyl alcohol is used externally. See Gerald McDonnell & A. Denver Russell, *Antiseptics and Disinfectants: Activity, Action, and Resistance*, 12 CLINICAL MICROBIOLOGY REV. 147, 148-151 (1999).
67. See e.g., 26 U.S.C. §5601(a)(8) (2006); VA. CODE ANN. §§ 4.1-100, 4.1-302; LAKEWOOD, COLO. MUN. CODE § 9.41.070 (2015).
68. See Gina K. Grimes & Morris C. Massey, *Medical Marijuana – Differences Among States’ Regulatory Frameworks and Land Use and Zoning Regulation*, 29 PROBATE & PROPERTY MAGAZINE (Nov. 2015), available at [https://www.americanbar.org/groups/real\\_property\\_trust\\_estate/publications/probate\\_property\\_magazine\\_home/2015/november\\_deember\\_2015/2015\\_aba\\_rpte\\_pp\\_v29\\_6\\_article\\_grimes\\_massey\\_medical\\_marijuana\\_differences\\_among\\_states.html](https://www.americanbar.org/groups/real_property_trust_estate/publications/probate_property_magazine_home/2015/november_deember_2015/2015_aba_rpte_pp_v29_6_article_grimes_massey_medical_marijuana_differences_among_states.html).
69. Robert Careless, *Zoning Hurdles for Budding Pennsylvania Cannabis Businesses*, THE TEMPLE 10-Q (Oct. 27, 2017), <https://www2.law.temple.edu/10q/zoning-hurdles-budding-pennsylvania-cannabis-businesses/>.
70. After Abernathy died of acute alcohol intoxication, his estate sued whiskey distiller, Schenley, for failure to warn of the hazards of acute intoxication. The Fourth Circuit Court of Appeals held that fulfilling the statutory labeling obligations was sufficient to eschew liability. See *Abernathy v. Schenley Industries, Inc.*, 556 F.2d 242, 243 (4th Cir. 1977) (holding that fulfilling statutory labeling obligations was sufficient to eschew liability). Garrison sued Heublein, manufacturer and distributor of Smirnoff Vodka, under a failure to warn theory for mental and physical injuries arising from two decades of heavy vodka consumption. Adopting Restatement (Second) of Torts § 402A as Illinois law, the court dismissed the case, holding that the dangers of alcohol were common knowledge, and the product was not unreasonably unsafe. See *Garrison v. Heublein, Inc.*, 673 F.2d 189 (7th Cir. 1982).

of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.”<sup>71</sup>

### B. Tobacco

Tobacco is also a poor choice as a paradigm for medical marijuana regulation. Tobacco has no recognized medicinal use.<sup>72</sup> It is permitted, but regulated by numerous federal, state, and local laws.<sup>73</sup> Marijuana is not regulated by any federal laws, only prohibited.<sup>74</sup> Severe, adverse health effects are widely recognized, in part due to the ubiquitous warning labels on each cigarette pack.<sup>75</sup> Since 1984, cigarette manufacturers have been required to display on each pack of cigarettes one of four health warning labels on a quarterly rotating basis.<sup>76</sup>



Figure 2. Cigarette Warning Labels

### C. Nutritional Supplements

Nutritional supplements and medical marijuana are both promoted for their salutary effects,<sup>77</sup> although compelling scientific evidence of the

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71. 27 C.F.R. § 16.21 (1990).
  72. John Harvey Kellog, *Tobaccoism*, 92 AM. J. PUB. HEALTH 932, 932 (2002).
  73. *Local Tobacco Regulation*, RJREYNOLDS, <https://www.rjrt.com/commercial-integrity/state-local-regulation/> (last visited Sept. 21, 2018).
  74. Donna Leinwand Leger, *Marijuana to Remain Illegal Under Federal Law, DEA Says*, USA TODAY (Aug. 11, 2016, 5:54 PM), <https://www.usatoday.com/story/news/2016/08/11/dea-marijuana-remains-illegal-under-federal-law/88550804/>.
  75. 15 U.S.C. § 1333(a)(1) (2010).
  76. *Making Decisions Regarding Tobacco Use*, RJREYNOLDS, <http://www.rjrt.com/tobacco-use-health/public-health-information/> (last visited Oct. 14, 2018).
  77. *Dietary Supplements: What you Need to Know*, NIH - NAT'L INST. HEALTH, [https://ods.od.nih.gov/HealthInformation/DS\\_WhatYouNeedToKnow.aspx](https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx) (last updated June 17, 2011); Peter Grinspoon, *Medical Marijuana*, HARV. HEALTH PUB. (Jan. 15, 2018), <https://www.health.harvard.edu/blog/medical-marijuana-2018011513085>.

benefits of supplements is lacking.<sup>78</sup> Supplements are federally regulated by the Food and Drug Administration (FDA) under the Dietary Supplement Health and Education Act of 1994,<sup>79</sup> however, the FDA does not evaluate dietary supplements for effectiveness and safety in the premarketing phase.<sup>80</sup> The FDA is only authorized to restrict the sale of misbranded or adulterated dietary supplements in the marketplace.<sup>81</sup>

While the FDA does not currently regulate medical marijuana, that may change soon. On October 3, 2017, the FDA Commissioner, Scott Gottlieb, indicated that the agency would investigate dubious health claims made by marijuana producers, especially anti-tumor/anti-cancer effects of THC.<sup>82</sup>

With rare exceptions, dietary supplements have no psychoactive effects and are not recommended for the treatment of any condition or disease in traditional modern medicine.<sup>83</sup> Most supplements are required to have a disclaimer that any claims of benefit have not been evaluated by the FDA.<sup>84</sup> They may be recommended by some physicians, especially those practicing alternative medicine, but prescriptions and certifications are not required.<sup>85</sup>

#### D. *Pharmaceuticals*

Medical marijuana is most closely related to pharmaceuticals. Cannabis has specific medical indications defined by statute while

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78. *Should You Take Dietary Supplements?*, NIH NEWS IN HEALTH (Aug. 2013), <https://newsinhealth.nih.gov/2013/08/should-you-take-dietary-supplements>.
79. *Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/dietarysupplements/> (last updated Nov. 16, 2018).
80. *See Id.*
81. *Id.*
82. *FDA and Marijuana*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm> (last updated June 25, 2018).
83. NIH NEWS IN HEALTH, *supra* note 78.
84. *Understanding the Claims on Dietary Supplement Labels*, AM. CANCER SOC., <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/reading-labels.html> (last updated Mar. 31, 2015); *Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm480069.htm> (last updated Jun. 19, 2018).
85. *Where Can I Purchase Dietary Supplements?*, NAT'L INST. HEALTH, [https://ods.od.nih.gov/Health\\_Information/ODS\\_Frequently\\_Asked\\_Questions.aspx](https://ods.od.nih.gov/Health_Information/ODS_Frequently_Asked_Questions.aspx), (last updated July 1, 2013).

medications have specific medical indications defined by the FDA.<sup>86</sup> A patient can only obtain medical cannabis if it has been recommended by a physician and can only obtain many pharmaceuticals if they have been prescribed by a physician. Prior to patient certification for medical cannabis, in some states a physician must perform a medical history and physical examination, review prior medical records, and weigh the risks and benefits of medical marijuana for the particular patient.<sup>87</sup> This process closely resembles traditional medical practice with pharmaceuticals.

Perhaps, the most persuasive reason for comparing medical marijuana and pharmaceuticals is that plant-derived THC is identical to the drug, Marinol (dronabinol).<sup>88</sup> Marinol is a synthetic version of THC,<sup>89</sup> with important similarities. Marinol is a Schedule III<sup>90</sup> controlled substance indicated for the treatment of AIDS-related anorexia associated with weight loss, as well as chemotherapy-induced nausea and vomiting when standard antiemetics are ineffective.<sup>91</sup> Marinol users are warned against operating a motor vehicle and heavy machinery or engaging in other hazardous activities.<sup>92</sup> Oral dosages range from 2.5 milligrams to 20.0 milligrams per day.<sup>93</sup> Multiple drug interactions have been reported, most commonly with antidepressants, antihistamines, benzodiazepines, and barbiturates.<sup>94</sup>

From the products liability perspective, one of the most important questions is whether the Learned Intermediary Doctrine will apply to medical cannabis as it does to pharmaceuticals. If the doctrine applies to both, much of the liability from harm related to medical marijuana will be redirected from the participants in the supply chain to the physicians.

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86. Omudhome Ogbu, *Indications for Drugs (Uses), Approved vs. Non-Approved*, MEDICINE NET (Aug. 20, 2015), [https://www.medicinenet.com/indications\\_for\\_drugs\\_\\_approved\\_vs\\_non-approved/views.htm](https://www.medicinenet.com/indications_for_drugs__approved_vs_non-approved/views.htm).
87. *The Role of the Physician in "Medical" Marijuana*, AM. SOC'Y ADDICTION MED. 20-21 (2010), available at [https://www.asam.org/docs/public-policy-statements/1role\\_of\\_phys\\_in\\_med\\_mj\\_9-10.pdf?sfvrsn=0](https://www.asam.org/docs/public-policy-statements/1role_of_phys_in_med_mj_9-10.pdf?sfvrsn=0).
88. U.S. FOOD & DRUG ADMIN., NDA 18-651/S-021, MARINOL (2004).
89. ALISON MACK & JANET JOY, MARIJUANA AS MEDICINE? 142 (2001).
90. A Schedule III drug has "a moderate to low potential for physical and psychological dependence." *Drug Scheduling*, *supra* note 42.
91. MACK & JOY, *supra* note 89 at 8.
92. FOOD & DRUG ADMIN., REFERENCE ID: 4145204, FULL PRESCRIBING INFORMATION: MARINOL (2017).
93. U.S. FOOD & DRUG ADMIN., NDA 18-651/S-025 AND S-026, MARINOL (2004).
94. *Id.*



The Learned Intermediary Doctrine limits a manufacturer's duty to warn about the potential adverse consequences of a pharmaceutical or medical device to the prescribing physician and not the patient.<sup>95</sup> For example, in *Toole v. McClintock*, the adequacy of the manufacturer's warning about the hazards of its breast implant was based solely on the efficacy of the warning to the patient's physician.<sup>96</sup> The court held that the manufacturer had no duty to warn the patient.<sup>97</sup>

Notwithstanding the Learned Intermediary Doctrine, some courts have implicitly or explicitly held that a manufacturer has a duty to directly warn patients of the potential hazards of their drugs or medical devices.<sup>98</sup> Three exceptions to the Doctrine have been carved out: (1) warnings to parents of minor children;<sup>99</sup> (2) direct marketing of drugs to consumers;<sup>100</sup> and (3) treatment decisions driven predominantly by patient choice with minimal physician input.<sup>101</sup>

The applicability of the Learned Intermediary Doctrine to medical cannabis is uncertain. The following reasons illustrate why it is likely that the Learned Intermediary Doctrine will not apply and participants in the cannabis supply chain will bear the majority of the liability for harms suffered by patients. Most medical marijuana evaluations are performed at "specialty" medical marijuana clinics that have only one purpose - to ascertain whether a patient is a suitable candidate for

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95. Hill v. Wyeth, Inc., No. 4:03CV1526 JCH, 2007 WL 674251 (E.D. Mo. Feb. 28, 2007).

96. Toole v. McClintock, 999 F.2d 1430, 1436 (11th Cir. 1993).

97. *Id.* at 1433.

98. See e.g., Reyes v. Wyeth Lab., 498 F.2d 1264, 1274 (5th Cir. 1974); Perez v. Wyeth Lab., 734 A.2d 1245, 1247 (N.J. 1999); McDonald v. Ortho Pharm. Co., 475 N.E.2d 65, 68 (Mass. 1985).

99. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1279 (5th Cir. 1974).

100. In a case involving the subdermal insertion of the contraceptive, Norplant, the Supreme Court of New Jersey opined "that the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers . . . ." Perez v. Wyeth Laboratories, 734 A.2d 1245, 1257 (N.J. Sup. Ct. 1999). Plaintiffs argued that Norplant was advertised directly to women, not to doctors, but did not warn consumers of the potential dangers. The Court held that Defendant cannot engage in deceptive advertising and they had a duty to warn.

101. In *MacDonald v. Ortho Pharmaceutical Corp.*, the Massachusetts Supreme Court concluded that, due to the significant participation of the patient in birth control pill decisions, the limited participation of doctors, the ease of making direct warnings to patients, and the considerable risks of the medication, the manufacturer had a duty to provide warnings directly to the patients and could not simply rely on warnings made to their doctors. *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985).

medical marijuana.<sup>102</sup> The medical history and physical exam focuses on whether the patient has (or might have) a certifiable condition.<sup>103</sup> Laboratory testing is not required and no other medications are prescribed.<sup>104</sup> Doctors may perform evaluations as frequently as every fifteen minutes<sup>105</sup> and clinics may be open six or seven days per week.<sup>106</sup> Clinics advertise heavily on the internet and in print.<sup>107</sup> Facilities may even waive the evaluation fee if the doctor cannot certify the patient for medical marijuana.<sup>108</sup> The physicians working in medical marijuana clinics, predominantly naturopathic physicians,<sup>109</sup> have no special medical training in the pharmacology or prescribing of medical cannabis.<sup>110</sup> Because medical cannabis is not regulated by the federal government like a prescription drug, cannabis manufacturers are not required to provide health care providers with continuing education, product information, dosing instructions, warnings, or

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102. Kevin P. Hill, *Medical Marijuana for the Treatment of Chronic Pain and Other Psychiatric Problems: A Clinical Review*, 313 J. AM. MED. ASS'N 2474 (2015).
103. *What to Expect*, CANNA-CENTERS, <https://www.canna-centers.com/what-to-expect/> (last visited Sep. 22, 2018).
104. See Dianne Cochrane, *Marijuana Card: Medical Marijuana OK'd After 8 Minutes, 6 Questions*, BILLINGS GAZETTE (Aug. 21, 2010), [https://billingsgazette.com/news/local/medical-marijuana-card-ok-d-after-minutes-questions/article\\_873a0ad2-adaf-11df-8799-001cc4c002e0.html](https://billingsgazette.com/news/local/medical-marijuana-card-ok-d-after-minutes-questions/article_873a0ad2-adaf-11df-8799-001cc4c002e0.html); Melissa Sherrard, *What to Expect When You Visit a Medical Marijuana Doctor*, CIVILIZED (June 5, 2017), <https://www.civilized.life/articles/what-to-expect-when-you-visit-the-medical-marijuana-doctor/>.
105. See, e.g., *Frequently Asked Questions*, SW. MEDICAL MARIJUANA EVALUATION CTR., [http://www.evaluationtoday.com/medical\\_marijuana\\_faqs.html](http://www.evaluationtoday.com/medical_marijuana_faqs.html) (last visited Jan. 10, 2019).
106. See, e.g., ARIZ. GREEN LIFE, <https://azgreenlife.com/> (last visited Jan. 10, 2019).
107. Eli McVey, *Chart: Most Effective Forms of Advertising for Cannabis Businesses*, MARIJUANA BUS. DAILY (Nov. 12, 2017), <https://mjbizdaily.com/wp-content/uploads/2017/11/11-13-17-COTW.png>.
108. MEDICAL MARIJUANA TREATMENT CLINICS FLA., <https://www.mmtcfl.com/> (last visited Jan. 11, 2019).
109. *Medical Marijuana Annual Report A.R.S. §36-2809*, ARIZ. DEP'T. HEALTH SERV. 26 (Jan. 14, 2016), <https://www.azdhs.gov/documents/licensing/medical-marijuana/reports/2015/2015-mm-annual-report-160114.pdf>.
110. ARIZ. DEP'T HEALTH SERV., ADHS12-017291, MEDICAL MARIJUANA ANNUAL REPORT A.R.S. § 36-2809 (Jan. 14, 2016), *available at* <https://www.azdhs.gov/documents/licensing/medical-marijuana/reports/2015/2015-mm-annual-report-160114.pdf>.

contraindications.<sup>111</sup> Dispensaries provide limited information and most patients are left to educate themselves.

In summary, medical marijuana is a pharma-pseudical, dispensed in a manner that circumvents the Learned Intermediary Doctrine, similar to birth control medication,<sup>112</sup> because: (1) the product is heavily marketed directly to consumers; (2) patients take a very prominent role in the decision to use the medication; and (3) the role of the physician is less significant in comparison to other therapeutic decisions. Participants in the medical marijuana supply chain have a duty to warn, which must be directed at the patient rather than the physician.

