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> The country's relationship with marijuana is changing, slowly, and one person's pusher is another's caregiver.
>
> - Chief Judge Scott W. Dales[1]

INTRODUCTION

From the passage of Proposition 215 to present day, California's cannabis industry has transformed from access solely for medical patients to a nearly three billion dollar a year industry with legal medicinal and adult-use consumption.[2] With this rise in accessibility, edible cannabis products are being consumed more than ever.[3] "Edibles" are food and drink products infused with cannabis, a mix of THC (i.e., delta 9 - tetrahydrocannabinol) and CBD (i.e., cannabidiol)—with varying levels of each, depending on the desired effect.[4] CBD is a nonintoxicating compound often used to treat physical ailments and chronic conditions, while THC delivers a euphoric high.[5] Edibles appeal to a consumer market that does not want to smoke to

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1. In re Johnson, 532 B.R. 53, 54 (Bankr.W.D.Mich. 2015).

2. Thomas Fuller, *Now for the Hard Part: Getting Californians to Buy Legal Weed*, N.Y. TIMES (Jan. 2, 2019), https://www.nytimes.com/2019/01/02/us/buying-legal-weed-in-california.html (citing that the $2.5 billion of legal cannabis sold in California in 2018 is half a billion dollars less than in 2017, when only medical marijuana was legal. California continues to have a robust black market—CFDA report showed the state produces as much as 15.5 million pounds a year and is consuming only 2.5 million pounds; most of this surplus is leaching out across the country illegally); Janissa Delzo, *California Could Make More Money From Legal Pot Than Beer by 2019*, NEWSWEEK (Dec. 30, 2017), https://www.newsweek.com/california-money-legal-pot-beer-766698.

3. Mike Montgomery, *Edibles are the Next Big Thing for Pot Entrepreneurs*, FORBES (July 19, 2017), https://www.forbes.com/sites/mikemontgomery/2017/07/19/edibles-are-the-next-big-thing-for-pot-entrepreneurs/#2307fcfd576b.

4. John Campbell & Sahib Singh, *Budding Torts: Forecasting Emerging Tort Liability in the Cannabis Industry*, 30 LOY. CONSUMER L. REV. 338, 345 (2018).

5. *CBD vs. THC: What's the Difference?*, LEAFLY (July 3, 2018), https://www.leafly.com/new

get high (increasingly, senior citizens), and can "account for 25 to 60 percent of a dispensary's profits."[6] In 2016 alone, Californian's consumed more than $180 million in cannabis-infused edibles.[7] The edible market is competitive, having transformed from melted-down, mass-produced chocolate (where taste was an afterthought) to handmade chocolate bars with Tahitian vanilla beans.[8]

California has promulgated a complex regulatory scheme for cannabis entrepreneurs.[9] Governor Gavin Newsom estimates it will "take at least five years to fully develop."[10] "Fragmented and uncoordinated" enforcement allows California's black market to flourish.[11] As of September 2019, 887 pot retailers were licensed in the state, yet "as much as 80% of the marijuana sold in California [continues to] come from the black market."[12] This disparity creates unfair competition for licensed businesses, as well a public safety hazard—areas where both regulation and enforcement are crucial.[13] Despite this, under federal law possession, cultivation and the sale of marijuana remains illegal.[14] Federally criminalized cannabis leaves

s/cannabis-101/whats-the-deal-with-these-high-cbd-strains/print/.

6. Senior citizens are increasingly turning away from opioids and turning to cannabis to treat various aches, and sleeplessness. Professor of Psychiatry and Aging at UCLA, Dr. Gary Small, espoused that adults 65 and over are the fastest-growing segment of the marijuana-using population, and the side effects of cannabis can be quite serious for seniors—dizziness can lead to falling and impaired memory if dosage is "incorrect." This usage by seniors should be considered when considering product liability issues. John Rogers, *Bingo and Bongs: More Seniors Seek Pot for Age-Related Aches*, WASH. POST (Mar. 25, 2019), https://www.washingtonpost.com/business/bingo-and-bongs-more-seniors-seek-pot-for-age-related-aches/2019/03/25/98869586-4eb3-11e9-bdb7-44f948cc0605story.html?noredirect=on&utm_term=.27f518468ad9; *see also* Montgomery, *supra* note 3.

7. Montgomery, *supra* note 3.

8. *Id.*

9. CAL. BUS. & PROF. CODE §§ 26000 – 26134 (2019); *State Licensing Authorities*, CALIFORNIA CANNABIS PORTAL, https://cannabis.ca.gov/state-licensing-authorities/ (last visited Oct. 19, 2019).

10. Patrick McGreevy, *California's Black Market for Pot is Stifling Legal Sales. Now the Governor Wants to Step up Enforcement*, L.A. TIMES (Feb. 18, 2019), https://www.latimes.com/politics/la-pol-ca-gavin-newsom-crackdown-pot-black-market-20190219-story.html?sfns=mo.

11. *Id.*

12. *Bureau of Cannabis Control – License Search*, CALIFORNIA CANNABIS PORTAL, https://cannabis.ca.gov/licensed-cannabis-businesses/, (last visited Oct. 19, 2019) (noting that retailers includes both storefront and non-storefront retailers); McGreevy, *supra* note 10 ("According to an estimate by New Frontier Data, a firm that tracks cannabis sales and trends"); Thomas Fuller, *Getting Worse, Not Better': Illegal Pot Market Booming in California Despite Legalization*, N.Y. TIMES (Apr. 27, 2019), https://www.nytimes.com/2019/04/27/us/marijuana-california-legalization.html.

13. McGreevy, *supra* note 10 ("According to an estimate by New Frontier Data, a firm that tracks cannabis sales and trends"); Fuller, *supra* note 2; Andrew Bowen, *Chief of California's Bureau of Cannabis Control is 'Really, Really Busy'*, KPBS (July 25, 2018), https://www.kpbs.org/news/2018/jul/25/bureau-cannabis-control-lori-ajax-marijuana-legal/.

14. CONTROLLED SUBSTANCES ACT, 21 U.S.C. § 812(b)(1); CONTROLLED SUBSTANCES ACT 21 U.S.C. § 812 – Schedule I (c)(17).

California's edible industry devoid of any civil federal regulation.[15] This lapse, in conjunction with California's regulatory scheme, poses particularly unique challenges to edible companies that are trying to stay in compliance with the law, avoid lawsuits, and enforcement actions.[16] As one might surmise, this rise in consumption is troublesome for cannabis manufacturers and a potential boon for product liability attorneys.[17] Edibles are unique, and face product liability exposure as both a food, and as an intoxicating substance, typically "arising from design defects, specific language in advertising and inadequate warnings."[18]

This Note illuminates how even in the current regulated California environment, edible cannabis products can pose a serious risk to consumers if not properly made, labeled, and consumed, which may subsequently increase demand for product liability attorneys in the very near future. As a foundation for understanding, Part One of this Note provides a brief historical background on cannabis laws in California, the current regulatory scheme under the Medicinal and Adult-Use Cannabis Regulation and Safety Act ("MAUCRSA") and explores continued federal prohibition of cannabis issues. If cannabis were not a controlled substance under the Controlled Substances Act ("CSA") and was regulated by the U.S. Food & Drug Administration ("FDA") under the Food, Drug Cosmetic Act of 1938 ("FDCA"), cannabis could be regulated as a food additive or as a new dietary ingredient. Consideration of what that would look like is relevant here. Part Two of this Note will discuss the relevant California regulatory requirements for edible products under the Bureau of Cannabis Control and California Department of Public Health, and what that regulation might look like under the FDA.

Part Three of this Note lays out the impact of product liability issues facing current edible cannabis manufacturers, distributors, and retailers. This Note will consider manufacturing defects, design defects, and failure to warn issues for edible cannabis products that comply with the FDCA and California regulations in tandem, and those that do not comply with the FDCA, but do comply with California regulations. This analysis shows how current regulations in California are still slightly inadequate for the industry *and for consumers.* As such, all cannabis companies should incorporate a policy of over-compliance. This policy will require cannabis companies to

15. Michelle L. Burton & Robert S. May, *New Era of Liability: Comparative Analysis of Regulation of Marijuana and Other Controlled Substances*, 60 No. 9 DRI for Def. 26, 6 (Sept. 2018).

16. Daniel G. Barrus, *Tasty THC: Promises and Challenges of Cannabis Edibles*, METHODS REP RTI PRESS 6 (Nov. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817/pdf/nihms-830225.pdf.

17. Montgomery, *supra* note 3.

18. Burton & May, *supra* note 15.

implement additional recall procedures, ensure proper consumer notification of intended side effects, and the dangers of overconsumption at the time of sale. Most importantly, a national standard for edibles must be set at 10mg and widely publicized. Lastly, this Note considers the possibility of implementing gram shop laws and liability immunity under California Civil Code section 1714.45.