#### IV. HEALTH EFFECTS OF CANNABIS & CANNABINOIDS

##### A. *Beneficial Effects of Cannabinoids*

Cannabis is an old remedy. Written records of cannabis use date back to the sixth century B.C.E.<sup>113</sup> Cannabis was introduced to Western medicine in the mid-1800's and was included in the Third Edition of the United States Pharmacopeia in 1851.<sup>114</sup> It was used as an analgesic, anticonvulsant, and sedative-hypnotic until its sale and distribution became illegal under federal law in 1937.<sup>115</sup> In 1996, cannabis became legal for medicinal purposes in California.<sup>116</sup> Because medical marijuana is still illegal under federal law, research into the benefits and risks of its administration has been sharply circumscribed in the United States.<sup>117</sup> For example, in a letter to Congressman Tim Walz, Department of Veterans Affairs Secretary David Shulkin wrote, "VA is committed to researching and developing effective ways to help Veterans cope with post-traumatic stress disorder and chronic pain conditions . . . [h]owever, federal law restricts VA's ability to conduct

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111. See *PLR Requirements for Prescribing Information*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/1awsactsandrules/ucm084159.htm> (last updated Dec. 4, 2019).

112. *Supra* note Part VII.

113. Ethan B. Russo, *History of Cannabis and its Preparations in Saga, Science, and Sobriquet*, 4 CHEMISTRY & BIODIVERSITY 1614, 1625-26 (2007).

114. NAT'L ACAD. SCIENCES, ENG'G, & MED., *supra* note 11, at 43.

115. Kaloyan Ivanov, *High Times: The Evolution of the Stigma on Marijuana and Attempts to Tear it Down*, 13 EUKARYON 61 (2017).

116. NAT'L ACAD. OF SCI., ENG'G, & MED., *supra* note 11, at 67-68.

117. Sarah See Stith & Jacob Miguel Virgil, *Federal Barriers to Cannabis Research*, 332 SCIENCE 1182, 1182 (2016).

research involving medical marijuana, or to refer veterans to such projects.”<sup>118</sup>

Cannabis appears to be an effective treatment for the reduction of chronic pain, especially neuropathic pain.<sup>119</sup> In a review of five “high-quality randomized controlled clinical trials,” each demonstrated the analgesic effects of smoked cannabis.<sup>120</sup> In a meta-analysis of twenty-eight placebo-controlled studies using predominantly plant-derived cannabinoids, Whiting found that the odds of improvement in pain control in the cannabis group increased by thirty percent, and the effect was dose-dependent.<sup>121</sup> Chronic pain was mostly neuropathic but other etiologies were included.<sup>122</sup> A study of 244 chronic pain patients determined that medical cannabis use was associated with a sixty-four percent reduction in opioid use, fewer side effects, and a forty-five percent improved quality of life.<sup>123</sup>

The efficacy of cannabis as a treatment for cancer is speculative as there is insufficient primary research to suggest a therapeutic benefit.<sup>124</sup> However, there is conclusive evidence that cancer chemotherapy-induced nausea and vomiting can effectively be treated by oral cannabinoids as antiemetics.<sup>125</sup> Cannabinoids with high THC-concentrations were comparable to standard antiemetics in efficacy, but combinations of the two drugs were non-synergistic.<sup>126</sup> High CBD preparations have not been tested for treatment of chemotherapy-induced emesis.<sup>127</sup>

Anorexia and weight loss contribute to the morbidity and mortality of numerous diseases and cannabis is moderately beneficial in averting

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118. Katie Zezima, *VA Says it Won't Study Medical Marijuana's Effect on Veterans*, WASH. POST (Jan. 16, 2018), <https://www.washingtonpost.com/news/post-nation/wp/2018/01/16/va-says-it-wont-study-medical-marijuanas-effect-on-veterans/>.

119. Seddon R. Savage et al., *Cannabis in Pain Treatment: Clinical & Research Considerations*, 17 J. PAIN 654, 662 (2016).

120. *Id.* at 657.

121. Penny Whiting et al., *Cannabinoids for Medical Use: A Systematic Review and Metanalysis*, 313 J. AM. MED. ASS'N 2456, 2460 (2018).

122. The other conditions included cancer pain, multiple sclerosis, rheumatoid arthritis, musculoskeletal issues, and chemotherapy-induced pain. *Id.*

123. Kevin F. Boehnke et al., *Medical Cannabis Use is Associated with Decreased Opiate Medication Use in a Retrospective Cross-Sectional Survey of Patients with Chronic Pain*, 17 J. PAIN 739, 741 (2016).

124. NAT'L ACAD. SCIENCES, ENG'G, & MED., *supra* note 11, at 91.

125. Whiting et al., *supra* note 121, at 2459.

126. *Id.* at 2469.

127. *See id.*

those effects.<sup>128</sup> Two out of three studies showed some improvement in appetite in cancer patients.<sup>129</sup> In women with anorexia nervosa, low dose THC was associated with weight gain despite no change in the psychopathology of the eating disorder itself.<sup>130</sup>

An Israeli group reported on the treatment of seventy-four children and adolescents with cannabis for intractable epilepsy.<sup>131</sup> Although ethical considerations precluded the use of a control group, the results were dramatic. Eighteen percent of the subjects experienced a 75-100% reduction in seizures; thirty-four percent had a fifty to seventy-five percent reduction in seizures; twelve percent had a twenty-five to fifty percent reduction in seizures; and twenty-six percent had less than a twenty-five percent reduction in seizures.<sup>132</sup>

Medical marijuana has been advocated for treatment of spasticity associated with multiple sclerosis and spinal cord injury.<sup>133</sup> Multiple reviews have concluded that oral cannabis is probably effective for reducing spasticity in multiple sclerosis, but there was insufficient evidence to support its efficacy in spinal cord injuries.<sup>134</sup> In patients with tics from Tourette's syndrome, oral THC was effective in reducing tic frequency.<sup>135</sup> However, cannabis was of no benefit for Amyotrophic Lateral Sclerosis (ALS) or for the choreiform movements of Huntington's Disease.<sup>136</sup>

CBD capsules were found to improve the quality of life in a twenty-one-patient randomized, double-blind, placebo-controlled study of

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128. Jeffrey E. Beal et al., *Dronabinol as a Treatment for Anorexia Associated with Weight Loss in Patients with AIDS*, 10 J. PAIN SYMPTOM MGMT. 89, 89 (1995).
129. ESLEY A. SMITH ET AL., CANNABINOIDS FOR NAUSEA AND VOMITING IN ADULTS WITH CANCER RECEIVING CHEMOTHERAPY 14 (2015).
130. Alin Andries et al., *Dronabinol in Severe, Enduring Anorexia Nervosa: A Randomized Controlled Trial*, 47 INT. J. EATING DISORDERS 18, 22 (2014).
131. Intractable epilepsy is a seizure disorder in which a patient's seizures are not controlled with treatment. These seizures are also referred to as "refractory." Michal Tzadok et al, *CBD-Enriched Medical Cannabis for Intractable Pediatric Epilepsy: The Current Israeli Experience*, 35 SEIZURE: EUROPEAN JOURNAL OF EPILEPSY 41, 41 (2016).
132. *Id.*
133. NAT'L ACAD. SCIENCES, ENG'G, & MED, *supra* note 11, at 2463.
134. *Id.* at 103.
135. K.R. Müller-Vahl et al., *Influence of Treatment of Tourette Syndrome with D9-Tetrahydrocannabinol (D9-THC) on Neuropsychological Performance*, 34 PHARMACOPSYCHIATRY 19, 19 (2001).
136. NAT'L ACAD. SCIENCES, ENG'G, & MED, *supra* note 11, at 106.

Parkinson's disease.<sup>137</sup> Smoked cannabis also showed a statistically significant improvement in Parkinsonian rigidity, tremor, and bradykinesia in a similar study.<sup>138</sup> No therapeutic effect from cannabis was evident in dementia.<sup>139</sup>

Although cannabis lowers intraocular pressure for two hours,<sup>140</sup> it is ineffective for the treatment of glaucoma.<sup>141</sup> Patients with traumatic brain injury or intracranial hemorrhage had better outcomes with cannabis use.<sup>142</sup> Individuals with social anxiety disorder were benefitted by cannabis use.<sup>143</sup> Depression was unresponsive to cannabis; however, cannabinoids improved short-term sleep in patients with pathological sleep disturbances, including fibromyalgia, sleep apnea, and chronic pain.<sup>144</sup>

Psychological disorders also vary in their responsiveness. Randomized trials are underway to assess the potential benefits of cannabis in post-traumatic stress disorder (PTSD).<sup>145</sup> One study of male Canadian soldiers with PTSD showed a considerable reduction in nightmares and an improvement in general well-being with oral THC treatment.<sup>146</sup> Cannabis showed no benefit in patients with schizophrenia or other psychoses.<sup>147</sup>

The limited research conducted with medical cannabis has produced positive results in a variety of diagnoses; however, more research is needed to evaluate symptom relief and monitor outcomes.

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137. Marcos Hortes N. Chagas et al., *Effects of Cannabidiol in the Treatment of Patients with Parkinson's Disease: An Exploratory Double-Blind Trial*, 28 J. PSYCHOPHARMACOLOGY 1088, 1090 (2014).
138. Itay Lotan et al., *Cannabis (Medical Marijuana) Treatment for Motor and Non-Motor Symptoms of Parkinson Disease: An Open-Label Observational Study*, 37 CLINICAL NEUROPHARMACOLOGY 41, 42 (2014).
139. S. KRISHNAN, ET AL., CANNABINOIDS FOR THE TREATMENT OF DEMENTIA 8 (2009).
140. Ileana Tomida et al., *Effect of Sublingual Application of Cannabinoids on Intraocular Pressure: A Pilot Study*, 15 J. GLAUCOMA 349 (2006).
141. Whiting et al., *supra* note 121, at 2464.
142. NAT'L ACAD. SCIENCES, *supra* note 11, at 116.
143. Whiting et al., *supra* note 121, at 2463.
144. *Id.* at 2464.
145. Rakesh Jetly et al., *The Efficacy of Nabilone, A Synthetic Cannabinoid, in the Treatment of PTSD-Associated Nightmares: A Preliminary Randomized, Double-Blind, Placebo-Controlled Cross-Over Design Study*, 51 PSYCHONEUROENDOCRINOLOGY 585, 587 (2015).
146. *Id.*
147. See BENJAMIN C. MCLOUGHLIN ET AL., CANNABIS AND SCHIZOPHRENIA 3 (2014).

*B. Adverse Effects of Cannabinoids*

Medical cannabis has produced adverse reactions in certain disease states and in specific groups of patients. Increased risk of acute myocardial infarction was not found in cannabis users, but limited evidence suggested that cannabis use could acutely trigger a myocardial infarction or an ischemic stroke.<sup>148</sup> Inhalation of cannabis smoke by individuals with pre-existing angina reduces the amount of exercise required to precipitate an angina attack by fifty percent and has been associated with a “five-fold increase[d] risk of Myocardial Infarctions . . . in the first hour after” smoking.<sup>149</sup>

No statistically significant association was found between smoking cannabis and lung cancer,<sup>150</sup> head and neck cancers,<sup>151</sup> esophageal cancers,<sup>152</sup> or other cancers except for non-seminoma type testicular cancer.<sup>153</sup> Cannabis smoke, however, does contain many of the same compounds as tobacco smoke.<sup>154</sup> There is strong evidence that cannabis smoke is not only carcinogenic, but also potentially more cytotoxic and mutagenic than cigarette smoke.<sup>155</sup> Cannabis smokers retain three times the level of tar and five times the level of carbon monoxide in their lungs compared with tobacco smokers.<sup>156</sup> Cannabis smokers also inhale twenty times the level of ammonia and up to five times the level of

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148. NAT'L ACAD. SCIENCES, ENG'G, & MED, *supra* note 11, at 166.
149. Justin Lee et al., *Cannabis and Myocardial Infarction: Risk Factors and Pathogenetic Insights*, 1 SCIFED J. CARDIOLOGY 1 (2017).
150. Li Rita Zhang et al., *Cannabis Smoking and Lung Cancer Risk: Pooled Analysis in the International Lung Cancer Consortium*, 136 INT'L J. CANCER 894, 896 (2015).
151. M.F.F. de Carvalho et al., *Head and Neck Cancer Among Marijuana Users: A Meta-Analysis of Matched Case-Control Studies*, 60 ARCHIVES OF ORAL BIOLOGY 1750, 1753 (2015).
152. See Mia Hashibe et al., *Marijuana Use and the Risk of Lung and Upper Aerodigestive Tract Cancers: Results of a Population-based Case-control Study*, 15 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1829, 1830 (2006).
153. J. Gurney et al., *Cannabis Exposure and Risk of Testicular Cancer: A Systematic Review and Meta-Analysis*, 15 BMC CANCER 1, 5 (2015), available at <https://bmccancer.biomedcentral.com/articles/10.1186/s12885-015-1905-6>.
154. Rebecca M. Maertens et al., *The Genotoxicity of Mainstream and Sidestream Marijuana and Tobacco Smoke Condensates*, 22 CHEM. RES. TOXICOLOGY 1406, 1406 (2009).
155. *Id.*
156. Tzu-Chin Wu et al., *Pulmonary Hazards of Smoking Marijuana as Compared with Tobacco*, 318 NEW ENG. J. MED. 347, 350 (1988).

hydrogen cyanide as tobacco smokers.<sup>157</sup> Habitual smoking of cannabis is associated with a higher incidence of wheezing, coughing, and phlegm production as well as an increased risk of developing or exacerbating chronic obstructive pulmonary disease.<sup>158</sup> Cessation of cannabis smoking or switching to a vaporizer diminished these symptoms.<sup>159</sup>

Driving impairment occurs early in occasional cannabis users and requires a THC blood level of just 2-5 ng/ml.<sup>160</sup> Smoking or vaporizing ten milligrams of THC yielded blood levels at or above 5 ng/mL within ten minutes.<sup>161</sup> Consuming a fifteen-milligram edible produced the same blood level in two to four hours.<sup>162</sup> In other words, occasional cannabis users become impaired early and often. Not surprisingly, cannabis use is substantially linked to an increased risk of motor vehicle accidents and a higher blood THC level correlates with an increased likelihood of an accident.<sup>163</sup> It takes six to eight hours for the impairment to resolve.<sup>164</sup> Combined use of cannabis and alcohol increases accident risk more than either substance alone.<sup>165</sup>

Deaths related to cannabis use are extremely uncommon,<sup>166</sup> however, among the pediatric population, cannabis exposure was related to CNS and respiratory depression.<sup>167</sup> Physicians in Colorado conducted a retrospective analysis of children under age twelve who were evaluated at the emergency room of a tertiary care children's hospital in Colorado.<sup>168</sup> Prior to legalization, no pediatric cases of

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157. David Moir et al., *A Comparison of Mainstream and Sidestream Marijuana and Tobacco Cigarette Smoke Produced under Two Machine Smoking Conditions*, 21 CHEM. RES. TOXICOLOGY 494, 494 (2007).
158. NAT'L ACAD. SCIENCES, ENG'G, & MED, *supra* note 11, at 181-88.
159. *Id.* at 192.
160. Rebecca L. Hartman & Marilyn A. Huestis, *Cannabis Effects on Driving Skill*, 59 CLINICAL CHEMISTRY 478, 478 (2012).
161. COLO. DEP'T PUB. HEALTH & ENV'T, MONITORING HEALTH CONCERNS RELATED TO MARIJUANA IN COLORADO: 2016 (2016), *available at* <http://www.colorado.gov/cdphe/marijuana-health-report>.
162. *Id.* at 131.
163. Ole Rogeberg & Rune Elvik, *The Effects of Cannabis Intoxication on Motor Vehicle Collision Revisited and Revised*, 111 ADDICTION 1348, 1348 (2016).
164. COLO. DEP'T PUB. HEALTH & ENV'T, *supra* note 161, at vii.
165. *Combining Cannabis and Alcohol Amplifies Crash Risks*, ASS'N FOR PSYCHOL. SCI. (July 24, 2015), <https://www.psychologicalscience.org/news/motr/combining-cannabis-and-alcohol-amplifies-crash-risks.html>.
166. NAT'L ACAD. SCIENCES, ENG'G, & MED, *supra* note 11, at 231-232.
167. Sophie Le Garrec et al., *Cannabis Poisoning in Children*, 40 INTENSIVE CARE MED. 1394, 1394 (2014).
168. George Sam Wang et al., *Pediatric Marijuana Exposures in a Medical Marijuana State*, 167 J. AM. MED. PEDIATRICS, 630, 630 (2013).



cannabis overdose occurred; post-legalization, there were fourteen confirmed cases within a two-year period.<sup>169</sup> Of the eight patients admitted to hospital, two required admission to the intensive care unit.<sup>170</sup> Seven of the eight exposures were from edibles,<sup>171</sup> likely because they often look like and taste like regular candies, soft drinks, and baked goods.<sup>172</sup>

Compared with adults, the effects of pediatric cannabis intoxication are more pronounced and occur at lower doses.<sup>173</sup> Common symptoms include ataxia, somnolence, lethargy, altered mental status, and obtundation (reduced alertness).<sup>174</sup> Rarely, children will present with severe symptoms, such as apnea, cyanosis (discoloration of skin), bradycardia (slowed heart rate), hypotonia (decreased muscle tone), and opisthotonus (severe hyperextension and spasticity).<sup>175</sup>

The Committee on Obstetric Practice of the American College of Obstetrics and Gynecology reviewed the effects of marijuana use during pregnancy and lactation.<sup>176</sup> Children exposed to marijuana *in utero* achieved lower scores on visual problem solving, visual-motor coordination, and visual analysis tasks.<sup>177</sup> Reduced attention spans and increased behavioral problems were evident.<sup>178</sup> Newborns exposed to cannabis *in utero* had shorter birth lengths, lower birth weights, and smaller head circumferences, all of which correlated with the amount of maternal marijuana use during the first and second trimesters of pregnancy.<sup>179</sup> This committee recommended counseling pregnant women about the potential adverse health consequences of cannabis use

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169. *Id.* at 631.