1. CALIFORNIA'S TWO DECADE FIGHT FOR LEGALIZATION AND REGULATION OF ADULT-USE CANNABIS

1.1 HISTORICAL BACKGROUND ON PROP. 215 AND CALIFORNIA'S MEDICAL MARIJUANA

Proposition 215 ("Prop. 215"), commonly known as the Compassionate Use Act ("CUA"), passed in California on November 1996 with 56% of the vote.[19] Prop. 215 exempted a seriously ill patient, or their primary caregiver, from state prosecution for possession and cultivation of marijuana, so long as their physician recommended the use of cannabis for medical treatment.[20] In short, Californians decided that "criminalizing sick people who smoked pot was bad public policy."[21] However, Prop. 215 did not specifically address how patients could legally obtain their medically-recommended marijuana nor did it set age limits on consumption, or even spell out how someone could legally sell the herb.[22] The proposition was novel because it, technically, did not legalize cannabis, "it simply created a doctor-recommended exception to state enforcement."[23] Prop. 215's careful wording allowed it to circumvent the federal CSA, which does not speak to recommending the therapeutic use of cannabis.[24] However, those opposed to the legalization aimed to roll back the CUA by "utiliz[ing] the courts to put on show trials, send the innocent to prison, deny medication to the seriously ill, and terrorize America's weakest citizens with fascistic paramilitary raids that ransacked their homes and property."[25] Thus, California's gray market

19. U.S. v. Cannabis Cultivators Club, 5 F. Supp. 2d 1086, 1091 (N.D.Cal. 1998); *see also* CAL. HEALTH & SAFTEY CODE § 11362.5 (West 2019).

20. CAL. HEALTH & SAFTEY CODE § 11357 (West 2019); CAL. HEALTH & SAFTEY CODE § 11362.5 (West 2019); *see also Cannabis Cultivators Club*, 5 F. Supp. at 1091; CAL. HEALTH & SAFTEY CODE § 11358 (West 2019).

21. MARTIN A. LEE, SMOKE SIGNALS: A SOCIAL HISTORY OF MARIJUANA – MEDICAL, RECREATIONAL, AND SCIENTIFIC 247 (Scribner 2012).

22. *Id.* at 240.

23. *Id.*

24. *Id.* at 251.

25. *Id.* at 249.

was largely run by people willing to put their name on the line for people with illnesses and in recovery.[26] This collective movement created complicated precedent, and dispensaries operated at the whim of the DEA and local law enforcement, knowing that they could be "busted at a moment's notice."[27] Following the enactment of the CUA, there was no substantive regulation of the edible cannabis products available to medicinal cannabis users in California for the next 20 years.

1.2 MAUCRSA AND CURRENT REGULATORY BODIES IN CALIFORNIA: BCC, CDPH, CDFA

On November 8, 2016, 20 years after the passage of Prop. 215 California legalized adult-use of cannabis with Proposition 64, also known as the Adult Use of Marijuana Act ("AUMA").[28] AUMA allowed adults, 21 years of age or older, to legally grow, possess, and use cannabis for non-medicinal purposes, with few restrictions.[29] AUMA also legalized the sale and distribution of marijuana through a regulated business as of January 1, 2018.[30] To consolidate the governance of adult-use and medical marijuana, the California State Legislature passed Senate Bill 94 in 2017, creating the Medicinal and Adult-Use Cannabis Regulation and Safety Act ("MAUCRSA").[31]

Following the passage of AUMA, three state agencies were charged with cannabis licensing authority: the Bureau of Cannabis Control ("BCC"), the California Department of Food and Agriculture ("CDFA"), and the

26. *Id.* at 255.

27. Marijuana collectives were established to grow and provide cannabis as a compassionate care non-profit. Some collectives would donate the flower to low-income, terminally ill patients. Due to the legalization of cannabis (and thus, taxation) collectives simply could not sustain themselves legally, unless licensed, or financially. *See generally* U.S. v. Cannabis Cultivators Club, 5 F. Supp. 2d 1086 (N.D. Cal. 1998); U.S. v. Rosenthal, No. 03-10370, D.C. No. CR-02-00053-3-CRB (9th Cir. 2006); City of Corona v. Naulls, 166 Cal.App.4th 418 (2008); People v. Baniani, 229 Cal. App. 4th 45 (2014); Mary Carreon, *California's New Cannabis Laws Squeeze Out Compassionate Care Programs*, FORBES (Jan. 28, 2019), https://www.forbes.com/sites/marycarreon/2018/01/29/californias-new-cannabis-laws-push-out-compassionate-care-programs/#5eb5abbb25fd; John Schroyer, *End of an Era: After Jan. 9, Cannabis Unlicensed Medical Cannabis Collectives/Co-ops Illegal*, MARIJUANA BUSINESS DAILY (Jan. 3, 2019), https://mjbizdaily.com/california-unlicensed-medical-marijuana-collectives-illegal-jan-9/; LEE, *supra* note 21.

28. Thomas Fuller, *Californians Legalize Marijuana in Vote That Could Echo Nationally*, N.Y. TIMES (Nov. 9, 2016), https://www.nytimes.com/2016/11/09/us/politics/marijuana-legalization.html; CAL. HEALTH & SAFETY CODE §§ 11362.1 – 11362.3 (West 2019).

29. *About Us*, CALIFORNIA CANNABIS PORTAL, https://cannabis.ca.gov/about_us/ (last visited Oct. 26, 2019); CAL. HEALTH &SAFETY CODE §§ 11362.1 – 11362.3 (West 2019).

30. *Id.*; CAL. HEALTH & SAFETY CODE § 11362.3 (West 2019).

31. MAUCRSA melded MCRSA, California's medical-only regulations passed by the legislature, and the AUMA. CALIFORNIA CANNABIS PORTAL, *supra* note 29.

California Department of Public Health ("CDPH").[32] The BCC is the principal regulatory agency for California commercial cannabis; it is responsible for licensing retailers, distributors, testing laboratories, microbusinesses, and temporary cannabis events.[33] The CDFA is charged with licensing and regulating commercial cannabis cultivators.[34] Lastly, the CDPH is in authority of the regulation of all commercial cannabis manufacturing.[35] Legalization of cannabis brought an end to over two decades of zero edible cannabis product regulation. Consequently, California's loosely regulated system of medical cannabis collectives became illegal on January 9, 2019.[36] On January 16, 2019, the Office of Administrative Law officially approved state cannabis regulations for the BCC, CDPH, and CDFA, which became effective immediately.[37]

1.3 FEDERAL PROHIBITION REMAINS PROBLEMATIC – POSSIBLE REGULATION UNDER FDA & FDCA

Sixty five percent of Americans believe that marijuana should be legalized, double what it was nearly 20 years ago.[38] Today, adult-use cannabis is legal in 11 states, including D.C., and medicinal cannabis is legal in 33.[39] Given this nationwide shift, cannabis will very likely become federally decriminalized within a decade.[40] For now, however, the CSA

32. *State Licensing Authorities*, CALIFORNIA CANNABIS PORTAL, https://cannabis.ca.gov/state-licensing-authorities/ (last visited Oct. 19, 2019).

33. *Id.*

34. *Id.* (explaining that CalCannabis is split into three branches: Licensing, Compliance and Enforcement, and Administration, and establishes and manages California's track-and-trace system).

35. *Id.* (stating that the CDPH's mission is to "protect public health and safety by ensuring commercial cannabis manufacturers operate safe, sanitary workplaces and follow good manufacturing practices to produce products that are free of contaminants, meet product guidelines and are properly packaged and labeled").

36. Fuller, *supra* note 2.

37. U.S. v. Pisarski, 274 F.Supp.3d 1032 (2017) (enjoining criminal prosecution for those who could establish full compliance with California law); *see also, New Cannabis Regulations Approved by the Office of Administrative Law*, CALIFORNIA CANNABIS PORTAL (Jan. 16, 2019), https://cannabis.ca.gov/2019/01/16/new-cannabis-regulations-approved-by-the-office-of-administrative-law/.

38. Brandi Kellam, *Legalizing Marijuana? Americans Support it, But Not Enough to Sway Their Vote in 2020*, CBS NEWS (Apr. 23, 2019), https://www.cbsnews.com/news/legalizing-marijuana-americans-support-it-but-not-enough-to-sway-their-vote-in-2020/; *see also*, Hannah Hartig & Abigail Geiger, *About Six-in-Ten Americans Support Marijuana Legalization*, PEW RESEARCH CENTER: FACTTANK (Oct. 8, 2018), https://www.pewresearch.org/fact-tank/2018/10/08/americans-support-marijuana-legalization/.

39. Jiachuan Wu & Daniella Silva, *MAP: See the States Where Marijuana is Legal*, NBC NEWS (Nov. 20, 2018), https://www.nbcnews.com/news/us-news/map-see-if-marijuana-legal-your-state-n938426.

40. Eric Sandy & Melissa Schiller, *Democrats Are Building Their 2020 Presidential Campaigns. Where Do They Stand on Cannabis Reform?*, CANNABIS BUSINESS TIMES (Apr. 22, 2019), https://www.cannabisbusinesstimes.com/article/democrat-contenders-presidential-election-2020-cannabis-policy/.

classifies cannabis as a Schedule I drug, designating that there are no currently accepted medical uses and a high potential for abuse.[41] The FDA has sole authority to approve any drug or food for use in the United States.[42] Under the FDCA, it is currently unlawful to introduce food containing added CBD or THC into interstate commerce because "both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements."[43] However, the recently passed "Farm Bill of 2018" legalized hemp-derived CBD, and a public meeting was held on May 31, 2019 for the FDA to begin developing a set of rules for CBD regulation.[44] The meeting was largely organized for the FDA to collect scientific data and information about the marketing, quality, sale, and safety of CBD products on the market today.[45] The FDA espouses that they are "committed to sound, science-based policy on CBD."[46] Despite this, the current patchwork regulatory system across the U.S. remains incredibly problematic for the health and safety of retailers and consumers.

Comparatively, there are no such plans for THC to become regulated under the FDA, yet there are edibles in the current market in California (and many other states) that are labeled and packaged according to specific state standards. The Nutritional Labeling and Education Act ("NLEA") enumerates that no state may directly or indirectly establish any requirement for the labeling of food that is "not identical to" the federal requirements.[47] "Not identical to" is defined as a state requirement that imposes obligations concerning the composition or labeling of food, which are not imposed by corresponding federal regulations, or differ from those specifically imposed

41. CONTROLLED SUBSTANCES ACT, 21 U.S.C § 812(c)(17); *see generally* Gonzales v. Raich, 545 U.S. 1 (2005); *Drug Scheduling*, DEA, https://www.dea.gov/drug-scheduling (last visited Oct. 19, 2019).

42. *Drugs of Abuse, A DEA Resource Guide: 2017 Edition*, U.S. DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION, 75 (2017), https://www.dea.gov/sites/default/files/drug_of_abuse.pdf.

43. *New Steps to Advance Agency's Continued Evaluation of Potential Regulatory Pathways for Cannabis-Containing and Cannabis-Derived Products*, FDA (2019) (statement of Scott Gottlieb, M.D., FDA Commissioner), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635048.htm (noting that CBD is an active ingredient in the FDA-approved Epidiolex, setting a precedent for any products containing CBD to require R&D and clinical trials to obtain FDA approval).

44. AGRICULTURE IMPROVEMENT ACT OF 2018, H.R. 2, 115th Cong. § 10113 (2018); Gottlieb, *supra* note 43.

45. *Presentations: FDA's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds Public Hearing*, FDA (July 3, 2019), https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/presentations-fdas-scientific-data-and-information-about-products-containing-cannabis-or-cannabis.

46. Amy Abernethy, M.D., Ph.D., & Lowell Schiller, J.D., *FDA is Committed to Sound, Science-based Policy on CBD*, FDA (July 17, 2019), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd.

47. U.S. CONST. art. 6, cl. 2; 21 U.S.C.A. § 343-1(a)(5) (West 2019).

by or contained within relevant federal regulations.[48] The FDCA lays out federal packaging and labeling standards for food products.[49] However, the illegality of edibles under the CSA leaves the California edible industry void of any federal civil regulation.[50] It is pertinent that cannabis is *de-scheduled* from the CSA for it to be properly regulated by the FDA. Congress' categorization of products as either a food or drug is determined by "the use which the product is to be put will determine the category into which it will fall." [51] Therefore, it is likely that THC added to food will be considered a food additive or a new dietary ingredient.

1.3.1 Unapproved Food Additive

A food additive is defined as a substance whose intended use is reasonably expected to "become a component" or "affect the characteristics of any food" not 'generally recognized as safe' ("GRAS").[52] The 1958 Food Additives Amendment states that "the use of any 'food additive'. . . renders a food adulterated unless the use complies with an FDA food additive regulation."[53] A food is adulterated if it contains any food additives that are not GRAS, or contains a dietary supplement or ingredient that "presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling" or "for which there is inadequate information to provide reasonable certainty that such ingredient does not present a significant or unreasonable risk of illness or injury."[54] This 'reasonable certainty' can be shown "through the presentation of scientific evidence," submitted in a food additive petition to the FDA showing with "a reasonable certainty that no harm will result from the proposed use of an additive."[55]

A food additive petition must contain "data bearing on the physical or other technical effect which the additive is intended to produce."[56] The FDA is empowered by statute to attach specific labeling requirements and

48. 21 C.F.R. § 100.1(c)(4)(i-ii) (West 2019).

49. 21 U.S.C.A. § 343 (West 2019).

50. Burton & May, *supra* note 15.

51. Gottlieb, *supra* note 43; Lewis A. Grossman, *Food, Drugs, And Droods: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1116 (2008).

52. 21 U.S.C.A § 321(s) (West 2019); *see also*, CAL. HEALTH & SAFETY CODE § 109940 (West 2019) (GRAS means generally recognized as safe under the FDA.).

53. 21 U.S.C.A § 321(s) (West 2019); Grossman, *supra* note 51, at 1129.

54. 21 U.S.C.A § 321(s) (West 2019); Grossman, *supra* note 51, at 1129.

55. Grossman, *supra* note 51.

56. 21 U.S.C.A. § 348(b)(2)(C) (West 2019).

conditions for safe use to any food additive.[57] If the additive's tolerance limitation cannot be articulated to ensure "intended physical or technical effect," the FDA will simply not approve it.[58] Currently, "under section 301(ll) of the FD&C Act," it is illegal to introduce "into interstate commerce any food . . . to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."[59] At this time, the FDA has determined that THC does not fit into any exceptions to this rule.[60] The Amendment's legislative history articulates that proof of a reasonable certainty that no harm would result from use is necessary, however, "it does—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances."[61] Therefore, it seems plausible that cannabis could be regulated as an FDA approved food additive. Proper support from federal scientific data and pre-market approval from the FDA, or an act of Congress, will be necessary. For now, cannabis is currently categorized as an unapproved food additive.

1.3.2 New Dietary Ingredient

The Dietary Supplement Health and Education Act of 1994 broadly defined the safety regulations for dietary supplements, which are:

> [A] product (other than tobacco) intended to supplement the diet that bears or contains one or more . . . dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described [above].[62]

A dietary supplement is unadulterated if it "contains only dietary ingredients . . . present in the food supply" which "ha[ve] not been chemically altered" or have a history of safety when used under the

57. 21 U.S.C.A. § 348(c)(1)(A) (West 2019).

58. 21 U.S.C.A. § 348(c)(4)(B) (West 2019).

59. *FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers*, FDA, https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm (last visited Oct. 19, 2019).

60. *Id.*

61. Food Additive Amendment of 1958, S. Rep. 85-2422, 2d Sess., at 6 (1958).

62. 21 U.S.C.A § 321(ff)(1) (West 2019).

conditions clearly proscribed upon the label.[63] Most notably, dietary ingredients in supplements are not subject to the same pre-market approval process as food additives, regardless of being qualified as GRAS.[64] Additionally, at least 75 days before entering interstate commerce, the manufacturer or distributor must provide the Secretary of Health and Human Services with scientific data upon which they based their safety assessment of the ingredient.[65] The FDA warns that "selling unapproved products with unsubstantiated therapeutic claims can put patients and consumers at risk."[66] No cannabis-derived products have been fully evaluated by the FDA, and thus, those on the market may contain other ingredients that are not properly disclosed, posing a consumer hazard.[67]

Moreover, there is ample scientific research being conducted on cannabis' effects on the health of humans, and the FDA has concluded THC products are "excluded from the dietary supplement definition under §201(ff)(3)(B) of the FD&C Act."[68] An exception to §201(ff)(3)(B) is if the "substance was 'marketed as' a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized,"—the FDA has also determined "this is not the case for THC."[69] Although scientific data can be submitted to rebut this exclusion, a current review of presented information has "not caused us [the FDA] to change our conclusions."[70] This exclusion applies until the FDA issues a "regulation, after notice and comment, finding that the article would be lawful under the FD&C Act."[71] A regulation exempting THC as a dietary ingredient is necessary for the FDA to properly regulate it as such.

Considering the totality of the circumstances, cannabis should be regulated by the FDA as a food additive. It is clear that dietary ingredients are much easier to get onto the consumer market since they do not require the same stringent pre-market approval as food additives, but safety should come before business ease. One of the FDA's core policy goals is to place

63. 21 U.S.C.A § 350b(a)(1-2) (West 2019).

64. 21 U.S.C.A § 321(s)(6) (West 2019).

65. 21 U.S.C.A § 350b(a)(2) (West 2019).

66. Gottlieb, *supra* note 43.

67. *Id*.