170. *Id.* at 632.

171. *Id.* at 630.

172. *Id.* at 633.

173. Laura M. Borgelt et. al., *The Pharmacologic and Clinical Effects of Medical Cannabis*, 33 PHARMACOTHERAPY 195, 205 (2013).

174. *Id.*

175. Borgelt et al., *supra* note 173, at 205.

176. AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION NO. 722, MARIJUANA USE DURING PREGNANCY AND LACTATION (2017), available at <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation?IsMobileSet=false>.

177. *Id.*

178. *Id.*

179. *Id.*

during pregnancy.<sup>180</sup> Because cannabinoids are found in breast milk, they also advised lactating women to discontinue marijuana use.<sup>181</sup>

A study of 975 individuals in upstate New York to assess whether cannabis use over an eight-year period during childhood, adolescence, and the early twenties was predictive of neurocognitive and behavioral problems in the late twenties.<sup>182</sup> The study, which was controlled for age, gender, income, and other mental disorders, clearly demonstrated that marijuana use was predictive of later health problems.<sup>183</sup> Cannabis users were thirty-six percent more likely to have neurocognitive problems, twenty-six percent more likely to have lower academic functioning and achievement, and fifty-two percent more likely to have general malaise.<sup>184</sup> The researchers hypothesized that “neurocognitive impairment may be a mechanism that mediates the association between marijuana use and lower academic achievement and functioning.”<sup>185</sup>

The results of studies on the effects of marijuana use by adolescents and young adults have been reported by the Colorado Retail Marijuana Public Health Advisory Committee (Colorado Retail Committee).<sup>186</sup> The Colorado Retail Committee found moderate evidence that adolescents and young adults who are regular marijuana users are: (1) more likely than non-users to have cognitive and academic ability impairment for at least twenty-eight days after last use; (2) less likely than non-users to graduate from high school; (3) more likely than non-users to increase their use and become addicted to marijuana in adulthood; and (4) more likely than non-users to use and become addicted to alcohol or tobacco in adulthood.<sup>187</sup> The Colorado Retail Committee found “substantial evidence that adolescent and young adult marijuana users are more likely than non-users” to: (1) “use and be addicted to illicit drugs in adulthood;” and (2) develop psychotic symptoms or disorders like schizophrenia in adulthood.<sup>188</sup> Quitting

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180. *Id.*

181. *Id.*; See also Kerry A. Bertrand et al., *Marijuana Use by Breastfeeding Mothers and Cannabinoid Concentrations in Breast Milk*, 142 PEDIATRICS 1, 3-5 (2018).

182. Judith S. Brook et al., *The Association Between Early Marijuana Use and Subsequent Academic Achievement and Health Problems: A Longitudinal Study*, 17 AM. J. OF ADDICTION 155, 156-59 (2008).

183. AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, *supra* note 176.

184. *Id.*

185. Whiting et al., *supra* note 121, at 2469.

186. *Marijuana Use Among Adolescents and Young Adults*, COLO. DEP'T PUB. HEALTH & ENV'T at 95 (January 12, 2015), [http://dhss.alaska.gov/dph/Director/Documents/marijuana/Monitoring\\_Health\\_Concerns\\_Related\\_to\\_Marijuana\\_in\\_Colorado\\_2014.pdf](http://dhss.alaska.gov/dph/Director/Documents/marijuana/Monitoring_Health_Concerns_Related_to_Marijuana_in_Colorado_2014.pdf).

187. *Id.* at 98.

188. *Id.*

marijuana was associated with lower risks of cognitive and mental health problems than for those who continued to use.<sup>189</sup>

A prospective, longitudinal study was conducted to examine the association between persistent cannabis use and neuropsychological functioning in more than 1,000 individuals over a twenty-year period, starting at birth.<sup>190</sup> Persistent cannabis use commencing in adolescence was associated with a statistically significant decline in overall neuropsychological functioning.<sup>191</sup> Moreover, the cannabis users who began persistent use in adolescence and later discontinued cannabis use for at least one year did not see restored neuropsychological functioning.<sup>192</sup>

Adverse effects from cannabis most frequently involve the CNS.<sup>193</sup> The most common effects are intoxication reactions, such as dizziness, drowsiness, and impairment of perceptual and sensory functions.<sup>194</sup> Twenty-four percent of patients using cannabis as an antiemetic became “high,” a state characterized by laughing, elation, and hyperawareness.<sup>195</sup> Up to ten percent of medical marijuana users developed paranoia and abnormal thinking; more than ten percent developed amnesia and hallucinations; and less than one percent experienced depersonalization and confusion.<sup>196</sup>

A meta-analysis of 83 studies was performed, investigating the relationship between cannabis and the age of onset of psychosis.<sup>197</sup> The authors found the onset of psychosis among cannabis users occurred almost three years earlier than non-users, supporting their hypothesis that cannabis use has a causal role in the development of psychosis in predisposed individuals.<sup>198</sup>

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189. *Id.*; See generally Ciera Parish, *Rules Are Meant to Be Broken: The Organ Procurement and Transplantation Network Should Allow Pediatric Transplantation of Adult Lungs*, 28 J.L. & HEALTH 319, 323-324 (2015).

190. Madeline H. Meier et al., *Persistent Cannabis Users Show Neuropsychological Decline from Childhood to Midlife*, 109 PROCEEDINGS OF THE NAT'L ACAD. OF SCI. OF THE U.S. 1, 1 (2012).

191. *Id.* at 6.

192. *Id.* at 5.

193. HEALTH CAN., INFORMATION FOR HEALTHCARE PROFESSIONALS: CANNABIS (MARIHUANA, MARIJUANA) AND THE CANNABINOIDS 87 (2018), available at <http://www.veterans.gc.ca/pdf/services/health/cannabis-medical-purposes/information-for-health-professionals.pdf>.

194. *Id.*

195. *Id.*

196. *Id.*

197. Matthew Large et al., *Cannabis Use and Earlier Onset of Psychosis: A Systematic Meta-Analysis*, 68 ARCHIVES OF GEN. PSYCHIATRY 555 (2011).

198. *Id.*

THC use has been correlated with episodes of acute psychosis. In a randomized, controlled trial, intravenous doses of THC equivalent to typical cannabis cigarette usage (1.0 to 3.5% THC) produced acute cognitive and behavioral effects, including paranoid and grandiose delusions, hallucinations, depersonalization, distorted sensory perceptions, altered bodily perceptions, feelings of unreality, and extreme slowing of time.<sup>199</sup> Subjects manifested a flat affect, reduced rapport, absence of spontaneity, psychomotor retardation, and emotional withdrawal.<sup>200</sup>

Cannabis use increased the risk of adverse psychiatric effects for individuals with frank schizophrenia or with a family history of the disorder.<sup>201</sup> Cannabis users developed schizophrenia an average of 1.5 years earlier than non-users.<sup>202</sup> In a study of 1,000 children followed from birth to age twenty-six, cannabis use was associated with a three-fold risk of the development of psychotic disorders.<sup>203</sup> The authors suggested that “psychologically vulnerable adolescents” should be strongly discouraged from using cannabis.<sup>204</sup>

THC causes acute and transient episodes of anxiety, similar to panic attacks, in naïve cannabis users.<sup>205</sup> In a study of French high-school students, cannabis users reported significantly higher rates of depression and suicidal behaviors.<sup>206</sup> Cannabis is one of the most frequently abused drugs in bipolar individuals, and there is a strong association between cannabis use and manic/hypomanic episodes or symptoms.<sup>207</sup> Cannabis use also reduced the age of onset of bipolar disease by an average of nine years.<sup>208</sup>

Frequent cannabis use may also lead to additional problems. Adults who smoked cannabis regularly as adolescents manifest impaired neural connectivity in the precuneus of the superior parietal lobe and the hippocampal fimbria,<sup>209</sup> which control integration functions (alertness

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199. DC D’Souza et al., *The Psychotomimetic Effects of Intravenous delta-9-tetrahydrocannabinol in Healthy Individuals: Implications for Psychosis*, 29 NEUROPSYCHOPHARMACOLOGY 1558 (2004).

200. *Id.* at 1563.

201. HEALTH CAN., *supra* note 193, at 92.

202. *Id.*

203. *Id.*

204. *Id.*

205. *Id.* at 90.

206. Henri Chabrol et al., *Cannabis Use and Suicidal Behaviours in High-School Students*, 33 ADDICTIVE BEHAVIOR 152, 154 (2008).

207. HEALTH CAN., *supra* note 193, at 90.

208. *Id.* at 91.

209. *Id.*

and awareness) and learning and memory, respectively.<sup>210</sup> Reduced connectivity has also been reported in executive functioning areas of the prefrontal cortex.<sup>211</sup> Approximately nine percent of individuals who experiment with marijuana become addicted according to the DSM-IV criteria.<sup>212</sup> The addiction rate increases to seventeen percent in teenage smokers and twenty-five to fifty percent in daily smokers.<sup>213</sup>

The safety of cannabis use (12.5% THC) in chronic non-cancer pain was examined in a prospective cohort study.<sup>214</sup> Non-serious adverse events occurred 818 times in the cannabis group compared with only 581 events in non-users.<sup>215</sup> Compared with controls, the rates of nervous system disorders, respiratory disorders, infectious disorders, and psychiatric disorders were significantly higher in the cannabis group.<sup>216</sup> In a similar study, the rate of non-serious adverse events was eighty-six percent higher in participants using medical cannabinoids versus controls.<sup>217</sup> The incidence of serious adverse events was not higher in the cannabis group.<sup>218</sup>

Foods and beverages infused with cannabis have added risks, including a greater risk of poisoning.<sup>219</sup> Unlike smoked marijuana, edibles require two hours or more to reach their peak effect, subject to food intake and concomitant use of alcohol or other medications.<sup>220</sup> This

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210. *Id.*

211. Nora D. Volkow et al., *Adverse Health Effects of Marijuana Use*, 370 NEW ENG. J. MED. 2219 (2014).

212. *Id.*

213. NIH - NAT'L INST. DRUG ABUSE, MARIJUANA FACTS FOR TEENS 3 (2013), available at [https://www.drugabuse.gov/sites/default/files/teens\\_brochure\\_2013.pdf](https://www.drugabuse.gov/sites/default/files/teens_brochure_2013.pdf).

214. Mark A. Ware et al., *Cannabis for the Management of Pain: Assessment of Safety Study (COMPASS)*, 16 J. PAIN 1233, 1234 (2015).

215. *Id.* at 1237.

216. *Id.*

217. Tongtong Wang et al., *Adverse Effects of Medical Cannabinoids: A Systematic Review*, 178 CAN. MED. ASS'N J. 1669, 1676 (2008).

218. *Id.* at 1669.

219. See Ont. Pub. Health Ass'n, Position Paper on The Public Health Implications of the Legalization of Recreational Cannabis (2017) at 17, available at <http://www.opha.on.ca/getmedia/6b05a6bc-bac2-4c92-af18-62b91a003b1b/The-Public-Health-Implications-of-the-Legalization-of-Recreational-Cannabis.pdf.aspx?ext=.pdf>.

220. Mary Barna Bridgeman et al., *Medicinal Cannabis: History, Pharmacology, And Implications for the Acute Care Setting*, 42 PHARMACY & THERAPEUTICS 180, 182 (Mar. 2017).

delayed effect leads some individuals to use excess amounts, which can lead to symptoms of overdose and poisoning.<sup>221</sup>

Drug interactions are common, especially when cannabis is used in conjunction with other CNS depressants, such as sedative-hypnotics or alcohol.<sup>222</sup> THC is oxidized via the hepatic cytochrome P450 pathway; therefore, drugs that inhibit the P450 pathway may increase the bioavailability of THC and cause overdosing.<sup>223</sup> Examples of these drugs include selective serotonin reuptake inhibitors (Prozac, Luvox), proton pump inhibitors (Prilosec, Tagamet), antibiotics (Biaxin, Emycin), anti-fungals (Nizoral, Diflucan), and calcium antagonists (Calan, Cardizem).<sup>224</sup>

Health Canada has promulgated a list of nine precautions that their physicians should consider before recommending medical cannabis:

- Cannabis should not be used in any person under the age of 18, or in any patient who has a history of hypersensitivity to any cannabinoid or to smoke. The adverse effects of cannabis use on mental health are greater during development, particularly during adolescence, than in adulthood . . .
- Cannabis should not be used in patients with severe cardiopulmonary disease because of occasional hypotension, possible hypertension, syncope, or tachycardia . . .
- Smoked cannabis is not recommended in patients with respiratory insufficiency such as asthma or chronic obstructive pulmonary disease . . .
- Cannabis should not be used in patients with severe liver or renal disease. Patients with ongoing chronic hepatitis C should be strongly advised to abstain from daily cannabis use, as this has been shown to be a predictor of steatosis severity in these individuals . . .

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221. *Marijuana: How Can It Affect your Health*, CENTERS FOR DISEASE CONTROL & PREVENTION (Jan. 27, 2017), <https://www.cdc.gov/marijuana/health-effects.html>.

222. HEALTH CAN., *supra* note 193, at 15.

223. Adrian Devit-Lee, *CBD-Drug Interactions: Role of Cytochrome P450*, PROJECT CBD (Sep. 8, 2015) <https://www.projectcbd.org/science/cannabis-pharmacology/cbd-drug-interactions-role-cytochrome-p450>; *See Drugs that May Interact with CBD Oil*, CBD OIL REV. <https://cbdoilreview.org/cbd-cannabidiol/cbd-p-450-enzyme/> (last visited Sep. 29, 2018).

224. HEALTH CAN., *supra* note 193, at 80.

- Cannabis should not be used in patients with a personal history of psychiatric disorders (especially schizophrenia), or a familial history of schizophrenia . . .
- Cannabis should be used with caution in patients with a history of substance abuse, including alcohol abuse, because such individuals may be more prone to abuse cannabis, which itself, is a frequently abused substance . . .
- Patients with mania or depression and using cannabis or a cannabinoid should be under careful psychiatric monitoring . . .
- Cannabis should be used with caution in patients receiving concomitant therapy with sedative-hypnotics or other psychoactive drugs because of the potential for additive or synergistic CNS depressant or psychoactive effects. Cannabis may also exacerbate the CNS depressant effects of alcohol and increase the incidence of adverse effects. Patients should be advised of the negative effects of cannabis/cannabinoids on memory and to report any mental or behavioral changes that occur after using cannabis . . .
- Cannabis is not recommended for women who are pregnant, breastfeeding, planning to become pregnant, or not using a reliable method of contraception.<sup>225</sup>

Like most medications, cannabis has salutary effects and side effects.<sup>226</sup> With the paucity of research performed in the United States, it is not possible to determine whether cannabis will ultimately be viewed as a blessing or a curse. Nonetheless, some individual or entity will be responsible for alerting patients to possible side effects. While the Learned Intermediary Doctrine puts the onus on doctors to warn patients about ethical pharmaceuticals, medical cannabis will be the exception. Medical cannabis is heavily marketed directly to patients by producers, and doctors only play a peripheral role as “recommenders” and not “prescribers.” Cannabis retailers are well advised to train their employees to discuss the use and misuse of cannabis as a way to limit liability.