68. 21 U.S.C.A. § 321(ff)(3)(B) (West 2019); FDA, *supra* note 59; *FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers*, FDA, https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm (last visited Apr. 22, 2019); John A. Gilbert & Larry K. Houck, *Medical Cannabis Research Act Stirs DEA Marijuana Registration Pot*, FDA LAW BLOG (Apr. 10, 2019), http://www.fdalawblog.net/2019/04/medical-cannabis-research-act-stirs-dea-marijuana-registration-pot/; *Current Studies*, CENTER FOR MEDICINAL CANNABIS RESEARCH, https://www.cmcr.ucsd.edu/index.php/studies/active-studies (last visited Apr. 23, 2019).

69. *Id*.

70. *Id*.

71. *Id*.

safe products on the market, as such, cannabis would best fit under the food additives regulation. As a food additive, the FDA could place reasonable restrictions and requirements for labeling and safe use by consumers. California continues to conduct research on cannabis and its effects on humans, and it is likely that the state (and others) will be able to provide the FDA with a reasonable certainty that cannabis does not present a significant, or unreasonable, risk of illness or injury.

2. REGULATORY REQUIREMENTS FOR EDIBLE CANNABIS PRODUCTS

Once a regulatory free-for-all, edible cannabis products are now heavily regulated in California. Regulation of edibles currently fall under the purview of the BCC and the CDPH. The CDFA is also in charge of the state's track-and-trace system, which is crucial to the regulatory scheme and the production of edibles.[72] Edible cannabis products are intended for oral human consumption, including those which "dissolve or disintegrate in the mouth," and includes "tinctures, capsules and tablets."[73] The regulations cover every integral part of the edible manufacturing process through their placement in retail dispensaries.

2.1 MANUFACTURING

2.1.1 CDPH Manufacturing Requirements for Edible Products

Obviously, a manufacturer would want to start with a quality, uncontaminated flower from which to manufacture their cannabis edibles. "Manufacturing cannabis" is defined as "all aspects of the extraction process, infusion process, and packaging and labeling processes, including processing, preparing, holding, and storing of cannabis products and components and ingredients."[74] Manufacturers who produce edible products through extraction must obtain a Type N license and may package and label all products on-site of the licensed premise.[75] The manufacturing process regulations are particularly concerned with good production practices to

72. Track-and-trace is a seed-to-sale program that tracks cannabis from the clone to consumer. Flower is given a unique identifier number, which is entered into a statewide online accessible system. This tracking allows for quick identification of where the cannabis was cultivated, where the cannabis was manufactured, tested, distributed and the retail store it is sold in. *See* CAL BUS. & PROF. CODE § 26067 (2019).

73. CAL. CODE REGS. tit. 17, § 40100(q) (2019); CAL. CODE REGS. tit. 17, § 40100(hh) (2019).

74. CAL. CODE REGS. tit. 17, § 40100(ee) (2019).

75. CAL. CODE REGS. tit. 17, § 40118 (c)(1-2) (2019).

ensure a quality product. Employees must be properly trained in health and safety hazards, emergency response, security, quality control, record keeping, security, work safety, and cleanliness.[76] Licensees producing edible products must also require employees to obtain a "CA food handler certificate with from an entity accredited by the American National Standards Institute" within 90 days of employment.[77]

The multitude of prohibitions related to the production of edible cannabis act solely as safeguards for the public health. Edibles may not contain alcohol, nicotine, or caffeine additives, but this does not apply to "naturally occurring caffeine . . . i.e. coffee, tea, or chocolate."[78] Edibles may not contain meat (except dried meat products), seafood, dairy products, or anything that requires it "be held at or below 41 degrees Fahrenheit."[79] All food ingredients, or components used, must be "permitted by the United States Food and Drug Administration for use in food or food manufacturing, as specified in *Substances Added to Food in the United States* . . . or is GRAS" under the FDCA.[80]

2.1.2 FDA Good Manufacturing Practices for Dietary Supplements

Under the standards set by the FDA's "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," dietary supplements face stringent manufacturing process controls that ensure supplements contain what the manufacturer intends them to contain.[81] The CGMPs establish requirements for laboratory controls and testing methods, including robust requirements to conduct quality control on labeling and packaging.[82] Cleanliness, uniformity, and homogeneity are all policy goals espoused by the CGMPs.

2.1.3 BCC Testing Requirements for Manufacturers

The strict testing requirements for cannabis flowers and subsequent cannabis products have proven to be a web of complicated regulatory standards to meet. The BCC requires testing laboratories offering tests of cannabis goods in California to obtain and maintain an ISO/IEC 17025

76. CAL. CODE REGS. tit. 17, § 40280(a) (2019).
77. CAL. CODE REGS. tit. 17, § 40280(a)(3) (2019).
78. CAL. CODE REGS. tit. 17, § 40300 (a-b) (2019).
79. CAL. CODE REGS. tit. 17, § 40300(c) (2019); CAL. CODE REGS. tit. 17, § 40300(g-i) (2019).
80. CAL. CODE REGS. tit. 17, § 40305(a) (2019); 21 U.S.C.A. § 321(s) (West 2019); 21 U.S.C.A. § 348 (West 2019).
81. *See generally* 21 C.F.R. § 111 (2019).
82. 21 C.F.R. § 111.315 (West 2019); 21 C.F.R. § 111.160 (West 2019).

accreditation, an internationally recognized standard.[83] This accreditation is expensive because the testing staff must employ scientists with expertise in chemistry and microbiology and use the same equipment used in the food and pharmaceutical industries, including robotics.[84] Testing laboratories are required to ensure that the presence of contaminants does not exceed the levels set forth by the Bureau, standards made in conjunction with the American Pharmacopoeia monograph and the Department of Pesticide Regulation.[85]

Testing for cannabis flower and products was rolled out in three phases. Phase 1 testing began on January 1, 2018, and required testing for cannabinoids, category I pesticides, category II solvents and processing chemicals testing, microbial impurities, and moisture content.[86] Edible products were exempt from the moisture content and microbial impurities testing for A. fumigatus, A. flavus, A. niger, A. terreus, but were tested for homogeneity.[87] Phase 2 went into effect on July 1, 2018, requiring all Phase I elements plus category I solvents and processing chemicals, category II residual pesticides, and foreign material.[88] Phase 3 took effect December 31, 2018, requiring all Phase 1 and 2 testing, in addition to terpenoids, mycotoxins, heavy metals, and water activity testing of solid and semi-solid edibles.[89] Cannabis products that do not meet these testing requirements must be destroyed or remediated, if possible.[90] The laboratory test results are then articulated and issued in a certificate of analysis.[91]

Unlike cannabis flowers, edible cannabis products cannot be remediated and must be destroyed if they do not pass regulatory testing requirements.[92] Arguably, the most pertinent testing of edibles is for

83. *Testing Laboratories*, BUREAU OF CANNABIS CONTROL, https://www.bcc.ca.gov/licensees/testing_labs.html (last visited Apr. 22, 2019); CAL. BUS. & PROF. CODE § 26100(g) (2019) (defining "GRAS" to mean generally recognized as safe by the FDA).

84. *California Marijuana Products Delayed by Backlogs in Testing Labs*, NBC NEWS SAN DIEGO (Aug. 6, 2018, 6:01 PM), https://www.nbcsandiego.com/news/local/California-Marijuana-Products-Delayed-by-Backlogs-in-Testing-Labs-490191141.html.

85. CAL BUS. & PROF. CODE § 26100(1)(H)(2) (2019).

86. Microbial impurities tested: A. fumigatus, A. flavus, A. niger, A. terreus and Escherichia coli and Salmonella spp. *See Laboratory Testing*, BUREAU OF CANNABIS CONTROL, https://bcc.ca.gov/about_us/documents/17-261_required_testing_chart.pdf (2018).

87. *Id.*

88. *Id.*; *see also* Melissa Schiller, *California Prepares to Roll Out Additional Cannabis Testing Regulations July 1*, CANNABIS BUSINESS TIMES (June 18, 2018), https://www.cannabisbusinesstimes.com/article/california-additional-testing-regulations-july-1/.

89. BUREAU OF CANNABIS CONTROL, *supra* note 86.

90. Oren Bitan, *Testing Mandate is Straining California Cannabis Companies*, LAW360 (Aug. 9, 2018, 2:16 PM), https://www.law360.com/foodbeverage/articles/1071661/testing-mandate-is-straining-california-cannabis-cos-.

91. CAL. BUS. & PROF. CODE § 26100(d) (2019).

92. CAL. BUS. & PROF. CODE § 26104(b)(3) (2019); CAL. CODE REGS. tit. 17, § 40330(c) (2019).

measurements of cannabinoids, wherein all edibles must not exceed 10mg of THC per serving or no more than 100mg THC per package.[93] However, if an edible product fails the testing requirements solely because the product exceeded the "per package limit of THC," it can be remediated on a case-by-case basis approved by the CDPH, only if it can be returned to the distributor and repackaged but not altered in any way.[94]

2.1.4 Known Complications with Current Testing Requirements

Within the first two months of Phase 2 testing requirements, the BCC reported that one in five pot samples were being "red stamped," i.e., were failing a required test.[95] Phase 3 was initially slated to cause laboratory testing fees to "increase by 40-55% for some of the state's licensed cannabis cultivators as well as makers of concentrates and infused products."[96] Consequently, as of December 2018, there were only 52 licensed laboratories in the state, and only 14 of those labs were confirmed to offer Phase 3 compliance testing.[97] Naturally, a significant backlog occurred.[98] Early soil and flower samples were being tested for heavy metals at 10-20 times the legal allowance.[99] Between July and November 2018, 2,100 of 23,864 batches of various cannabis products failed due to overestimation of THC content, and 739 of those same 23,864 failed for pesticides.[100] Though this is only a fourteen percent failure rate, cannabis edibles have faced the

93. CAL. BUS. & PROF. CODE § 26130(c)(2) (2019); CAL. CODE REGS. tit. 17, § 40315(a)(1-2) (2019) (orally dissolving products and non-orally dissolving medical use edible cannabis, that is labeled "FOR MEDICAL USE ONLY" may contain up to 500 milligrams and 100 milligrams per package, respectively).

94. CAL. CODE REGS. tit. 17, § 40330(e-f) (2019).

95. Bitan, *supra* note 90.

96. For example, Somatik, a company that makes cannabis-infused cold brew-coffee expected "costs to increase more than 40%, from $620 to $890 per batch." Similarly, cannabis company Nug's edibles and concentrates were to "increase nearly 50%, from $615 to $915 for its edibles and $665 to $965 for its concentrates." Joey Peña, *California Marijuana Industry Braces For 'Another Enormous Burden' From Next Phase of Testing Costs*, MARIJUANA BUSINESS DAILY (Dec. 20, 2018), https://mjbizdaily.com/california-marijuana-phase-3-testing-costs/.

97. *Id.*

98. *California Marijuana Products Delayed by Backlogs in Testing Labs*, NBC SAN DIEGO (Aug. 7, 2018, 9:48 AM), https://www.nbcsandiego.com/news/local/California-Marijuana-Products-Delayed-by-Backlogs-in-Testing-Labs-490191141.html; Bitan, *supra* note 90.

99. Peter Fimrite, *Recall Deals Blow to California's Marijuana Industry*, SAN FRANCISCO CHRONICLE (Dec. 23, 2018, 2:57 PM), https://www.sfchronicle.com/news/article/Recall-deals-blow-to-California-s-marijuana-13487748.php.

100. Amelia McDonell-Parry, *Pot in California: What's Going on With Cannabis Testing?*, ROLLING STONE (Dec. 17, 2018, 5:16 PM), https://www.rollingstone.com/culture/culture-news/california-weed-testing-cannabis-lab-770320/; Fimrite, *supra* note 99.

most difficulty in meeting current standards.[101] Phase 3 heavy metal testing requirements will very likely continue to be one of "the biggest challenges for cultivators and product manufacturers" because there is not enough data yet to predict trends.[102] Additionally, some labs have failed industry standards, thus, sacrificing the public safety by falsifying testing results.[103] Laboratories are essential gatekeepers in the cannabis industry and it is crucial that laboratories strictly adhere to state regulations for the sake of the publics' safety. If followed, these stringent testing regulations will lessen the chance of contamination and likely ensure homogeneity.

2.2 LABELING AND PACKAGING REQUIREMENTS

2.2.1 CDPH Packaging Requirements for Edible Products

Once a product is manufactured and tested, the product is then packaged for retail distribution. CDPH packaging requirements largely focus on public safety, particularly on keeping edibles unattractive to children and preventing overconsumption by adults. Edibles must clearly delineate one serving (10mg) or be packaged so one serving is "readily identifiable or easily measurable."[104] Edibles containing more than one serving must be "homogenized so that each serving contains the same concentration of THC."[105] Products must not be packaged so as to be "easily confused with commercially available foods that do not contain cannabis," or shaped or imprinted with the shape of a "human being, animal, insect or fruit."[106] The CDPH also requires all products to be tamper-evident and child-resistant throughout the duration of its use, and must be packaged and sold in opaque packaging.[107] Cannabis products must

101. In this context, edibles include cookies, candies, and tinctures. *Id*.

102. Fimrite, *supra* note 99.

103. McDonell-Parry, *supra* note 100; John Schroyer, *Falsified California Testing Lab Data May Result in Major Marijuana Product Recall*, MARIJUANA BUSINESS DAILY (Dec. 3, 2018), https://mjbizdaily.com/falsified-california-testing-lab-data-may-result-in-major-marijuana-product-recall/. In November 2018, Sequoia Analytical Labs of Sacramento voluntarily handed over their license after failing to test for all 66 types of pesticides and contaminants (Sequoia was only testing for 44) and for secretly falsifying lab results. Despite the immediate recall for retesting and mandate of certain products tested by the lab to be destroyed, a majority of the product (between 700-800 batches of product, and tens of thousands of pounds of flower and oils) had likely already been consumed, obviously to the detriment and safety of the consumer. Testing laboratories that do not follow state regulations will be forced to forfeit their testing licenses to the state. Fimrite, *supra* note 99.

104. CAL. CODE REGS. tit. 17, § 40305(b)(1)(-2) (2019).

105. CAL. CODE REGS. tit. 17, § 40305(c) (2019).

106. CAL. CODE REGS. tit. 17, § 40300(l)-(m) (2019).

107. CAL. CODE REGS. tit. 17, § 40415(b)-(c) (2019); & CAL. CODE REGS. tit. 17, § 40415(g) (2019); CAL. CODE REGS. tit. 17, § 40417(a)(1) (2019); CAL. CODE REGS. tit. 17, § 40415(e) (2019); CAL. CODE

be in finished form for sale before release to distributors for retail.[108]

2.2.2 CDPH Labeling Requirements for Edible Products

Proper labeling is crucial for safe consumption. There are two parts to a label: the primary panel and the informational panel, typically on the back.[109] Labels cannot be attractive to children in any capacity and may not imitate candy or use the language "candy" (or any variation of the word).[110] An edible's primary label must contain the identity of the product and the universal symbol (as prescribed in § 40412).[111] The primary label must include "the words 'cannabis-infused' immediately above the identity of the product in **bold type** and a text size larger than the text size used for the identity of the product."[112]

The informational panel must contain any known major food allergens, artificial colorings, list of ingredients (in descending order by weight or volume), amount of sodium, sugar, carbohydrates and fat per serving, instructions for "method of consumption," "best by" date, and UID number.[113] All informational panels must also contain a boldfaced, all caps government warning.[114] The label may not contain any false or misleading information, any unsubstantiated health-related statements, and must adhere to Prop. 65 requirements including a warning stating that "this product can

REGS. tit. 17, § 40401(a) (2019).

108. CAL. CODE REGS. tit. 17, § 40401(a) (2019).

109. CAL. CODE REGS. tit. 17, § 40100(nn) (2019); CAL. CODE REGS. tit. 17, §§ 40405-40406 (2019) (primarily labeled as "part of the package most likely to be displayed to the consumer at retail" and informationally paneled "any other portion of the label"); CAL. CODE REGS. tit. 17, § 40408 (2019); 21 U.S.C. § 321(k)-(m) (2019) (defining the label as the explanatory matter upon the "immediate container of any article" and labeling includes the label and any accompanying matter).

110. CAL. CODE REGS. tit. 17, § 40410(b) (2019).

111. CAL. CODE REGS. tit. 17, § 40405(a) (2019).

112. CAL. CODE REGS. tit. 17, § 40406 (2019) (emphasis added).

113. CAL. CODE REGS. tit. 17, § 40408(a)(6)-(12)(2019).

114. CAL. CODE REGS. tit. 17, § 40408(a)(3) (2019) (stating that Government warning required for cannabis products: "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").

expose you to a chemical known to the State of California to cause cancer."[115] Cannabis products *may* also contain "information on the characteristic anticipated effects" if the "manufacturer has substantiation that the information is truthful and not misleading," and can include any common or expected physiological effects.[116]

2.2.3 FDA Regulation of Labeling and Packaging of Dietary Supplements and Food Additives

The FDA requires dietary supplement labels to contain basic components such as, an identity statement, net quantity of contents statements, ingredient statement, responsibility statement (name and place of business of manufacturer or distributor), and a nutrition statement that includes "Nutrition Facts and "Supplement Facts."[117] Similarly to edible labels, supplement labels are prohibited from making any unsubstantiated health claims.[118] Food additives must be labeled with "directions for safe use, and any specific limitation" for use.[119] If no such limitations exist, the label "must include information concerning the levels of the chemical that may be used in a manner consistent with good manufacturing practices."[120]

2.3 DISTRIBUTION AND RETAIL

2.3.1 BCC Distribution and Retail Requirements

Quality control and child-safety are essential for the success of a distributor and, thus, the BCC heavily regulates distributors because their non-compliance can impact the entire industry. Distributors must ensure that they are only working with properly licensed vendors and that all products comply with proper packaging requirements.[121] All edible packaging must

115. CAL. CODE REGS. tit. 17, § 40410(c)-(d) (2019) ("Any health-related statement must be supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims"); CAL. BUS. & PROF. Code § 26121 (2019); CAL. BUS. & PROF. Code § 26154 (2019); Burton & May, *supra* note 15, at 4.