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225. *Id.* at 79.

226. Kevin Loria, *23 Science-Backed Health benefits of Marijuana*, BUS. INSIDER (Mar. 8, 2018, 15:46) <https://www.iflscience.com/health-and-medicine/23-sciencebacked-health-benefits-of-marijuana/all/>.

## V. MANUFACTURING DEFECTS

### A. *General Considerations*

When a product differs from the manufacturer's design standards or intended result, or if it differs from supposedly identical products from the same manufacturer, the product has a manufacturing defect, *to wit*, the design has been executed in a defective manner.<sup>227</sup> Moreover, the defective product must be "dangerous" and "unfit for its intended or foreseeable uses."<sup>228</sup> A claim of defective manufacture "involves a deviation from the product's design specifications, to the injury or potential injury of a user."<sup>229</sup> Manufacturing claims can be brought in negligence, breach of warranty (implied and express), and strict liability.<sup>230</sup>

A negligence claim has three elements: (1) a legal duty to use reasonable care; (2) a breach of that duty; and (3) the breach was the "proximate or legal cause" of the injury.<sup>231</sup> Under the theory of strict liability in tort, a plaintiff has the burden of proving that: (1) he or she sustained an injury from the product; (2) the injury occurred because the product was defective; and (3) the defect existed when the product left the manufacturer's control.<sup>232</sup>

In a number of states, the Implied Warranty of Merchantability (U.C.C. § 2-314) has been codified in state law.<sup>233</sup> In Arizona, A.R.S. § 47-2314 is identical to U.C.C. § 2-314, which reads:

B. Goods to be merchantable must be at least such as:

1. Pass without objection in the trade under the contract description; and
2. In the case of fungible goods, are of fair average quality within the description; and

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227. *See Fisher v. Pelstring*, 817 F. Supp. 2d 791, 836 (D.S.C. 2012).

228. *Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (quoting *Dico v. Cisneros*, 953 S.W.2d 776, 783).

229. *Wankier v. Crown Equip. Corp.*, 353 F.3d 862, 867 (10th Cir. 2003).

230. *Products Liability*, JUSTIA, <https://www.justia.com/products-liability/> (last visited Sep. 29, 2018).

231. *U.S. Liability Ins. Co. v. Haidinger-Hayes, Inc.*, 1 Cal. 3d 586, 594 (Cal. 1970).

232. *Fender v. Medtronic, Inc.*, 887 F. Supp. 1326, 1333 (E.D. Cal. 1995).

233. *What Is the Warranty of Merchantability?*, FINDLAW, <https://consumer.findlaw.com/consumer-transactions/what-is-the-warranty-of-merchantability.html> (last accessed Sep. 29, 2018); Edward M. Kimmel, *Used Goods and Merchantability*, 13 TULSA L.J. 627, 628 (2013).



3. Are fit for the ordinary purposes for which goods of that type are used; and
4. Run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
5. Are adequately contained, packaged, and labeled as the agreement may require; and
6. Conform to any promises or affirmations of fact made on the container or label if any.<sup>234</sup>

The implied warranty of merchantability, which operates as a matter of law, “does not impose a general requirement that goods precisely fulfill the expectations of the buyer.”<sup>235</sup> Under the U.C.C., the Implied Warranty of Fitness for Particular Purpose states:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller’s skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.<sup>236</sup>

This warranty is not limited to merchants and does not require any showing that the product was defective.

U.C.C. § 2-313 sets out the elements of an express warranty:

- (1) Express warranties by the seller are created as follows:
  - (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
  - (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
  - (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

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234. Ariz. Rev. Stat. Ann. § 47-2314 (2018); U.C.C. § 2-314 (AM. L. INST. & UNIF. L. COMM’N 2002).

235. Skelton v. General Motors Corp., 500 F. Supp. 1181, 1191 (N.D. Ill. 1980) (*rev’d* on other grounds, 660 F.2d 311 (7th Cir. 1981)).

236. U.C.C. § 2-314 (AM. L. INST. & UNIF. L. COMM’N 2002).

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as “warrant” or “guarantee” or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller’s opinion or commendation of the goods does not create a warranty.<sup>237</sup>

Under various codes, statutes, and the common law, medical marijuana product liability claims can be prosecuted for manufacturing defects when the edible product differs from its intended result and the product is more dangerous or unfit for its intended purpose under the theories of negligence, strict liability, and implied warranty.

*B. Medical Marijuana Manufacturing Defect Claims*

1. Pesticides

The presence of a harmful pesticide in unprocessed cannabis is most likely a manufacturing defect, which may result in contamination of the final product with toxic chemicals or inaccurate concentrations of THC and other active components. When a product contains banned pesticides or unacceptable levels of permissible pesticides, it has deviated from the manufacturer’s specifications. Pesticides, by their very nature, have the potential to cause physical injury to humans.<sup>238</sup> If an injury occurs from an improper pesticide in cannabis, manufacturing defect claims may be made under the theories of negligence, strict liability in tort, and warranty.

The Environment Protection Agency (EPA) sets strict standards for permissible levels of pesticides in commodities sold in the United States, typically in the range of 10 to 10,000 parts per billion.<sup>239</sup> Unfortunately, the EPA has refused to regulate pesticides in cannabis plants, citing marijuana as an illegal drug under federal law.<sup>240</sup> Consequently, pesticide regulation in marijuana cultivation can be controlled by the states.<sup>241</sup> While the EPA has not established standards

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237. *Id.*

238. Christos A. Damalas & Ilias G. Eleftherohorinos, *Pesticide Exposure, Safety Issues, and Risk Assessment Indicators*, 8 INT’L J. ENV’T L RES. & PUB. HEALTH 1402, 1403 (2011).

239. RODGER VOELKER & MOWGLI HOLMES, PESTICIDE USE ON CANNABIS, CANNABIS SAFETY INST. 1, 7-9 (June 2015), available at <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/CSI-Pesticides-White-Paper.pdf>.

240. Jack Kaskey, *Pot Laced with Pesticides Forces States to Act as EPA Stays Away*, BLOOMBERG (Aug. 7, 2017), <https://www.bloomberg.com/news/articles/2017-08-02/pot-laced-with-pesticides-forces-states-to-act-as-epa-stays-away>.

241. Jay Feldman, *Pesticide Use in Marijuana Production: Safety Issues and Sustainable Options*, 34 BEYOND PESTICIDES 14, 14 (2015).

for cannabis,<sup>242</sup> it is reasonable to extrapolate that the permissible pesticide level would be comparable to other regulated commodities. Thus, states have used EPA regulations as guidelines for cannabis.<sup>243</sup>

In Oregon, cannabis samples contained pesticide concentrations in excess of 10,000 parts per billion in twelve percent of the cases and in excess of 100,000 parts per million in 1.9% of the samples.<sup>244</sup> Moreover, cannabis extracts frequently have THC concentrations five to ten times higher than cannabis flower.<sup>245</sup> “THC might concentrate at five to seven times what’s in the original plant material, but pesticides might concentrate up to 100 times their original level.”<sup>246</sup> As manufacturers work to get higher THC levels for the final product, pesticide levels are concentrating at a much higher rate. These pesticide levels grossly exceed acceptable tolerances for any commodity sold to the public for human consumption.<sup>247</sup>

The study of cannabis from Oregon shows a widespread pesticide problem. For example, 389 samples of cannabis flower and 154 samples of cannabis extract (concentrate) were tested for sixty-five pesticides.<sup>248</sup> Of the samples tested, seven percent of flower and twenty-four percent of concentrate samples exceeded Oregon’s statutory pesticide tolerances.<sup>249</sup> Some concentrates were found to contain the pesticides carbaryl, myclobutanil, and chlorfenapyr at levels greater than 100,000 parts per billion, grossly exceeding acceptable levels for these pesticides in any commodity.<sup>250</sup> Moreover, chlorfenapyr is not permitted in any food commodities.<sup>251</sup>

In 2015, Oregon Live reported the results of its own testing in “A Tainted High.”<sup>252</sup> They found that cannabis extract sold to medical marijuana patients had unacceptable levels of pesticide even though the

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242. *Id.*

243. *Id.* at 17, 19.

244. VOELKER & HOLMES, *supra* note 239, at 10.

245. *Id.* at 11.

246. Madison Margolin, *Cannabis Concentrates Have a Problem with Pesticides*, LA WEEKLY (Feb. 27, 2017, 8:12 AM), <https://www.laweekly.com/news/la-weekly-tagged-along-for-emerald-cup-cannabis-judging-10118373>.

247. VOELKER & HOLMES, *supra* note 239, at 11. One hundred parts per billion is the recommended rate for products made for human consumption. *Id.* at 15.

248. *Id.* at 7.

249. *Id.* at 8.

250. *Id.* at 11.

251. *Id.*

252. Noelle Crombie, *A Tainted High*, OR. LIVE (June 11, 2015), <http://www.oregonlive.com/marijuana-legalization/pesticides/>.

products passed mandated state testing.<sup>253</sup> Of the ten concentrates tested by independent labs, eight tested positive for excessive pesticide levels.<sup>254</sup> Of the fourteen pesticides found in those eight samples, six were classified by the federal government as possibly or probably carcinogenic.<sup>255</sup> The Oregonian article suggested that laboratory certified products sold at dispensaries are likely to contain inconsistent and unacceptable levels of pesticide concentrations or banned pesticides.<sup>256</sup>

The Oregonian determined that Mad Pharmaceuticals' *OG Propane Hash Oil* extract contained the active ingredient in Raid insecticide as well as three pesticides not approved for use in Oregon.<sup>257</sup> Seven pesticides were found in *Dab Society Dutch Treat* extract, including bifenthrin, one of the pesticides on the EPA's list of carcinogens.<sup>258</sup> The concentration was so high (0.5 to 0.8 parts per million), that one toxicologist suggested that the plants used to make *Dutch Treat* must have been "soaked" in bifenthrin prior to harvesting.<sup>259</sup>

A case involving the misuse of pesticides in marijuana cultivation was filed in Denver, Colorado on October 5, 2015.<sup>260</sup> Brandan Flores and others filed suit against LivWell, Inc., a cannabis grower and operator of at least fourteen retail marijuana dispensaries in Colorado.<sup>261</sup> During the first quarter of 2015, LivWell employed a chemical "cocktail" including the fungicide, Eagle 20, to rid the cannabis plants of fungus, mites, worms, and other natural agents.<sup>262</sup> Eagle 20 was not on the list of approved pesticides in Colorado at that time.<sup>263</sup> When burned during the process of smoking marijuana, Eagle 20 releases

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253. *Id.*

254. *Id.*

255. *Id.*

256. *Id.*

257. *Id.*

258. *Id.*

259. VOELKER & HOLMES, *supra* note 239, at 11.

260. Flores v. LivWell, Inc., No. 2015CV33528 (2d Dist. Colo. filed Oct. 05, 2015).

261. Matt Lamers, *Leading US Marijuana Retailer LivWell Takes 'Significant' Ownership Stake in Canadian Producer*, MARIJUANA BUS. DAILY (Nov. 8, 2017), <https://mjbizdaily.com/leading-us-marijuana-retailer-livwell-takes-significant-ownership-stake-canadian-producer/>.

262. David Kelly, *A First for the Marijuana Industry: A Product Liability Lawsuit*, L.A. TIMES (Oct. 8, 2015, 4:00 AM), <http://www.latimes.com/nation/la-na-marijuana-lawsuit-20151008-story.html#>.

263. *Id.*

hydrogen cyanide gas, a potent and well-known poison, directly into the lungs of the smoker.<sup>264</sup>

After being alerted to the use of Eagle 20, the Denver Department of Environmental Health placed a hold on 60,000 marijuana plants pending an assay of the residue.<sup>265</sup> The hold was removed after the Department found acceptable levels of pesticide for vegetation, although the range would have been too high for tobacco.<sup>266</sup> Individuals who unknowingly smoked Eagle 20-contaminated cannabis filed a class action lawsuit, alleging breach of contract, breach of implied covenant of good faith and fair dealing, breach of express warranty, breach of implied warranty for a particular purpose, breach of implied warrant of merchantability, intentional misrepresentation and concealment of material facts, unjust enrichment, and civil conspiracy.<sup>267</sup> Plaintiffs did not assert bodily injury, only that they overpaid for a product with a manufacturing defect.<sup>268</sup>

In response, Defendant LivWell filed a motion to dismiss, which was granted on February 11, 2016.<sup>269</sup> The court held that the plaintiffs lacked standing because they did not suffer any physical, emotional, or economic injuries.

Dismissal of the case against LivWell was anticipated for lack of damages. However, had the plaintiffs been able to show a cognizable injury-in-fact, the case would likely have been heard by a jury. As a consequence of this case, Eagle 20 was banned, and marijuana manufacturers and distributors recalled forty different contaminated cannabis products during 2016.<sup>270</sup>

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264. Hydrogen cyanide was the active ingredient in Zyklon B, exterminating agent used Nazi death camps during World War II. *The "Final Solution"*, HOLOCAUST ENCYCLOPEDIA, <https://encyclopedia.ushmm.org/content/en/article/the-final-solution> (last visited Sep. 30, 2018).

265. Debra Borchardt, *Marijuana Grower Sued for Using Pesticides*, FORBES (Oct. 14, 2015, 7:00 AM), <https://www.forbes.com/sites/debraborchardt/2015/10/14/marijuana-grower-sued-for-using-pesticides/#2cea99194fd3>.

266. *Id.*

267. *Flores v. LivWell, Inc.*, No. 2015CV33528 (2d Dist. Colo. filed Oct. 05, 2015).

268. *Id.*

269. *Id.*

270. *See* Colo. Exec. Order No. D 2015-015 (Nov. 12, 2015), [https://www.colorado.gov/governor/sites/default/files/executive\\_orders/2015\\_d\\_015.pdf](https://www.colorado.gov/governor/sites/default/files/executive_orders/2015_d_015.pdf); Ashley Simpson et al., *Recent Developments in Toxic Tort and Environmental Law*, 52 TORT & INS. L.J. 683, 690 (2017).

## 2. Heavy Metals and Fungus

At least one author has reported that medical marijuana is often laced with heavy metals and fungus, which are derived from the soil in which the marijuana grows.<sup>271</sup> Concentrating the THC (which many manufacturers aim to do) can lead to increased amounts of heavy metals in the end product.<sup>272</sup> Some manufacturers also employ butane, another toxic chemical, to strip the plant of many other compounds to maximize the percent of THC and profitability.<sup>273</sup>

One such fatality related to medical marijuana contamination likely occurred in early 2017.<sup>274</sup> According to CBS News, a young California man undergoing intensive cancer chemotherapy and stem cell therapy succumbed to a rare systemic fungal infection.<sup>275</sup> He smoked medical cannabis for the relief of chemotherapy-induced nausea and vomiting.<sup>276</sup> After his death, twenty samples of medical marijuana taken from across the state were predominantly contaminated with the same rare fungus that caused his demise.<sup>277</sup> Contaminated cannabis is the suspected cause of at least one other life-threatening fungal infection in a non-immunocompromised cannabis smoker.<sup>278</sup>

## 3. Inaccurate Medical Marijuana Testing

Testing for THC concentration in cannabis, particularly edibles, is notoriously inaccurate.<sup>279</sup> When products with a high THC concentration are incorrectly labeled with a lower THC concentration, this manufacturing defect may be responsible for the untoward effects of excess THC consumption. Multiple parties along the chain of product

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271. Brian Handwerk, *Modern Marijuana is Often Laced with Heavy Metals and Fungus*, SMITHSONIAN (Mar. 23, 2015), <http://www.smithsonianmag.com/science-nature/modern-marijuana-more-potent-often-laced-heavy-metals-and-fungus-180954696/?no-ist>.

272. *Id.*

273. *Id.*

274. *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/>.

275. *Id.*

276. *Id.*

277. *Id.*

278. Bryan B. Shapiro et al., *Cryptococcal Meningitis in a Daily Cannabis Smoker Without Evidence of immunodeficiency*, BMJ CASE REPORTS (2018), <https://casereports.bmj.com/content/2018/bcr-2017-221435.full>.

279. Steve P. Calandrillo & Katelyn J. Fulton, “*High*” Standards: The Wave of Marijuana Legalization Sweeping America Conveniently Ignores the Hidden Risks, Paper No. 2018-07 (U. Wash. Sch. L. Res. 2018), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3163729](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3163729).

distribution may be liable for the injury. Moreover, failure to properly test THC concentrations violates state law and is negligence *per se*.<sup>280</sup>

In 2014, the Oregon Live opened another investigation by testing the THC concentration of fifteen cannabis-infused edibles and comparing it to the labeled concentration.<sup>281</sup> Only one of fifteen samples was accurately labeled.<sup>282</sup> Two products underestimated the THC concentration.<sup>283</sup> For example, cannabis ice cream had fifty-four percent more TCH than the stated amount.<sup>284</sup> Twelve products overstated the THC concentration.<sup>285</sup> Chocolate chip cookies were found to have fifty-two milligrams of THC instead of the indicated 197 milligrams.<sup>286</sup> *Como Treats* pizza was labeled as having 350 milligrams of THC but contained only fifty-two milligrams – an eighty-five percent difference.<sup>287</sup> The Oregonian also pointed out that product labels were “inconsistent and confusing” and “[o]nly four [edibles] had expiration dates.”<sup>288</sup>

The accuracy of cannabis labeling was reported on in the Journal of the American Medical Association.<sup>289</sup> Seventy-five marijuana edibles - baked goods, beverages, and candy - were purchased in random dispensaries located in San Francisco, Los Angeles, and Seattle.<sup>290</sup> Two samples of each product were assayed for THC and CBD levels using state of the art, high-performance liquid chromatography.<sup>291</sup> Accurate labeling was defined as within +/- 10% of labeled values, consistent with typical United States Pharmacopeia requirements that drugs meet

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280. Alison Malsbury, *Inaccurate MJ Testing Will Lead to Lawsuits*, CANNA L. BLOG, (Mar. 27, 2015), <https://www.cannalawblog.com/inaccurate-marijuana-testing-will-lead-to-lawsuits/>.

281. Noelle Crombie, *How Potent Are Marijuana Edibles? Lab Tests Yield Surprising Results*, OR. LIVE (June 4, 2015, 2:17 PM) [https://www.oregonlive.com/marijuana/index.ssf/2015/03/how\\_potent\\_are\\_marijuana\\_edibl.html](https://www.oregonlive.com/marijuana/index.ssf/2015/03/how_potent_are_marijuana_edibl.html).

282. *Id.*

283. *Id.*

284. *Id.*

285. *Id.*

286. *Id.*

287. *Id.*

288. *Id.*

289. Ryan Vandrey et al., *Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products*, 313 J. AM. MED. ASS'N 2491 (2015).

290. *Id.*

291. *Id.*

a 90-110% potency specification.<sup>292</sup> Of the thirteen products labeled for CBD, none were accurately labeled; nine were over-labeled and four were under-labeled.<sup>293</sup> With respect to THC content, only seventeen percent of the edibles were accurately labeled, sixty percent were over-labeled, and twenty-three percent were under-labeled.<sup>294</sup> Thus, eighty-three percent of the samples were inaccurately labeled for THC concentration. Insufficient THC concentration is unlikely to produce the desired medical benefits. Excessive THC places patients at risk for adverse effects.<sup>295</sup>

When medical marijuana is labeled with the incorrect THC concentration, there is a viable claim for breach of an express warranty. The THC concentration is a description of the goods and forms part of the basis of the bargain. If the producer or retailer was aware, or should have been aware, that the product was mislabeled and likely to cause harm, fraud may be added to the claim. If testing has not been performed or performed in an inadequate manner, the plaintiff may have a *prima facie* claim for negligent misrepresentation.

Medical marijuana marked with the incorrect THC concentration is not considered of average quality, would not pass without objection in the trade, and is not fit for the ordinary purposes for which it is used. Therefore, mislabeled cannabis breaches the implied warranty of merchantability.

Consumers of medical marijuana probably lack the ability to differentiate between dozens of strains with various chemical compositions. In the current paradigm for obtaining medical marijuana, the retailer often possesses the most knowledge about the products and their effects. This places the retailer in the best position to assist the consumer in selecting a cannabis strain or an edible that is suitable for treating a specific symptom or debilitating condition. This is especially true in certain diseases, like epilepsy. One study reported a reduction in seizures of fifty percent or more in 272 patients with the use of artisanal forms of cannabis very high in CBD.<sup>296</sup> Strains low in CBD were significantly less efficacious.<sup>297</sup>

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292. Allen V. Loyd et al., *Strength and Stability Testing for Compounded Preparations*, U.S. PHARMACOPEIA, <https://www.usp.org/sites/default/files/usp/document/FAQs/strength-stability-testing-compounded-preparations.pdf> (last visited Sept. 28, 2018).

293. Vandrey et al., *supra* note 289, at 2491.

294. *Id.*

295. *Id.*

296. See Dustin Sulak et al., *The Current Status of Artisanal Cannabis for the Treatment of Epilepsy in the United States*, 70 EPILEPSY BEHAVIOR 328 (2017).

297. Kerstin Iffland & Franjo Grotenhermen, *An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies*, 2 CANNABIS & CANNABIDIOL RES. 139, 152 (2017).



If the customer asks the seller to recommend a cannabis strain or an edible to treat seizures, the customer is relying on the seller's skill and judgment to select the proper product. The seller must understand that only a product with a very high CBD concentration will be efficacious. If the seller recommends a product without the requisite concentration of CBD because the medical marijuana has been incorrectly assayed and labeled or because the seller is unaware of the association between CBD concentration and seizure abatement, the seller has breached the warranty of fitness for a particular purpose.

Manufacturing defect claims will be prolific without significant reforms in the cannabis industry. Plants need to be cultivated without noxious pesticides, heavy metals, or fungi. Concentrations of THC and CBD need to be accurate assayed and labeled. Retailers should know which cannabis strain is an effective remedy for a particular symptom or disease.

## VI. DEFECTIVE DESIGN

### A. Theory

At the most basic level, a defectively designed product is one designed in a way that is not suitable or safe for its intended purpose. Courts have articulated various criteria and tests for determining whether a design is defective. Nonetheless, it is generally true that the tests advanced under theories of strict liability in tort, negligence, and breach of implied warranty are comparable.<sup>298</sup>

The Restatement (Second) of Torts § 402A refers to a product that is “in a defective condition unreasonably dangerous . . . .”<sup>299</sup> The term, “unreasonably dangerous,” has been defined as more dangerous than an average consumer expects, so risky that a reasonable seller would not sell the product, or that the risks of the product's design outweigh its benefits.<sup>300</sup>

Courts have chosen consumer expectations,<sup>301</sup> risk-utility analysis,<sup>302</sup> or both, to ground strict tort liability.<sup>303</sup> In Arizona, for example, strict liability requires three premises: (1) the product is “in a defective condition unreasonably dangerous;” (2) the product does not perform

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298. See generally Kristine C. Karnezis, Annotation, *Products Liability: Modern Cases Determining Whether Product is Defectively Designed*, 96 A.L.R.3d 22 (2017).

299. RESTATEMENT (SECOND) OF TORTS § 395 (AM. L. INST. 1965).

300. *Id.*

301. See Aaron D. Twerski, *From Risk-Utility to Consumer Expectations: Enhancing the Role of Judicial Screening in Product Liability Litigation*, 11 HOFSTRA L. REV. 861, 895-96 (1983).

302. *Id.*

303. *Id.*

as safely as expected by an ordinary consumer when used in a reasonable or intended fashion; and (3) the design's risks outweigh its benefits.<sup>304</sup> Comment g of the Restatement (Second) of Torts § 402A is incorporated as part of the premise: "[t]he rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him."<sup>305</sup> On the other hand, a negligence claim starts with the contention that the product's design does not meet its intended purpose<sup>306</sup> and the manufacturer has not made the product safe for its intended uses by taking reasonable care in the product's design.<sup>307</sup> Regardless of whether the claim is filed under theories of strict tort liability or negligence, Arizona holds that when the user knows of the dangers, when the dangers are very obvious, or when the dangers are widely known, the manufacturer is not liable for those dangers.<sup>308</sup>

Cases asserting a breach of the implied warranty of merchantability either: (1) use a generalized test for defective design, such as fitness for the product's intended purpose; or (2) consider the product's safety for its intended use as a measure of fitness.<sup>309</sup>

The decision of how to characterize a pharma-pseudical, such as medical marijuana, involves a battle between the Second and Third Restatements of Torts and their respective comments. Regarding prescription drugs, the Second Restatement states that manufacturers should not be subject to strict tort liability for drugs that have therapeutic benefit but are also "unavoidably unsafe."<sup>310</sup> In the Third Restatement, a product is defective when a reasonable alternative design would have limited or eliminated the foreseeable risk inherent in the use of the product.<sup>311</sup> The most radical approach is taken by the Third Restatement, which limits design defects to those drugs that no reasonable health care provider, knowing the foreseeable risks and benefits, would prescribe for any patient.<sup>312</sup> In other words, if a drug is

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304. *Stilwell v. Smith & Nephew, Inc.*, 482 F.3d 1187, 1194 (9th Cir. 2007) (Internal citations omitted).

305. RESTATEMENT (SECOND) OF TORTS § 402(A) (comment g defective condition) (AM. L. INST. 1979).

306. *Stilwell*, 482 F.3d at 1194.

307. RESTATEMENT (SECOND) OF TORTS § 395 (AM. L. INST. 1965); *See Mather v. Caterpillar Tractor Corp.*, 23 Ariz. App. 409 (1975).

308. *Mather*, 23 Ariz. App. at 412.

309. *Products Liability: Modern Cases Determining Whether Product is Defectively Designed*, 96 A.L.R.3d 22 (1979).

310. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. L. INST. 1965).

311. RESTATEMENT (THIRD) OF TORTS § 2(b) (AM. L. INST. 1977).

312. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §6(c) (AM. L. INST. 1998).

prescribed by a reasonable healthcare provider for any reasonable indication, it is not defectively designed.

Certain basic facts must be known to determine whether a medical cannabis edible is defective. Are cannabis edibles useful for any medical purpose? If so, what are the indications? What are the risks? Are edibles safe, unavoidably unsafe with a therapeutic benefit, or unreasonably dangerous? Would a reasonable alternative design diminish the foreseeable risk?

*B. Defective Design in Medical Marijuana*

Marijuana-infused edibles are likely to be the main source of products liability litigation in medical marijuana. For edibles to be safe, they must have a reasonable concentration of THC that is uniform from one batch of edibles to another. Proper product sampling techniques and accurate testing by high quality laboratories are required. The product must also have a portion size that is reasonable relative to the total dose of THC in the product.

Stoney Bakes produces a double chocolate chip cookie. It resembles a true home-baked cookie, and has received five-star rave reviews on the Leafly website.<sup>313</sup> The cookie is described as “fresh and moist,” “very tasty,” and “A+ top quality.”<sup>314</sup> One user, plagued by untreatable, bimonthly migraine headaches, reports obtaining complete relief from a headache within two hours of eating the cookie.<sup>315</sup> On its face, the cookie appears to be a very well-made and successful product; however, it has a very serious design defect that makes it unreasonably unsafe.

The suggested THC dose in an edible for a new cannabis user is five milligrams.<sup>316</sup> Experienced users often take at least a ten-milligram dose.<sup>317</sup> As in most areas of medicine, the smallest effective dose of

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313. *250mg Double Chocolate Chip Cookie Reviews*, LEAFLY, <https://www.leafly.com/products/details/stoney-bakes-a-division-of-asfas-genetics-confetti-sugar-cookie/reviews> (last visited Sept. 19, 2018) [hereinafter *250 mg Cookie*, LEAFLY].
314. *Stoney Bakes*, LEAFLY, <https://www.leafly.com/products/details/stoney-bakes-a-division-of-asfas-genetics-confetti-sugar-cookie/reviews> (last visited Sept. 28, 2018).
315. *Id.*
316. *Part 1, 5 Tips to Safely Dose and Enjoy Cannabis Edibles*, LEAFLY, <https://www.leafly.com/news/cannabis-101/5-tips-to-safely-dose-and-enjoy-cannabis-edibles> (last updated Mar. 14, 2018) [hereinafter *5 Tips*, LEAFLY].
317. *The THC Dosage Guide: Flower, Edibles, Concentrates and More*, KEY TO CANNABIS, <https://keytocannabis.com/blogs/cannabis/the-thc-dosage-guide-flower-edibles-concentrates-and-more> (last visited Oct. 14, 2018).

medication is preferred because it lessens the number and severity of side effects.<sup>318</sup>

A cookie this size is typically eaten all at once. Many people may even have more than one. The problem with Stoney Bakes' product is that one cookie contains 250 milligrams of THC,<sup>319</sup> enough THC for fifty novice users or twenty-five experienced users. To obtain a five-milligram dose of THC, the cookie must be divided in fifty equal pieces, a virtual impossibility. Then, just one piece can be consumed, and I'll "bet you can't eat just one."<sup>320</sup> Because it is highly likely that a novice consumer of this THC-infused cookie will overdose on THC based on the minuscule serving size, the cookie is in a defective condition and unreasonably dangerous. A normal consumer would not anticipate the need to cut a cookie into fifty equal pieces and eat just one to obtain the correct dose; therefore, the cookie is not as safe as an ordinary consumer would expect it to be when used in a reasonable fashion. Finally, the design's risks greatly outweigh its benefits. A safer alternative design is simple – put less THC in the cookie. For example, the cookie could be made with a single dose of THC, perhaps 2.5 milligram, 5.0 milligram, or 10.0 milligram cookies, for consumption in one sitting. Instead of charging \$20 for a 250 milligram cookie,<sup>321</sup> the retailer could charge \$5 for a 10.0 milligram cookie. Profit margins would skyrocket and liability would tumble. In other words, individually wrapped servings with proper dosages would eliminate the design defect and are eminently feasibly.

Producers can alter *Cannabis sativa* plants in various ways and usually aim for high THC concentration hybrids.<sup>322</sup> A consumer could ground a defective design claim on the fact that the design of marijuana plants or its derivatives created to additional health risks, made the product more dangerous in some way, or increased its addiction potential.

The potency of cannabis has changed dramatically over the past two decades. The THC concentration of 38,681 samples of marijuana confiscated by the DEA between 1995-2014 was assayed in a 2016

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318. James P. McCormack et al., *Is Bigger Better? An Argument for Very Low Starting Doses*, 183 CANADIAN. MED. ASS'N. J. 65 (2011).

319. *250 mg Double Chocolate Chip Cookie*, LEAFLY, <https://www.leafly.com/products/details/stoney-bakes-a-division-of-asfas-genetics-confetti-sugar-cookie> (last visited Sept. 14, 2018).

320. Eben Shapiro, *The Media Business: Advertising; Crisper Chips, Fresh Slogans*, N.Y. TIMES, (May 8, 1992) <https://www.nytimes.com/1992/05/08/business/the-media-business-advertising-crisper-chips-fresh-slogans.html>.

321. *250 mg Cookie*, LEAFLY, *supra* note 313.

322. David McLeod, *A New Crop of Marijuana Geneticists Sets Out to Build Better Weed*, WIRED (Apr. 20, 2016, 7:00 AM), <https://www.wired.com/2016/04/the-science-of-marijuana/>.

study.<sup>323</sup> Two trends were evident. First, the average potency of THC increased linearly from four percent in 1995 to twelve percent in 2014, a three-fold increase.<sup>324</sup> Second, the concentration of CBD dropped from 0.28% in 1995 to 0.15% in 2014.<sup>325</sup> The increased THC potency is desirable for growers and retailers because consumers will pay more for higher concentrations of THC that engender greater euphoric effects for the same amount ingested (or smoked).<sup>326</sup>

The effects of CBD have been reviewed at length.<sup>327</sup> In many ways, CBD is the antithesis of THC. CBD inhibits the reuptake and degradation of anandamide, an endogenous cannabinoid, while THC results in relative depletion of anandamide. Anandamide depletion causes the psychotomimetic effects of THC.<sup>328</sup> CBD exerts agonist activity at the 5-hydroxytryptamine receptors (serotonin receptors), mediating its anxiolytic, antidepressant, and precognitive effects.<sup>329</sup> While CBD has salutary effects in the clinical setting,<sup>330</sup> THC use is associated with anxiety, mood disturbances, sleep disturbance, depression, mania, and schizophrenia.<sup>331</sup>

Medical marijuana that is designed to maximize THC and minimize CBD may be defectively designed for therapeutic purposes. It is not fit for its intended purpose because it may promote, rather than treat, a symptom or a disease. High THC concentration also makes marijuana more addictive,<sup>332</sup> engendering more frequent and intensive use. An

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323. Mahmoud A. ElSohly et al., *Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States*, 79 *BIOLOGICAL PSYCHIATRY* 613, 614-616 (2016).