116. CAL. CODE REGS. tit. 17, § 40411 (2019) (emphasis added).

117. Nathalie Bougenies, *Hemp-CBD and FDA: Labeling Dietary Supplements*, CANNA LAW BLOG (Jan. 4, 2019), https://www.cannalawblog.com/hemp-cbd-and-fda-labeling-dietary-supplements/.

118. *Id.*

119. U.S. FOOD & DRUG ADMINISTRATION, *CPG Sec. 500.250 Food Additives – Labeling Directions Necessary For Safe Use,* https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074414.htm (last visited Oct. 19, 2019).

120. *Id.*

121. CAL. BUS. & PROF. CODE § 26120(a) (2019); Melissa Schiller, *4 Things Your Distributor Wants*

not imitate any package commonly marketed towards children and must be child-resistant.[122] To be certified child-resistant, packaging must comport with the "requirements of the Poison Prevention Packaging Act of 1970" or must be plastic and "at least 4 mils thick and heat-sealed without an easy-open tab, dimple, corner, or flap."[123] Most importantly, the BCC requires distributors to perform a quality-assurance review for the labeling of total cannabinoids and terpenoids claimed to be present; products are considered accurate if they are within "plus or minus 10.0%" of what is stated on the certificate of analysis.[124]

2.3.2 BCC Retail Requirements

Edible packaging is largely under the jurisdiction of the CDPH; however, the BCC also articulates a few additional requirements. Cannabis goods must adhere to the strict exit packaging requirements articulated in the CDPH regulations—all goods must be placed in a "resealable, tamper-evident, and child resistant" opaque package.[125] Retailers are also strictly prohibited from packaging "accept[ing], possess[ing,] or selling" any cannabis goods which are not already properly packaged for final sale.[126]

2.3.3 FDA Tamper-Evident Guidelines

Similarly, the FDA has guidelines to safeguard products and notify consumers if they were opened. Tamper-evident packaging is defined by the FDA as "having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred," which would hopefully mitigate prior sale liability.[127] The World Health Organization, whose standards are considered by the FDA and National Association of Cannabis Businesses, strongly believes tamper-evident packaging will protect not only a product,

You to Know, CANNABIS BUSINESS TIMES (Sept. 7, 2018); *see generally* CAL. BUS. & PROF. CODE § 26110 (2019).

122. CAL. BUS. & PROF. CODE § 26120 (b) (2019); CAL. BUS. & PROF. CODE § 26120 (a)(1)(B)(9)(d) (2019).

123. CAL. CODE REGS. tit. 17, § 40417(b)-(c) (2019); POISON PREVENTION PACKAGING ACT OF 1970, 16 C.F.R. §1700.15(b)(1) (Rev. July 1995).

124. A Certificate of Analysis is issued by a laboratory post-testing with results of required analytes. The results are reported to the BCC and must be accurately reflective at all times. CAL. BUS. & PROF. CODE § 26110(e)-(f) (2019).

125. CAL. BUS. & PROF. CODE § 26070.1 (2019); CAL. BUS. & PROF. CODE § 26120 (a) (2019).

126. CAL. BUS. & PROF. CODE § 26120 (a) (2019).

127. 21 C.F.R § 211.132(b) (2019); Burton & May, *supra* note 15, at 30.

but also its consumer against both incidental and accidental poisoning.[128]

2.4 Policy Goals of the California Regulations: Public Health and Safety

Ultimately, current edibles regulations strive to protect the public health and safety. Both the CDPH and the BCC have promulgated guidelines that strive for consumers to purchase edibles "free from contaminants, [that] meet product guidelines and are properly packaged and labeled."[129] At every level of the manufacturing chain, there are safeguards to protect the consumer: exhaustive testing requirements for all cannabis flower and completed edibles, good manufacturing guidelines to ensure homogeneity which correlates to the proper labeling, combing stringent tamper-evident, and child-resistant packaging.[130] Still, things can go wrong, and suits may arise. Even if a California cannabis edible manufacturer follows all of these guidelines, including the possible FDA regulations, there are additional steps needed to lessen the possibility of a product liability lawsuit.

3. PRODUCT LIABILITY ISSUES WITH CANNABIS EDIBLE PRODUCTS

3.1 LEGAL STANDARD

Edibles are unique in that product liability exposure can arise from it being both a food and an intoxicating substance. Cannabis edibles are

128. Burton & May, *supra* note 15, at 7; *see generally NACB National Standards: Packaging and Labeling*, NATIONAL ASSOCIATION OF CANNABIS BUSINESSES (May 17, 2018), https://www.nacb.com/national-standards-packaging;*NACB National Standards: Advertising Standards*, NATIONAL ASSOCIATION OF CANNABIS BUSINESSES (Nov. 5, 2018), https://www.nacb.com/national-advertising-standards. The National Association of Cannabis Businesses (NACB), the only self-regulatory organization for the U.S. cannabis industry, requires all members to maintain compliance with set standards or face expulsion. In the face of federal prohibition, the NACB has promulgated industry standards for packaging, advertising, and lab testing and product integrity. These standards could potentially be used as guidance in states that do not already have a statute for strict products liability, (not the case in California. The FDA could also use these standards as guidance in setting their own future policies. NACB President Andrew Kline posits that if NACB "set standards that are higher than what they're required to do in their states, the federal government will stay out of their way." *See NACB National Standards: Lab Testing and Product Integrity, Public Comment Now Closed*, NATIONAL ASSOCIATION OF CANNABIS BUSINESSES (accessed Feb. 17, 2019), https://www.nacb.com/national-lab-testing-product-integrity-standards. Burton & May, *supra* note 15, at 7; *WHO Technical Report Series, NO. 902 – §1.5 Protection of Patients*, WORLD HEALTH ORGANIZATION 131 (2002), http://apps.who.int/medicinedocs/documents/s19638en/s19638en.pdf

129. CALIFORNIA DEPARTMENT OF PUBLIC HEALTH: MANUFACTURED CANNABIS SAFETY BRANCH, https://www.cdph.ca.gov/Programs/CEH/DFDCS/MCSB/Pages/MCSB.aspx (last visited Oct. 19, 2019).

130. *See generally* CAL. BUS & PROF. CODE §§ 26130 — 26135 (2019); CAL. CODE REGS. tit. 17, ch. 13, subch. 4 (2019).

uniquely more potent as compared to when an individual smokes the plant.[131] Edibles also have a much "slower onset time and greater challenge in metering dosage."[132] If you get *too high* you may experience panic, hallucinations, anxiety, or feel frightened, although no one has ever died from a cannabis overdose.[133] Product liability typically arises "from design defects, specific language in advertising and inadequate warnings."[134] Product liability claims only cover physical injury, and the person harmed must have used the product "in a way that was reasonably anticipated by the manufacturer."[135] The plaintiff has the initial burden of proof of injury when using the product in "an intended or reasonably foreseeable manner."[136] If proven, the defendant must then "prove that the plaintiff's injury resulted from a misuse of the product."[137] If the product is proven to be the sole cause of injury, its misuse is a "complete defense to strict product liability."[138] In California, if misuse or modification is not the sole, but rather a substantial factor in injury, comparative fault of plaintiff or of a third-person is weighed.[139] However, California has a strict liability standard for three types of defects: manufacturing, design, and warning.[140] Manufacturing defects claims arise out of "errors in the process of making the product."[141] "Design defects focus . . . on the design itself," and warning defects arise out of a manufacturers failure to warn.[142]

"The purpose of such [strict] liability is to insure that the costs of

131. Campbell & Singh, *supra* note 4, at 345; *see also*, Donald W. Sieveke, *California's Changing Marijuana Laws Grow New Opportunities*, 59 ORANGE COUNTY LAWYER 42, 46 (2017).

132. Neil Juneja, *Are Cannabis Retailers & Producers Liable for Consumer Harm?*, GLEAM LAW (2018), https://www.gleamlaw.com/cannabis-product-liability/.

133. *How Does Marijuana Affect You?*, WEBMD, https://www.webmd.com/mental-health/marijuana-use-and-its-effects#1 (last visited Oct. 19, 2019); Lisa Rough, *8 Ways to Counteract a Too-Intense Cannabis High*, LEAFLY, https://www.leafly.com/news/cannabis-101/8-ways-to-counteract-a-too-intense-cannabis-high (last visited Oct. 19, 2019).

134. Burton & May, *supra* note 15, at 30.

135. Campbell & Singh, *supra* note 4, at 349; Ian A. Stewart & Francis J. Mootz III, *Insuring the Product Liability Risks of Cannabis*, SSRN 1 (Sept. 1, 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3111600; CACI § 1200 – Strict Liability 669 (2017); Johnson v. United States Steel Corp, 192 Cal.Rptr.3d 158, 164 (Cal. Ct. App. 2015).