324. *Id.*

325. *Id.*

326. Mike Pizzo, *If You're Buying Your Weed Solely on the THC Level, You're Doing it Wrong*, *MEDIUM* (May 5, 2017), <https://medium.com/trykucultivator/if-youre-buying-your-weed-solely-based-on-the-thc-level-you-re-doing-it-wrong-ec5422d4ddfd>.

327. Rong et al., *supra* note 15.

328. *Id.* at 214.

329. *Id.*

330. *Id.* at 215.

331. Amber L. Bahorik et al., *Patters of Marijuana Use Among Psychiatry Patients with Depression and its Impact on Recovery*, 213 *J. AFFECTIVE DISORDERS* 168, 170 (2017); Keren I. Bolla et al., *Sleep Disturbance in Heavy Marijuana Users*, 31 *SLEEP* 901, 906 (2008); Nora D. Volkow et al., *Decreased Dopamine Brain Reactivity in Marijuana Abusers is Associated with Negative Emotionality and Addiction Severity*, 111 *Proc. of the Nat'l Acad. Sciences of the U.S.* E3149, E3155 (2014); Wayne Hall & Louisa Degenhardt, *Cannabis Use and the Risk of Developing a Psychotic Disorder*, 7 *WORLD PSYCHIATRY* 68, 70 (2008).

332. *Marijuana*, *NAT'L INST. DRUG ABUSE*, <https://www.drugabuse.gov/publications/drugfacts/marijuana>.

ordinary consumer would not reasonably anticipate that medical marijuana would make his or her symptom or disease worse and foster addiction. An alternative design (low THC/high CBD) is safer, imminently feasible, less costly, and likely to eliminate many of the foreseeable risks of high THC edibles.

Defective design claims will arise in cannabis production. At present, numerous edibles are unreasonably dangerous because they contain concentrations of THC that will overdose the naïve or average user. In addition, production of edibles high in THC and low in CBD tends to increase the toxicity of cannabis while lowering its medicinal utility.

## VII. FAILURE TO WARN

### A. *General Considerations*

Products may be defective despite flawless design and precise manufacture. When a product becomes dangerous due to a lack of adequate instructions or warnings, the “failure to warn” makes the product defective.<sup>333</sup> “[M]anufacturers have a duty to warn consumers about the hazards inherent in their products,”<sup>334</sup> including their safe and proper use. The duty to warn extends to “latent dangers resulting from foreseeable uses” of the product that the manufacturer knew, or should have known, and to unintended uses of the product that were reasonably foreseeable.<sup>335</sup> In general, there is no duty to warn of obvious dangers.

The Restatement (Third) of Torts also characterizes warning defects:

#### § 2 Categories of Product Defect

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

....

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the

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333. *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 452 (Cal. 1978).

334. *Taylor v. Elliot Turbomachinery Co.*, 171 Cal. App. 4th 564, 577 (2009).

335. *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (N.Y. 1998).

omission of the instructions or warnings renders the product not reasonably safe.<sup>336</sup>

In Arizona, “product liability action” is defined as:

any action brought against a manufacturer or seller of a product for damages for bodily injury, death or property damage caused by or resulting from . . . the failure to warn or protect against a danger or hazard in the use or misuse of the product or the failure to provide proper instructions for the use or consumption of any product.<sup>337</sup>

A complaint alleging that a manufacturer failed to provide adequate warnings of a product’s dangers may be brought under at least three legal doctrines: strict liability, implied warranty, and negligence.<sup>338</sup> The failure to warn may be viewed as negligent under a negligence theory, as the defect itself under strict liability in tort, or as a breach of the warranty of merchantability since the product is not fit for ordinary uses without the warning.

#### *B. Warnings About Pharmaceuticals*

Earlier, this article described how prescription drugs are different from other products.<sup>339</sup> Prescription drugs are even described as “unavoidably unsafe products.”<sup>340</sup> However, they are not considered defective or unreasonably dangerous when accompanied by proper directions for use and adequate warnings of potential side effects.<sup>341</sup> A pharmaceutical manufacturer has a duty to warn of potential side effects of a medication that are known or knowable in view of the medical and scientific knowledge at the time of manufacture.<sup>342</sup> Because pharmaceutical manufacturers receive constant feedback about drug

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336. RESTATEMENT (THIRD) OF TORTS § 2(c) (AM. LAW INST. 1977).

337. Ariz. Rev. Stat. Ann. § 12-681(5) (2018).

338. David G. Epstein, *Products Liability: Defenses Based on Plaintiff’s Conduct*, 1968 UTAH L. REV. 267, 268 (1968).

339. See discussion *supra* note Part III.

340. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

341. Aaron v. Wyeth, No. 2:07cv927, 2010 WL 653984, at \*5, \*6 (W.D. Pa. Feb. 19, 2010); ELLEN FLANNERY & SANDFORD N. GREENBERG, WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES VOL. 2 93 (Anna C. Mastroianni et al. eds., 1994).

342. Muilenberg v. Upjohn Co., 320 N.W.2d 316, 331 (Mich. Ct. App. 1982).

side effects and dangers from multiple sources, they have a continuing duty to warn.<sup>343</sup>

In a negligence action, a drug manufacturer's liability is based on its duty. In other words, these actions depend on whether a duty to warn existed, what the nature of the duty was, whether there was a breach of that duty, and whether the breach of the duty proximately caused the plaintiff's injury.<sup>344</sup>

A warning is sufficient when it is reasonable.<sup>345</sup> A reasonable warning must: (1) describe the extent of the danger; (2) convey the seriousness of the danger; (3) alert a prudent health care practitioner to the danger; and (4) present the information in a satisfactory manner.<sup>346</sup> Warnings about specific drugs should include: (1) harmful propensities of the drug known (or that should be known) to the manufacturer; (2) side effects; (3) dangerous interactions with other drugs; and (4) potential exacerbation of other medical conditions by the drug.<sup>347</sup> A manufacturer must possess the knowledge of an expert in the relevant area of medicine and keep current with the scientific literature and discoveries in the field.<sup>348</sup> The duty to warn extends to the risks the pharmaceutical manufacturer discovers from continuous monitoring of drug safety.<sup>349</sup>

In strict liability actions under the Restatement (Second) of Torts, or under products liability in the Restatement (Third) of Torts, a drug manufacturer's failure to adequately warn of side effects associated with a prescription drug renders the drug "unreasonably dangerous," or "not reasonably safe" and therefore defective.<sup>350</sup> Strict tort liability is not concerned with notions of culpability.<sup>351</sup> Unlike

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343. The duty to warn may vary by state requirements. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §10(a-b) (AM. LAW INST. 1997); Kenneth Ross, *Post-Sale Duty to Warn: A Critical Cause of Action*, 27 WM. MITCHELL L. REV. 339, 346 (2000); Brian J. Hunt, *Is the Door Opening for Plaintiffs?*, FOR THE DEFENSE 60, 61 (2014).

344. *See* *Muilenberg v. Upjohn Co.*, 320 N.W.2d at 365.

345. *Id.*

346. *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1196 (D. N.D. 2002).

347. *Weilbrenner v. Teva Pharmaceuticals*, 696 F. Supp. 2d 1329, 1333-40 (M.D. Ga. 2010).

348. *Braun v. Roux Distrib. Co.*, 312 S.W.2d 758, 763 (Mo. 1958); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 149 (Mo. 1967).

349. Brittany L. Raposa, *Caveat Emptor: Protecting Inexpensive Generic Drugs at the Expense of Patient Safety*, 27 HEALTH LAW. 28, 29 (2015).

350. RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. LAW INST. 1997).

351. *Strict Liability*, JUSTIA, <https://www.justia.com/injury/negligence-theory/strict-liability/> (last visited Dec. 18, 2018).



negligence, strict liability for failure to warn extends beyond the manufacturer to all entities in the supply chain.<sup>352</sup>

In implied warranty actions, drug manufacturer liability may be similarly analyzed in terms of a duty to warn;<sup>353</sup> however, it has also been suggested that the implied warranty of merchantability does not apply to prescription drugs because they are characterized as unavoidably unsafe *ab initio*.<sup>354</sup>

In failure to warn cases involving unavoidably dangerous drugs, the standards for liability under negligence and strict liability are very similar or even “functional equivalents.”<sup>355</sup> Regardless of the claim or claims asserted in a failure to warn case, the basic factual elements that must be proven are fundamentally the same.<sup>356</sup> In *Werner*, the Fourth Circuit observed that any distinction between negligence and strict liability diminishes considerably in failure to warn cases.<sup>357</sup> Whether the defendant exercised due care in formulating the warning is the issue under negligence,<sup>358</sup> while under strict liability theory, the issue is whether an inadequate warning created an unreasonably dangerous product.<sup>359</sup> The salient question is whether the warning was adequate. If the manufacturer provided an adequate warning, Restatement (Second) of Torts § 402A, comment k, makes it clear that a drug manufacturer is not strictly liable for injuries caused by an unavoidably dangerous prescription drug.

A warning is only adequate when it is directed at the correct party. In Part III, the Learned Intermediary Doctrine and its three recognized exceptions were discussed (minor children, direct marketing, and patient-driven choice). One example of an exception is mass vaccination cases where vaccines were marketed directly to consumers. The Ninth Circuit has held that the manufacturer knew that each individual patient would not have been evaluated and counseled by a physician in advance of the immunization; therefore, the usual risks and benefits of

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352. *Cf.* 8 Am. Jur. Proof of Facts 3d 547 (last updated 2018); *see generally* Randy R. Koenders, Annotation, *Products Liability: Liability of Manufacturer or Seller as Affected by Failure of Subsequent Party in Distribution Chain to Remedy or Warn Against Defect of Which He Knew*, 45 A.L.R. Fed. 4th Art. 777 (1986).

353. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974).

354. *Taylor v. Danek Medical, Inc.*, No. Civ.A. 95-7232, 1998 WL 962062 at \*7, \*13-14 (E.D. Pa. Dec. 29, 1998).

355. *Feldman v. Lederle Laboratories*, 479 A.2d 374, 386 (N.J. 1984).

356. *Cf.* 8 Am. Jur. Proof of Facts 3d 547 (last updated 2018).

357. *Werner v. Upjohn Co., Inc.*, 628 F.2d 848, 858 (4th Cir. 1980).

358. *Id.* at 858.

359. *Id.* at 857.

treatment would not have been considered or discussed.<sup>360</sup> In that circumstance, it was the responsibility of the manufacturer to ensure that vaccination warnings reached the consumer either directly or through the purchaser of the vaccine (i.e., the vaccinator).<sup>361</sup> The Court equated this to over-the-counter drugs where warnings can be given with proper labeling, posters, and advertisements.<sup>362</sup>

In the second exception, a manufacturer is also required to directly warn a consumer about a drug's dangerous risks when that drug is directly promoted and marketed to consumers through advertising. In *Perez v. Wyeth Labs, Inc.*, the Supreme Court of New Jersey held that the Learned Intermediary Doctrine was inapplicable when pharmaceuticals were directly marketed to consumers, and manufacturers were responsible to directly warn patients of a drug's dangerous propensities.<sup>363</sup> If warnings were inadequate, manufacturers were subject to consumer claims for failure to warn.<sup>364</sup>

Another exception concerned the long-term use of birth control pills. When a woman selects a contraceptive, the physician often plays a peripheral or secondary role in the selection.<sup>365</sup> The choice is typically based on patient preference rather than the physician's comprehensive discussion of the risks, benefits, and alternatives of any therapeutic modality.<sup>366</sup> In that regard, the *McDonald* court held that a birth control pill manufacturer had a duty to directly warn consumers of the risks of its product, also noting that direct warnings were eminently feasible.<sup>367</sup>

*C. Failure to Warn and Adequately Label Marijuana Products*

Professor David Owen developed a helpful rubric for evaluating the adequacy of warnings based on content and form.<sup>368</sup> Owen refers to content as, "Substantive Adequacy," and relates it to the clarity and completeness of the description of a product's specific risks.<sup>369</sup> The form

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360. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968).

361. *See id.* at 131.

362. *Id.*

363. *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. Sup. Ct. 1999).

364. *Id.* at 1252.

365. *See* Christine Dehlendorf et al., *Women's Preferences for Contraceptive Counseling and Decision Making*, HHS PUBLIC ACCESS (Nov. 21, 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4026257/>.

366. *Id.*

367. *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985).

368. DAVID G. OWEN, *PRODUCTS LIABILITY IN A NUTSHELL* 284-95 (West Academic Publishing, 9th ed., 2015).

369. *Id.* at 285-286.

of the warning is its “Procedural Adequacy,” describing the mode of conveyance of the message.<sup>370</sup>

While the primary focus of this paper is on medical marijuana, it is at least as important that users of recreational marijuana be provided with appropriate and effective warnings and product labeling. Consumers generally understand that there are potential risks and side effects associated with the use of medications. Consumers may not appreciate the risks of using recreational marijuana, especially when the edible form of the product resembles common products and sizes that have been in the public domain for decades. Furthermore, in most states, medical marijuana users do not receive more product information than a purchaser for recreational purposes would.<sup>371</sup>

The scope of the duty to warn with respect to medical marijuana has not been defined or articulated because the industry is still in its infancy, and clinical trials in the United States are very limited.<sup>372</sup> Nonetheless, failure to warn will likely be the most significant area of cannabis products liability litigation. All participants in the cannabis supply chain should consider what extent of disclosure is necessary to limit failure to warn liability.

#### 1. Kirk v. Nutritional Elements

One medical marijuana case, *Kirk v. Nutritional Elements*, is being litigated predominantly on a theory of failure to warn.<sup>373</sup> It is a sad case, but its themes are instructive. Kristine and Richard Kirk, a married couple in Denver, had three sons, ages seven, eleven, and thirteen.<sup>374</sup> In early 2014, Richard purchased a THC-infused edible, *Karma Kandy*

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370. *Id.* at 286.

371. John M. Malouff et al., *Cannabis Users’ Recommended Warnings for Packages of Legally Sold Cannabis: An Australia-Centered Study*, 1 CANNABIS & CANNABINOID RESEARCH 239, 240 (2016). See 4 *Differences When Serving Medical Marijuana Patients vs. Recreational Customers*, INDICAONLINE (May 25, 2018), <https://indicaonline.com/blog/4-differences-serving-medical-marijuana-patients-vs-recreational-customers/>.

372. Israel is the international leader in cannabis research with 110 active clinical trials. See Yardena Schwartz, *The Holy Land of Medical Marijuana*, U.S. NEWS (Apr. 11, 2017, 11:04 AM), <https://www.usnews.com/news/best-countries/articles/2017-04-11/israel-is-a-global-leader-in-marijuana-research>.

373. *Kirk v. Nutritional Elements, Inc.*, No. 2016CV31310 (2d Dist. Colo. filed May 9, 2016).

374. See Plaintiff’s First Amended Complaint and Jury Demand at 3, *Kirk v. Nutritional Elements, Inc.*, No. 16CV31310 (2d Colo. May 9, 2016).

*Orange Ginger*, from Nutritional Elements.<sup>375</sup> The product was packaged, sold, and distributed by Gaia's Garden.<sup>376</sup> It has been debated whether Richard purchased the edible to treat his back pain or whether it was for recreational use.<sup>377</sup>

The product is described as a "delectable taffy"<sup>378</sup> containing a "101 milligram hybrid THC with Tears of Phoenix hash oil infused for a very high CBD concentrate."<sup>379</sup> The packaging did not contain any instructions about proper consumption or use.<sup>380</sup> Specifically, there was no information about how much to take, whether it should be taken with food or drink, or how long the product required to take effect. There were no warnings about the possibility of an overdose or how to manage an overdose if it were to occur.<sup>381</sup> No other printed literature was included with the purchase.<sup>382</sup> Plaintiff's counsel pointed out that there were more warnings and instructions on toothpaste, chewing gum, hand cream, and dog treats.<sup>383</sup>

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375. Emma Gannon, *Insurer Refuses to Cover Marijuana Candy Murder*, COURTHOUSE NEWS SERV. (May 8, 2017), <https://www.courthousenews.com/insurer-refuses-cover-marijuana-candy-murder/>; Bobbi Sheldon, Allison Sylte & Anastasiya Bolton, *Man, High on Pot Candy, Get 30 Years Prison for Killing Wife*, USA TODAY, <https://www.usatoday.com/story/news/nation-now/2017/04/07/husband-killed-wife-pot-candy/100190066/> (last updated Apr. 7, 2017).

376. Gannon, *supra* note 375.

377. Richard Kirk had been prescribed opiates for his back pain, but his blood test for opiates was negative immediately after the homicide. *Denver Man Who Said Marijuana Made Him Kill His Wife Gets 30 Years*, NBC NEWS (Apr. 7, 2017, 8:04 PM), <https://www.nbcnews.com/news/us-news/denver-man-who-said-marijuana-made-him-kill-his-wife-n744056>.

378. *Karma Kandy*, GAIA GARDEN, <http://gaias.atwebpages.com/product/karma-kandy/> (last visited Jan. 5, 2019).

379. *Gaia's Garden Karma Kandy*, MMJ MENU, [https://mmjmenu.com/dispensaries/1313/menus/1313/menu\\_items/414021](https://mmjmenu.com/dispensaries/1313/menus/1313/menu_items/414021) (last visited Oct. 19, 2018).

380. David Kelly, *He Got High and Killed His Wife. A Lawsuit Claims Edible Marijuana is to Blame*, L.A. TIMES (June 1, 2016, 3:00 AM), <http://www.latimes.com/nation/la-na-cannabis-homicide-20160531-snap-story.html>.

381. *Gaia's Garden Karma Kandy – Orange Ginger – 101mg*, MMJ MENU, [https://mmjmenu.com/dispensaries/1313/menus/1313/menu\\_items/414021](https://mmjmenu.com/dispensaries/1313/menus/1313/menu_items/414021) (last visited Oct. 20, 2018).

382. Plaintiff's First Amended Complaint and Jury Demand, *Kirk v. Nutritional Elements, Inc.*, No. 16CV31310 (2d Colo. May 9, 2016).

383. *Id.*



Figure 3. Kandy Karma Orange Ginger<sup>384</sup>

By its appearance, the Karma Kandy Orange Ginger taffy resembles a caramel-colored Tootsie Roll. Richard Kirk bought a Karma Kandy like the one shown above, weighing 10 grams.<sup>385</sup> For reference, the Tootsie Roll “Midgee” shown below weighs 6.7 grams.<sup>386</sup> A single serving of Tootsie Rolls is six Midgees weighing 40 grams.<sup>387</sup>



Figure 4. Tootsie Roll Midgie<sup>388</sup>

The Karma Kandy contains 101 milligrams of THC.<sup>389</sup> According to Leafly, the world’s largest cannabis information resource, the “standard dose” according to Colorado’s edibles dosing guidelines is ten milligrams, “but a cannabis newbie or low-tolerance consumer should

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384. MMJ MENU, *supra* note 381.

385. Plaintiffs’ First Amended Complaint and Jury Demand at 7, Kirk v. Nutritional Elements, Inc., No. 16-CV-31310 (2d Colo. May 9, 2016).

386. *Tootsie Roll*, SELF NUTRITION DATA, <http://nutritiondata.self.com/facts/sweets/8014/2> (last visited Oct. 2, 2018).

387. *Id.*

388. PIXABAY, <https://pixabay.com/en/chocolate-candy-sugar-sweet-2202140/> (last visited Dec. 14, 2018).

389. Louise Boyle & Ashley Collman, *Did this Legal Marijuana-Laced Candy Called ‘Karma’ Make a Husband Hallucinate and Shoot His Wife?*, DAILY MAIL, <https://www.dailymail.co.uk/news/article-2607372/Did-legal-marijuana-laced-candy-make-man-hallucinate-shoot-wife.html> (last updated Apr. 18, 2014).

start with half of that.”<sup>390</sup> In other words, a regular cannabis user would eat one-tenth of one piece of Karma Kandy, and a cannabis-naïve user should start with one-twentieth of one piece of Karma Kandy. For comparison purposes, one-twentieth of a Karma Kandy is equivalent to one-fourteenth of a Tootsie Roll Midgee. It is difficult to imagine cutting a Tootsie Roll Midgee into fourteen equal pieces, each weighing 0.5 gm, and eating just one. Richard Kirk was cannabis-naïve and should have eaten one-twentieth of the piece of Karma Kandy taffy. Instead, he consumed the entire piece, 101 milligrams of THC, at one time.<sup>391</sup>

Richard reportedly became delirious, paranoid, and psychotic after consuming the Karma Kandy.<sup>392</sup> Kristine called 911 at 9:30 p.m., relating to the operator that Richard was delusional and actively hallucinating, and the children were terrified.<sup>393</sup> He rambled about the end of the world and asked Kristine and the children to kill him.<sup>394</sup> While Kristine spoke to the 911 operator, Richard shot her in the head with his revolver, killing her instantly.<sup>395</sup> Fortunately, the children escaped.<sup>396</sup> Police officers arrived on the scene and took Richard into custody.<sup>397</sup>

A professor of medicine at Johns Hopkins opined that Richard suffered an acute psychotic reaction from a cannabis overdose.<sup>398</sup> A forensic psychiatrist concluded that acute intoxication induced Richard’s cognitive distortions, especially in view of the fact that his personality profile was non-violent and non-aggressive.<sup>399</sup>

A failure to warn suit was filed against the manufacturer and the dispensary under theories of strict liability in tort and negligence.<sup>400</sup> Claims were also filed under strict liability for misrepresentation against the entities and negligence against Richard.<sup>401</sup> In February 2017,

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390. *See generally 5 Tips*, LEAFLY, *supra* note 316.

391. Plaintiffs’ First Amended Complaint and Jury Demand at 7, Kirk v. Nutritional Elements, Inc., No. 16-CV-31310 (2d Colo. May 9, 2016).

392. *Id.* at 5.

393. *Id.*

394. *Id.*

395. *Id.* at 6-7.

396. *Id.* at 5.

397. *Id.* at 7.

398. *Id.* at 19.

399. *Id.* at 18-19.

400. *Id.* at 20-21.

401. *Id.* at 22-23.

Richard pled guilty to second-degree murder and was sentenced to thirty years in prison.<sup>402</sup> The civil case is pending.<sup>403</sup>

## 2. One Candy Bar: Sixteen Servings

Maureen Dowd, a well-known columnist for The New York Times, reported her own frightening experience with THC-infused edibles in 2014.<sup>404</sup> Dowd purchased a THC-infused chocolate caramel bar similar to one of her childhood favorites. She took a few tiny bites, felt nothing, and took a few more.<sup>405</sup> Just over an hour later, Dowd developed a hallucinatory and paranoid state of mind.<sup>406</sup> Initially, Dowd thought she had died, but no one would tell her.<sup>407</sup> It was not until the next morning that the effects began to subside.<sup>408</sup> In preparation for the article, she interviewed a medical consultant at the dispensary. One chocolate caramel bar represented sixteen servings for novice users.<sup>409</sup> The bar was not labeled with dosage information, and no one at the dispensary warned her about the delay in effect of the edible or the possibility of overdosing.<sup>410</sup>

### *D. Suggestions for Reasonable Packaging and Verbal Warnings*

Kirk and Dowd are examples of the critical nature of dosage warnings, even for recreational users. Moreover, there are no additional protections or legal requirements for dosage warnings on products marketed to medical marijuana patients. Patients should start with low THC dosages and gradually increase until the desired effect is achieved without significant side effects. Certifying physicians could discuss dosages, but there is a paucity of medical literature or continuing medical education on cannabis therapeutics. Dispensary consultants should be required to discuss dosages. Most dispensary workers have

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402. Noelle Phillips, *Richard Kirk Sentenced to 30 Years in Prison in 2014* *Observatory Park: Slaying of his Wife*, DENVER POST (Apr. 8, 2017, 12:12 PM), <https://www.denverpost.com/2017/04/07/richard-kirk-2014-observatory-park-wife-homicide-sentencing/>.

403. *Id.*

404. 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>.

405. *Id.*

406. *Id.*

407. *Id.*

408. *Id.*

409. *Id.*

410. *Id.*

personal experience with cannabis,<sup>411</sup> which could be helpful to customers with questions or concerns. Beginning users should be told to start with 2.5 milligrams and not exceed 5.0 milligrams of THC; more experienced users may be advised that it is safe to increase dosage to 10.0 milligrams. Patients should be advised not to take cannabis edibles on an empty stomach because absorption is too rapid. Users should be cautioned about the time delay in experiencing the effect of the edible (up to two hours) and should be discouraged from consuming additional edibles before that time to prevent overdosing.

Verbal instructions alone about cannabis use are insufficient. At a minimum, dosage instructions and warnings should appear on the product label in a reasonable size font. In addition, it would be prudent to give the patient the equivalent of a pharmaceutical package insert, albeit one with less technical language. Medical dispensary consultants ought to be trained to discuss the package insert and document the date and time of the discussion, just like when getting a prescription from a pharmacy. The discussion requirement need not be fully informed consent, but there should be a requirement for the most important information to be conferred with initial dispensation.

Issues of short-term and long-term known health risks must be addressed, especially to vulnerable populations. However, the lack of clarity of the risks in the extant medical literature complicates matters. The most significant warnings should be given, but by whom? In the current structure, physicians claim to lack the time and the dispensary employees lack the knowledge. But, if no one takes the time to warn, everyone will get sued.

Even without the desired level of clarity, there are certain warnings that should be *de rigueur*. The following groups should always be advised about the potential complications and side effects:

- Pregnant women should be warned that cannabis use during pregnancy predisposes their offspring to be small in stature and at risk for cognitive dysfunction, inattention, and behavioral problems. Lactating women must be cautioned that cannabis metabolites are present in breast milk and their impact on a newborn is unknown.
- Young adults and adolescents should be knowledgeable about the ongoing cognitive impairments and diminished academic success associated with cannabis use accompanied by the increased likelihood of addiction to marijuana, alcohol, and illicit drugs.

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411. Nancy Haug et al., *Training and Practices of Cannabis Dispensary Staff*, 1.1 CANNABIS & CANNABINOID RES. 244, 247 (2016).



- Persons with mental health issues, such as depression, anxiety, and bipolar disorder, should be strongly warned about potential worsening of their condition.
- Novice users must be educated about what being “high” is like, with its attendant euphoria, altered perception, cognitive impairment, and psychomotor retardation. Unlike recreational users, the “high” experienced by a medical marijuana user is often an undesirable side effect. The purpose of medical marijuana is to increase functionality and comfort without cognitive and perceptual impairment.

Furthermore, the following should be discussed with every medical marijuana user:

- There are risks to others, particularly the increased likelihood of accidents and injury while driving or operating heavy machinery.
- What the symptoms of an overdose look or feel like. Users should be informed that if they develop paranoia, delusions, and hallucinations, they should seek emergency care and observation. The phone number to the local poison control center should be readily available with the dispensed product.
- The clear contraindications to cannabis use. For example, individuals with schizophrenia or with uncontrolled mental illness should avoid cannabis unless it is used under the care of a knowledgeable psychiatrist; angina can be exacerbated by THC; patients allergic to *Cannabis sativa* or plants within the same genus should be strongly cautioned.

There are numerous drug interactions that could produce serious side effects. The following is a list of the most important drugs and the type of interaction:

- Chlorpromazine – requires increased dosage
- Clozapine – clozapine level may rise rapidly after THC cessation
- CNS Depressants – increased drowsiness and CNS depression when THC is combined with alcohol, opioids, sedative hypnotics, barbiturates, benzodiazepines, buspirone, antihistamines, muscle relaxants, and others
- Disulfiram – possible mania or psychosis

- Hydrocortisone – increased serum cortisol
- Indinavir – decreases peak concentration of this drug
- Ketoconazole – increases peak THC concentration
- MAO Inhibitors – orthostatic hypotension
- Phenytoin – phenytoin level may rise rapidly after THC cessation
- Warfarin – THC may enhance anticoagulant effect<sup>412</sup>

*E. Labeling and Packaging*

Proper labeling and packaging can increase safety of use and mitigate liability. A number of states have promulgated very specific rules for labeling and packaging of cannabis.<sup>413</sup> Products sold in California are required to have the following comprehensive label on the product or insert, all in capital letters:

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412. COLO. DEP'T PUB. HEALTH & ENV'T, *supra* note 161, at 40.

413. *A State-by-State Guide to Cannabis Packaging and Labeling Laws*, LEAFLY (Sept. 22, 2015), <https://www.leafly.com/news/industry/a-state-by-state-guide-to-cannabis-packaging-and-labeling-laws> [hereinafter *State Labeling Laws*, LEAFLY].

GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS PRODUCTS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. THE INTOXICATING EFFECTS OF CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.<sup>414</sup>

Nevada has adopted a comprehensive system of labeling requirements for edibles:

Labeling requirements for concentrated cannabis, edible marijuana products or marijuana-infused products for sale to medical marijuana dispensary.

1. A facility for the production of edible marijuana products or marijuana-infused products shall label all concentrated cannabis, edible marijuana products and marijuana-infused products before it sells the products to a medical marijuana dispensary and shall securely affix to the package a label that includes, without limitation, in legible English:

- (a) The name of the medical marijuana establishment and its medical marijuana establishment registration certificate number;
- (b) The production run number;
- (c) The date of production;
- (d) The date of final testing;
- (e) The date on which the product was packaged;
- (f) The cannabinoid profile and potency levels and terpenoid profile as determined by the independent testing laboratory, which may include the potential total THC but shall not include any other calculated level of THC;
- (g) If the product is perishable, the expiration date;
- (h) The total amount of THC measured in milligrams;

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414. Cal. Bus. & Prof. Code § 2612(c)(1)(B) (2016).

- (i) A list of all ingredients and all major food allergens as identified in 21 U.S.C. § 343;
- (j) The net weight of the product; and
- (k) If concentrated cannabis was added to the product or if the product consists solely of concentrated cannabis, a disclosure of the type of extraction process used and any solvent, gas or other chemical used in the extraction process or any other compound added to the concentrated cannabis.<sup>415</sup>

In addition to these labeling requirements, retail products are required to have additional information and at least six warnings related to “intoxicating effects,” potential health risks, and appropriate use of the product.<sup>416</sup> There are even guidelines related to the placement, font, and size of the labels.<sup>417</sup>

In an effort to prevent overdose and unintended exposure of children to cannabis, some states require that marijuana edibles be packaged in single use, single dose, child resistant packages, limited to between 5.0 and 15.0 milligrams of THC.<sup>418</sup> California and Colorado limit edible dosages to 10.0 milligrams of THC.<sup>419</sup> Most states have child resistant packaging requirements. Oregon’s packaging goes one step further by specifying packaging that is not attractive to minors.

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415. Nev. Rev. Stat. § 453A.509 (2017).


416. Nev. Rev. Stat. § 453A.512 (2017).

417. Nev. Rev. Stat. §§ 453A.509, 512 (2017).

418. *State Labeling Laws*, LEAFLY, *supra* note 413.

419. Chris Roberts, *California’s New Edibles Limits Will Ban Popular Products*, LEAFLY (Nov. 27, 2017), <https://www.leafly.com/news/industry/californias-new-edibles-limits-will-ban-popular-products>.

**Marijuana items cannot be packaged in a manner that is attractive to minors.** Any of the following items would be considered "attractive to minors:"



(1) Cartoons;

(2) Designs, brands, or names that resemble a non-cannabis product that is typically marketed to minors;

(3) Symbols or celebrities that are commonly used to market products to minors would be considered "attractive to minors;" or

(4) Images of minors.

A "cartoon" is any drawing or depiction of an object, person, animal, creature or any similar caricature that:

(1) Uses comically-exaggerated features;<sup>421</sup>

(2) Attributes human characteristics to animals, plants or other objects; or

(3) Attributes unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation (i.e. Superheroes).<sup>422</sup>

A package holding a marijuana item cannot appear similar to any consumer product that is typically marketed towards minors or use the same types of symbols that are used to market products to children.

*Both images are "cartoons." The penguin (above) has comically-exaggerated features, and the winged character (below) displays unnatural or extra-human abilities.*




Figure 5. Oregon's Packaging Requirements<sup>420</sup>

In addition to text, warning symbols have been selected to identify products as containing marijuana:



Figure 6. Warning Symbols from Different States and Cities

420. OR. LIQUOR CONTROL COMM'N, MEDICAL & RECREATIONAL MARIJUANA PACKAGING AND LABELING GUIDE 3 (Aug. 2016), [http://www.oregon.gov/olcc/marijuana/Documents/Packaging\\_Labeling/PackagingandLabelingGuide\\_V2.pdf](http://www.oregon.gov/olcc/marijuana/Documents/Packaging_Labeling/PackagingandLabelingGuide_V2.pdf).

421. *Responsible Use*, COLO. MARIJUANA, <https://www.colorado.gov/pacific/marijuana/responsible-use> (last visited Oct. 10, 2018).

422. *Marijuana and Your Health*, OR. HEALTH AUTH., <https://www.oregon.gov/oha/PH/PreventionWellness/marijuana/Pages/symbol.aspx> (last visited Oct. 10, 2018).