136. Stewart & Mootz III, *supra* note 135.

137. *Id*.

138. *Id*.

139. *Id*.

140. Anderson v. Owens-Corning Fiberglas Corp., 53 Cal.3d 987, 995 (Cal. 1991); *see also*, Lauren M. Case, Latosha M. Ellis, Alana Long, Lindsay L. Rollins, & Cassandra C. Shivers, *How High: The Buzz on Emerging Issues in Coverage for Cannabis Operations*, AMERICAN BAR ASSOCIATION 18 n.2 (Aug. 21, 2018), https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/regionals-materials/2018-2019/win/8-Coverage-for-Cannabis-Operations/WIN-How-High-The-Buzz-on-Emerging-Issues-in-Coverage-for-Cannabis-Oper.pdf; Stewart & Mootz III, *supra* note 135.

141. Campbell & Singh, *supra* note 4, at 350.

142. *Id*.

injuries resulting from defective products are borne by the manufacturers" and not by "the injured persons who are powerless to protect themselves."[143] Every integral part of the manufacturing chain is considered liable for a final product that induces injury.[144] "A defendant will not be held strictly liable unless doing so will enhance product safety, maximize protection to the injured plaintiff, and apportion costs among the defendants."[145]

[T]o hold a defendant strictly liable under a marketing/distribution theory, the plaintiff must demonstrate that the defendant: (1) received a direct financial benefit from its activities and from the sale of the product; (2) played an integral role in the business enterprise, such that the defendant's conduct was a necessary factor in bringing the product to the initial consumer market; and (3) had control over, or a substantial ability to influence, the manufacturing or distribution process.[146]

This strict liability standard will certainly pose challenges for edible cannabis companies. Cannabis' current federal illegality "potentially undercuts [any first-party] claim" and a court may conclude that this establishes liability, if filed in federal court.[147] Third-party claims arise out of a person injured from someone else's use of cannabis, and are more likely to be filed because the federal illegality "potentially helps the claims."[148] Manufacturers and retailers are typically liable for placing "unreasonably dangerous products on the market," however, what is considered "unreasonably dangerous" is determined by community standards and expectations.[149] Since THC has been federally illegal, except for medicinal patients under various states' laws, what constitutes community standards and expectations may be difficult for courts to articulate.[150]

143. CACI § 1200 - Strict Liability 670 (2017); Greenman v. Yuba Power Products, Inc., 59 Cal.2d 57, 62-63 (1963).

144. Arriaga v. CitiCapital Commercial Corp., 167 Cal.App.4th 1527, 1534 (2008); Lauren M. Case, Latosha M. Ellis, Alana Long, Lindsay L. Rollins, & Cassandra C. Shivers, *How High: The Buzz on Emerging Issues in Coverage for Cannabis Operations*, AMERICAN BAR ASSOCIATION 18 n.2 (Aug. 21, 2018), https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/regionals-materials/2018-2019/win/8-Coverage-for-Cannabis-Operations/WIN-How-High-The-Buzz-on-Emerging-Issues-in-Coverage-for-Cannabis-Oper.pdf.; Stewart & Mootz III, *supra* note 135.

145. Hernandezcueva v. E.F. Brady Co., Inc., 243 Cal.App.4th 249, 258 (2015); CACI § 1200 – Strict Liability 670-71 (2017).

146. Arriaga v. CitiCapital Commercial Corp., 167 Cal.App.4th 1527, 1535 (2008); CACI § 1200 – Strict Liability 670-71 (2017).

147. Campbell & Singh, *supra* note 4, at 351-52.

148. *Id*.

149. Neil Juneja, *Are Cannabis Retailers & Producers Liable for Consumer Harm?*, GLEAM LAW (July 12, 2018), https://www.gleamlaw.com/cannabis-product-liability/.

150. *Id*.

3.2 PRODUCT LIABILITY CASES IN CANNABIS

At the time of writing, there has not been a product liability lawsuit related to edible cannabis in California. However, in 2016, the first cannabis third-party liability case was filed in the Denver District Court, *Kirk v. Nutritional Elements, Inc., and Gaia's Garden.*[151] Gaia's Garden was a medical marijuana bakery that produced THC edibles.[152] Richard Kirk consumed a candy with 101 mg of THC, ten-times the recommended dosage for edibles, and experienced "possible psychotic behavior" and hallucinations.[153] He got his gun and shot and killed his wife in front of their three children.[154] Kirk's children filed suit alleging the bakery and distributor, Nutritional Elements, Inc., failed "to warn that edibles could lead to paranoia, psychosis and hallucinations" and "negligently, recklessly and purposefully concealed vital dosage and labeling information from their actual and prospective purchasers . . . to make a profit."[155] Kirk ended up pleading guilty to second-degree murder, agreeing to serve 25-30 years in prison and giving up custody of his three children.[156] Kirk's plea deal ended a years-long debate surrounding cannabis and its influence on the slaying; coincidentally, he was later determined to not have been intoxicated by cannabis.[157] The only other product liability suit was also filed in the Denver

151. Kirk v. Nutritional Elements, Inc., and Gaia's Garden, No. 16-cv-31310, *complaint filed* (D. Colo. April 13, 2016), https://www.courthousenews.com/wp-content/uploads/2017/05/Kirk.v.Gaia_.pdf; *see also*, Lauren M. Case, Latosha M. Ellis, Alana Long, Lindsay L. Rollins & Cassandra C. Shivers, *How High: The Buzz on Emerging Issues in Coverage for Cannabis Operations*, AMERICAN BAR ASSOCIATION 18 (Aug. 21, 2018), https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/regionals-materials/2018-2019/win/8-Coverage-for-Cannabis-Operations/WIN-How-High-The-Buzz-on-Emerging-Issues-in-Coverage-for-Cannabis-Oper.pdf.; Stewart & Mootz III, *supra* note 135; Jason Schossler, *Insurer Says Marijuana Bakery on its Own for 'Karma Kandy' Killing*, 27 No. 32 WJINSC 1 (May 19, 2017).

152. Lauren M. Case, Latosha M. Ellis, Alana Long, Lindsay L. Rollins & Cassandra C. Shivers, *How High: The Buzz on Emerging Issues in Coverage for Cannabis Operations*, AMERICAN BAR ASSOCIATION 18 (Aug. 21, 2018), https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/regionals-materials/2018-2019/win/8-Coverage-for-Cannabis-Operations/WIN-How-High-The-Buzz-on-Emerging-Issues-in-Coverage-for-Cannabis-Oper.pdf.

153. *Id.*

154. *Id.*

155. Hilary Bricken, *Killer Pot? An Analysis of the Cannabis Wrongful Death Suit in Colorado*, ABOVE THE LAW (June 6, 2016), https://abovethelaw.com/2016/06/killer-pot-an-analysis-of-the-cannabis-wrongful-death-suit-in-colorado/.

156. *Id.*

157. Kirk's suit ended in a plea deal but the suit filed against Gaia's Garden and its distributor Nutritional Elements continues. Gaia's insurance, United Specialty, filed a federal complaint against Gaia's Garden and Kirk's children, denying any obligation to defend Gaia as their policy did not cover injury once Gaia had "relinquished possession' of the product" and excluded liability arising from "psychotropic substances." Jesse Paul, *Richard Kirk, Colorado man Accused in Slaying of his Wife, Pleads Guildy to Second-Degree Murder*, THE CANNABIST (Feb. 3, 2017), https://www.the

District Court, *Flores v. Liv Well, Inc.* There, plaintiffs alleged that the cultivator had used the toxic pesticide Eagle 20 (containing Myclobutanil) and failed to provide adequate warning.[158] However, the case was dismissed for lack of standing—plaintiffs had consumed the product without any injury.[159] In both cases, causation was an issue, and neither plaintiff was awarded damages on the merits.[160] Causation will certainly be a pertinent issue with edible cannabis consumption and liability in the near future.

3.3 MANUFACTURING DEFECTS AND PROPOSED RESPONSE: ADDITIONAL RECALL PROCEDURES

Manufacturing defect claims arise from procedural errors in making the product. Potential manufacturing defects in cannabis stem from the raw flower itself.[161] Growers must be diligent about keeping the plants insect and pest free, and yet, refrain from exposing the plant to a multitude of pesticides.[162] When tainted flower is then used to extract THC for edible products, the edible will also likely be tainted. To address such manufacturing and design defects, California laboratories must adhere to all FDA requirements and obtain an ISO/IEC 17025 international accreditation.[163] Manufacturers must only use food ingredients or components that are GRAS by FDA standards. The edible industry is similar to the dietary supplement industry's rise in products on the market before proper federal regulation.[164] Supplement companies were sued for "strict product liability, negligence, breach of warranty, misrepresentation, unfair business practices and fraud," leading to "product recalls and consumer class actions" due to "poor-quality control, contamination and misleading product claims."[165] The California cannabis industry can avoid the same legal pitfalls as the dietary supplement industry by instituting policies that go above and

cannabist.co/2017/02/03/richard-kirk-colorado-murder-marijuana-candyintoxication/72996/.