423. *Cannabis Packaging and Labeling Resources*, Wash St. Liquor & Cannabis Board, <https://lcb.wa.gov/laws/labeling-resources> (last visited Oct. 10, 2018).

To effectively maximize safety and minimize liability, a balance needs to be struck between too little and too much information. Too little information leads to poorly informed patients and enhances liability for marijuana suppliers. If patients are given too much information, they will probably not read it. The cannabis purveyor will be less exposed to liability when detailed risks and instructions are dispensed with the product. My recommendations include the following: (1) single dose, child resistant packaging; (2) warning labels with symbols on the product; and (3) a warning and instruction sheet similar to a pharmaceutical package insert, but written in layperson's language.

### VIII. YOUTH MARKETING OF MARIJUANA

Medical marijuana can be recommended for individuals eighteen and over, although rare exceptions exist for younger patients.<sup>424</sup> Recreational users must be twenty-one.<sup>425</sup> Marketing of marijuana in states that permit recreational use is supposed to be directed to individuals twenty-one years and older.<sup>426</sup> However, in states with recreational use, medicinal use, or both, marketing is often directed to the younger Millennials, individuals currently between the ages of eighteen and twenty-five years.<sup>427</sup> The marketing plan appears to be based on the fact that virtually anyone with a little knowledge and coaching can qualify for a medical marijuana card.<sup>428</sup> It is only necessary to remember the new four-letter word, "pain."

The most popular criterion for medical marijuana qualification is chronic pain.<sup>429</sup> Pain is entirely subjective and is hard to prove or disprove.<sup>430</sup> In Arizona, a sizeable and disproportionate number of Millennials are afflicted with "chronic pain" despite that fact that they may have no history of a disease process that causes chronic pain and

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424. *Medical Marijuana Age Requirement*, MARIJUANA DRs., <https://www.marijuanadoctors.com/blog/medical-marijuana-age-requirement/> (last visited Oct. 10, 2018).

425. *Id.*

426. Anna Gorman, *In the Age of Legalization, Talking to Kids About Marijuana Gets Tougher*, NPR (Nov. 10, 2009), <https://www.npr.org/sections/health-shots/2017/11/10/563051543/in-the-age-of-legalization-talking-to-kids-about-marijuana-gets-tougher>.

427. Melissa Jenco, *Study: Medical Marijuana Advertising Linked to Teen Use*, AAP NEWS (May 18, 2018), <http://www.aappublications.org/news/2018/05/18/marijuanaads051818>.

428. See Josh Harkinson, *How to Get a Pot Card (Without Really Trying)*, MOTHER JONES (Oct. 11, 2010), <https://www.motherjones.com/politics/2010/10/california-medical-marijuana-pot-card/>.

429. Hill et al., *Cannabis and Pain: A Clinical Review* 2.1 CANNABIS & CANNABINOID RES. 96, 97 (2017).

430. *Id.*

have not had a medical evaluation or appropriate testing to determine the source of the pain.<sup>431</sup>

In several states, the presence of chronic pain alone is not sufficient; the pain must be “debilitating.”<sup>432</sup> It appears that some medical marijuana clinics set a very low bar for certification of “debilitated” individuals. For example, the complaint of back pain lasting more than six months is considered to be debilitating by some clinics, notwithstanding the fact that the patient is entirely functional and without physical limitations.<sup>433</sup> The clinics use the catch phrase, “Get Legal,”<sup>434</sup> which appears to roughly translate into: (1) come to the clinic; (2) get certified; and (3) use marijuana legally.

Medical marijuana clinics frequently advertise in free newspapers available on college campuses.<sup>435</sup> Their appeal to youth is undeniable. Advertisements contain eye-catching color and layouts.<sup>436</sup> The names of the clinics evoke images of natural or organic products used in a holistic, patient-focused, and compassionate fashion letter.<sup>437</sup> Some clinics advertise that customers do not need prior medical records; everything necessary can be done at the visit.<sup>438</sup> However, in Arizona, it is almost certainly true that an individual with “a debilitating medical

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431. *See, e.g.*, ARIZ. DEPT’ HEALTH SERV., ARIZONA MEDICAL MARIJUANA PROGRAM DECEMBER 2018 MONTHLY REPORT (2018), <https://www.azdhs.gov/documents/licensing/medical-marijuana/reports/2018/2018-dec-monthly-report.pdf>; Eli McVey, *Chart: Arizona’s Massive Medical Marijuana Market Keeps Growing*, MARIJUANA BUS. DAILY (Feb. 5, 2018), <https://mjbizdaily.com/chart-arizonas-massive-medical-marijuana-market-keeps-growing/>; Britt Hermes, *I was a Pot Doctor; Naturopaths Blowing Smoke with Medical Marijuana*, NATUROPATHIC DIARIES (Dec. 21, 2016), <https://www.naturopathicdiaries.com/pot-doctor-naturopaths-medical-marijuana/>.

432. *How to Get a Legal Medical Marijuana Card or Authorization*, LEAFLY, <https://www.leafly.com/news/health/qualifying-conditions-for-medical-marijuana-by-state> (last updated Oct. 6, 2018).

433. *Chronic Pain Qualifies for Medical Marijuana In Ohio*, OHIO MARIJUANA CARD, <https://www.ohiomarijuanacard.com/pain> (last visited Jan. 4, 2019).

434. GET LEGAL, <http://getlegalarizona.com/> (last visited Oct. 21, 2018).

435. *See, e.g. The Holistic Center*, METRO, (Oct. 21, 2018), <http://boston.metro.us/html5/reader/production/default.aspx?pubname=&edid=7e725dc3-7488-4753-8501->.

436. *See* David K. Israel, *9 Medical Marijuana Ads*, MENTAL FLOSS (Mar. 15, 2010), <https://mentalfloss.com/article/24200/9-medical-marijuana-ads>.

437. *The 100 Best Dispensaries*, CANNABIS NOW (Mar. 24, 2017), <https://cannabisnow.com/100-best-dispensaries/>.

438. Jonathan Martin, *No Medical Records? No Problem. Got My Pot Card at Hempfest*, SEATTLE TIMES (Aug. 20, 2011, 6:28 PM), <https://www.seattletimes.com/seattle-news/no-medical-records-no-problem-got-my-pot-card-at-hempfest/>.

condition,” as defined by A.R.S. § 36-2801(3), would not suffer from a lack of medical records.<sup>439</sup>

Colorado has codified the limitations in retail marijuana youth marketing by adopting the standards of the alcohol industry.<sup>440</sup> Retail marijuana establishments must refrain from television, radio, print, internet, and pop-up advertising unless the establishment has reliable evidence that no more than thirty percent of the audience for the television program, radio broadcast, print publication, or website is reasonably expected to be under the age of twenty-one.<sup>441</sup>

RAND researchers<sup>442</sup> collected data from 8,200 students enrolled in grades six through eight (mean age of thirteen years) in California during 2010 and 2011.<sup>443</sup> Twenty-two percent of students reported seeing an advertisement for medical marijuana services at least once during a three-month period in 2010.<sup>444</sup> The frequency increased to thirty percent in 2011.<sup>445</sup> Adolescents who saw medical marijuana advertising were more likely to either report using marijuana or to say they planned to use it in the future.<sup>446</sup> The study is significant because onset of cannabis use during early adolescence has been correlated with neuropsychological performance deficits, poor school performance, and concomitant use of illicit drugs.<sup>447</sup> RAND recommended regulating medical marijuana advertisements in the same fashion as alcohol and tobacco products.<sup>448</sup>

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439. Ariz. Revised Statute § 36-2801(3) (West 2010). Debilitation medical conditions include: cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, hepatitis C, amyotrophic lateral sclerosis, Crohn’s disease, and agitation of Alzheimer’s disease.

440. Colo. Code Regs. § 212-2 (2018).

441. *Id.*

442. RAND CORPORATION, <https://www.rand.org/about/history.html> (last visited Oct. 21, 2018). Research and Development (RAND) is a non-partisan corporation that performs research and provides analysis to inform policy decisions.

443. Elizabeth J. D’Amico et al., *Gateway to Curiosity: Medical Marijuana Ads and Intention and Use During Middle School*, 29 PSYCHOLOGY OF ADDICTIVE BEHAVIORS 613, 614 (2015).

444. *Id.* at 615.

445. *Id.*

446. *Id.*

447. Emily D’Amico, *Adolescents Who View Medical Marijuana Advertising Are More Likely*

*to Use the Drug*, RAND CORPORATION (Jul. 6, 2015), <https://www.rand.org/news/press/2015/07/06.html>.

448. *Id.*



To make cannabis less appealing to youth, California Senator Ben Allen introduced Senate Bill 162, which would prohibit marijuana dispensaries, producers, and growers from advertising their businesses on clothing, hats, or other promotional merchandise.<sup>449</sup> The Bill also prohibits cannabis advertising within 1,000 feet of a daycare, grade school, playground, or youth center.<sup>450</sup> The legislation is endorsed by the RAND Drug Policy Research Center and supported by the American Academy of Pediatrics.<sup>451</sup> The Bill has been referred to the Committee on Appropriations.<sup>452</sup>

A bill to ban billboard advertising for medical marijuana, dispensaries, and businesses that promote medical marijuana has been introduced in Michigan and approved by the Senate Judiciary Committee in late September 2017.<sup>453</sup>

Twitter is a social media platform with over 300 million monthly users.<sup>454</sup> With its short messages and photos, it establishes trends and influences the consumption of goods and services.<sup>455</sup> Online magazines frequently list the most followed and influential cannabis-related

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449. Dennis Romero, *T-Shirts and Hats Used to Advertise Pot Products Could Be Banned*, L.A. WEEKLY (June 26, 2017, 6:03 AM), <https://www.laweekly.com/news/california-law-would-ban-some-marijuana-branded-clothing-8361493>.

450. S.B. 162, 2017 Leg. Sess. (Cal. 2017).

451. *California Bill Seeks to Ban Branded Cannabis Merchandise*, COLUM. NORML (Sept. 3, 2017), <http://columbianorml.org/norml-news/california-bill-seeks-to-ban-branded-cannabis-merchandise/>; Michael Kim, *Senate Aims to Protect the Youth of California by Banning the Use of Branded Merchandise in Cannabis Advertising*, CKB VIENNA (Oct. 10, 2017), <https://www.ckbvienna.com/blog/2017/10/31/senate-aims-to-protect-the-youth-of-california-by-banning-the-use-of-branded-merchandise-in-cannabis-advertising>.

452. S.B. 162, 2017 Gen. Assemb., Reg. Sess. (Cal. 2017).

453. *Senate Panel OKs Jones Bill to Regulate Medical Marijuana Ads*, Senator Rick Jones (Sept. 27, 2017),

<http://www.senatorrickjones.com/senate-panel-oks-jones-bill-to-regulate-medical-marijuana-ads/>.

454. *Number of Monthly Active Twitter Users Worldwide*, STATSLIA, <https://www.statista.com/statistics/282087/number-of-monthly-active-twitter-users/> (last visited Oct. 4, 2018).

455. *Id.*

Twitter accounts.<sup>456</sup> Weed Tweets, with 1.23 million followers, is number one.<sup>457</sup> *High Times Magazine*, with 640,000 followers, is considered a major influencer in the marijuana market.<sup>458</sup> Follower age is not restricted. If the cannabis industry is sending out pro-marijuana information on Twitter, the followers are subjected to industry marketing regardless of age.<sup>459</sup>

Researchers studied the content of tweets and the demographics of the followers of @stillblazingtho, a pro-marijuana Twitter handle with over one million followers.<sup>460</sup> Eighty-two percent of the comments were positive about marijuana.<sup>461</sup> The majority of followers (seventy-three percent) were nineteen-years old or younger.<sup>462</sup> Because this age category is highly influenced by social media and tends to establish patterns of drug use at an early age,<sup>463</sup> Twitter has enormous power, but no restraints, when it comes to advertising marijuana to youth.

Some states may be aggressive in limiting youth marketing of marijuana while others will be laissez-faire in legislation and enforcement. Prudent cannabis growers, manufacturers, and dispensers can take steps to ensure that their advertisements and marketing do not target youth.

Historically, tobacco companies were sued for improperly directing their marketing and advertising at youth, exposing young people to tobacco and tobacco addiction at a young age.<sup>464</sup> At present, Juul Labs,

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456. *Top 10 Twitter Accounts for Cannabis Lovers*, ZAMNESIA, <https://www.zamnesia.com/blog-top-10-twitter-accounts-for-cannabis-lovers-n1694> (last edited Apr. 10, 2018); *Top 20 Most Influential Marijuana Related Twitter Accounts*, HOW TO GROW BUD (May 6, 2010), <http://www.howtogrowbud.com/top-20-most-influential-marijuana-related-twitter-accounts/>; George Gott, *Weed Twitter Accounts to Follow*, POTENT (2016), <https://potent.media/weed-twitter-accounts-to-follow>; Jennifer Kregor, *Cannabis Industry Social Media Showdown - March 2018*, BRIGHTFIELD GROUP (Mar. 5, 2018), <https://www.brightfieldgroup.com/post/cannabis-industry-social-media-showdown-march-2018>.

457. ZAMNESIA, *supra* note 456.

458. *Id.*

459. Patricia Cavazos-Rehg et al. *Characterizing the Followers and Tweets of a Marijuana-Focused Twitter Handle*, 16 J. MED. INTERNET RES. e157, e157 (2014).

460. *Id.*

461. *Id.*

462. *Id.*

463. *Id.*

464. Laura Bach, *Tobacco Company Marketing to Kids*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 10, 2018), <https://www.tobaccofreekids.org/assets/factsheets/0008.pdf>.

an e-cigarette manufacturer, is in a nationwide class action.<sup>465</sup> The Plaintiffs allege that Juul marketed its product as safe and targeted youth at the outset.<sup>466</sup> A plaintiff could raise a similar claim against the marijuana industry - a youth marketing claim - if advertisements or marketing efforts are directed at youth.

## IX. CONCLUSION

The marijuana industry is in its infancy. Most of the industry's energy has been spent on cultivating, manufacturing, and distributing a profitable product without attracting too much attention from federal prosecutors. Products liability litigation in medical marijuana is just starting. It will grow and mature over the next two decades.

Medical marijuana shares characteristics with alcohol, tobacco, and nutritional supplements, but it is most analogous to pharmaceuticals. Product liability claims for medical marijuana will most resemble claims for pharmaceuticals, except that the Learned Intermediary Doctrine will be minimally applicable. Defective design and failure to warn claims are the most likely ones to prevail. They will predominantly be grounded in negligence and strict liability in tort.

At present, damages are difficult to assess because adequate medical research has not been done. However, it is clear that damages will be both short term and long term. In the short term, injuries will be related to an acute overdose with claims filed by consumers and injured bystanders. The evidence will show that products were improperly evaluated or inadequately labeled. Injured patients will prove that they were not instructed in the proper use of cannabis or in its potential side effects. All participants in the supply chain may be held liable for these misadventures.

Manufacturers and retailers can effectively mitigate liability in two ways. First, they can keep current with the latest scientific and medical information about cannabis and educate or warn their customers accordingly. Second, they can develop and market safer products. These include, *inter alia*, single dose, individually wrapped, edibles sold in child resistant packaging with CBD to THC ratios that are therapeutically effective and optimally safe. Liability cannot be designed or warned away, so insurance will be used to transfer the risk.

I predict that state governments will act to provide safer products and limit marketing to youth while promoting cannabis research. The

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465. Deanna Paul, E-Cigarette Maker Juul Targeted Teens with False Claims of Safety, *Lawsuit Says* (July 30, 2018), [https://www.washingtonpost.com/news/to-your-health/wp/2018/07/30/e-cigarette-maker-juul-targeted-teens-with-false-claims-of-safety-lawsuitclaims/?noredirect=on&utm\\_term=.50e77f2cdac2](https://www.washingtonpost.com/news/to-your-health/wp/2018/07/30/e-cigarette-maker-juul-targeted-teens-with-false-claims-of-safety-lawsuitclaims/?noredirect=on&utm_term=.50e77f2cdac2).

466. Pls.' Compl., *Yannuci v. Juul Labs*, No. 1:15cv24186 (S.D. Fla. Oct. 10, 2018).

DEA will either reschedule cannabis into Schedule II, III, or IV of its own accord or will be forced to by Congress. Medical marijuana will become accepted by the medical community as further research at home and abroad establishes its therapeutic efficacy and the critical nature of the endogenous cannabinoid system in the body's homeostasis. The patients, manufacturers, and retailers will greatly benefit from regulation that will reduce both injury and liability.