158. Julie A. Steinberg, *Pot Product Makers High on Strict Restrictions*, LITIGATION ON BLOOMBERG LAW (June 22, 2017), https://www.bna.com/pot-product-makers-n73014460652/; *see also* Campbell & Singh, *supra* note 4, at 357; Stewart & Mootz III, *supra* note 135.

159. Julie A. Steinberg, *Pot Product Makers High on Strict Restrictions*, LITIGATION ON BLOOMBERG LAW (June 22, 2017), https://www.bna.com/pot-product-makers-n73014460652/.

160. Thomas Stufano, *Through the Smoke: Do Current Civil Liability Laws Address the Unique Issues Presented by the Recreational Marijuana Industry?*, 34 TOURO L. REV. 1409, 1418 (2018).

161. Campbell & Singh, *supra* note 4, at 353.

162. *Id*. at 353-54.

163. *Testing Laboratories*, CAL. BUREAU OF CANNABIS CONTROL, https://bcc.ca.gov/licensees/testing_labs.html, (last visited Oct. 23, 2019).

164. Stewart & Mootz III, *supra* note 135.

165. Prop. 65 institutes warning requirements for all products sold in California, known to the state, that may expose an individual to a chemical that may cause cancer. There are more than 1,000 chemicals currently listed. For more information, visit www.P65Warnings.ca.gov. *Id*.

beyond the current California and FDCA regulations of dietary supplements or food additives, which will include incorporating additional recall procedures.

Under California law, the CDPH is the only agency with recall authority and requires all licensees to create and "implement written procedures for recalling cannabis products manufactured by the licensee that are determined to be misbranded or adulterated."[166] If the Department "has evidence" a product is "adulterated or misbranded," and the use will "cause serious adverse health consequences," the department will notify the manufacturer; a voluntary recall will be requested and a hearing is provided, unless the Department believes a mandatory recall is necessary.[167] Information regarding recalled products must be located in the CDFA track-and-trace system, likely enabling manufacturers to get products off the market before widespread consumption. Thus, all cannabis companies must not only have recall procedures in place—that are routinely tested by compliance departments—but also aggressive public notifications, as required by the FDA.[168] Such notifications should include press releases to consumers who may have purchased the product, including a picture of it on the website of the dispensary, the BCC, and on the local news. Timely and coordinated communication with all agencies and actors is tantamount to public safety during a recall. Cannabis companies are required to obtain insurance in California, however, product liability insurance is not mandated and should be, preferably through a state-regulated carrier.[169] Similarly, the FDA has strict procedures to protect consumers from adulterated products—in order to simplify recalls and consumer notification, it requires responsible parties to report foods that may have contaminated other foods into a registry accessible by the FDA, in addition to consumer notification.[170] These FDA procedures need to be emulated for cannabis in California.

166. CAL. CODE REGS. tit. 17, § 40297 (2019).

167. CAL. BUS & PROF. CODE § 26132(a)-(e) (2019); John Schroyer, *Here's How California Might Enforce Violations of Marijuana Business Rules*, MARIJUANA BUSINESS DAILY (July 3, 2018), https://mjbizdaily.com/heres-how-california-might-enforce-violations-of-marijuana-business-rules/.

168. 21 U.S.C. § 350***l*** (g) (2019).

169. There are four insurance companies that are approved state-regulated carriers offering liability insurance for the cannabis industry: Golden Bear Insurance Co., North River Insurance Co., U.S. Fire Insurance Co. and White Pine Insurance Co. Despite their ability to write surety bonds for cannabis businesses, there are still significant gaps in coverage, particularly in products liability. *See* Kevin Smith, *Cannabis Companies Now Have Access to Property, Liability Insurance in* California, CA.GOV (June 4, 2018), https://cannabis.ca.gov/2018/06/05/cannabis-companies-now-have-access-to-property-liability-in surance-in-california/.

170. 21 U.S.C.A. § 350f(d)(1)(A-B) (West 2019); 21 U.S.C.A. § 350f(g-h) (West 2019). This includes posting notification at or near the register, providing location of the reportable food, and providing targeted recall info. 21 U.S.C.A § 350***l*** (b) (West 2019).

3.4 DESIGN DEFECTS AND PROPOSED RESPONSE: SET NATIONAL STANDARD DOSAGE AT 10MG

Design defect claims focus on the design itself. What is a "reasonable" design is still debatable due to a patchwork of state standards and the lack of a federal standard. The CDPH requires a clear delineation of a single 10mg serving, but products can still contain up to 100mg per package. This can potentially expose consumers to serious intoxication if they found it "reasonable" to eat the whole product. For example, a manufacturer that makes chocolate covered espresso beans with 100mg per package, each bean is 5mg—how unreasonable is it that the consumer would think to eat more than one bean, maybe three or four? If a consumer were injured while intoxicated, they could very likely bring a suit against a manufacturer alleging the "product was unreasonably dangerous" and it was reasonable to eat the entire package.[171] The slow onset of cannabis oral consumption also implicates failure to warn issues. If cannabis was regulated like a food additive, the FDA could institute restrictions on labeling and serving size amounts, lessening liability for "inadequate" labeling or failure to warn issues. If cannabis was regulated as a dietary supplement, the FDA could institute conditions for recommended use under which the use will "reasonably be expected to be safe."[172]

Even if an edible comports with both the FDCA and California regulations, it would still be possible for a consumer to file a product liability suit for a design defect because what is considered "unreasonably dangerous" has not been properly determined by the FDA or by case precedent in California. Of particular note, the BCC and CDPH were recently asked to clarify the regulations around serving size because "if an edible cannabis product is labeled as containing 10 mg per serving, and testing shows that it contains 10.1 mg—which is within the BCC's 10% variance—it would also meet CDPH product requirements."[173] However, the statutory requirement states that a standard dose must not exceed 10mg, creating a possible liability issue. The lack of a uniform national legal standard of 10mg (with little to no variance), and the current acknowledged BCC/CDPH variance, leaves manufacturers, distributors, and retailers at risk. Proper articulation of serving sizes need to be nationally espoused by the FDA.

171. Campbell & Singh, *supra* note 4, at 361.

172. U.S. FOOD & DRUG ADMINISTRATION, *New Dietary Ingredients in Dietary Supplements – Background for Industry*, (last visited Oct. 19, 2019), https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm109764.htm.

173. *Id.*

3.5 INADEQUATE WARNINGS AND PROPOSED SOLUTION: ENSURING AN EDUCATED BUDTENDER AND CONSUMER

Warning defect claims arise from a manufacturers failure to warn. Edible packaging and labeling requirements under the FDCA (potentially) and California regulations (currently) would certainly overlap in their goal of keeping products unattractive and unattainable to children. Thus, design defect issues can be lessened by strict packaging and labeling requirements. The National Label Education Act espouses that no state may establish any requirement for the labeling of food that is not identical to the federal requirements, which is complicated given that there is no federal standard for edibles. Edibles must already be child-resistant and comport with the Federal Poison Prevention Packaging Act of 1970.

It is clear that manufacturers and retailers need to work together to lessen liability for failure to warn claims by instituting policies to *ensure* consumers are informed at the time of sale and prior to consumption. First and foremost, serving sizes need to be publicized through a national Public Service Announcement—10mg for the average adult. The Center for Disease Control ("CDC") has a portal about "marijuana and public health," but this portal does not address intoxication issues with edibles.[174] The CDPH also has a "Let's Talk about Cannabis" program, which is essentially a public relations experiment, which states that "by sharing science-based information, the CDPH is working to increase awareness about cannabis and its impacts on bodies, mind and health."[175] This portal is certainly a step in the right direction because consumers *are* eating food and drinks infused with cannabis and should be informed of their decisions. However, working with the FTC, cannabis companies need to be able to advertise similarly to what alcohol companies advertise on television, such as warning viewers to "Drink (Consume) Responsibly." For example, Bacardi Rum advertisements advise consumers to "Enjoy Responsibly Together."[176] Until it becomes "common knowledge" that 10mg is the average adult serving size, this needs to be publicized as much as possible through all available, regulated avenues.

174. *Marijuana and Public Health*, CENTER FOR DISEASE CONTROL, https://www.cdc.gov/marijuana/ (last visited Oct. 19, 2019).

175. CDPH Warning for Safe Edible Consumption: "When you smoke or vape cannabis you may feel the effects quickly, but it can take between 30 minutes and two hours to feel the effects of edibles like cookies, sodas, and ice cream. Start with less than a single serving (less than 10 mg of THC), then wait before using more. It is important to know about the delayed effects of edibles because if you eat too much too quickly, you are at greater risk of poisoning. "*Let's Talk Cannabis: Responsible Use*, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, https://www.cdph.ca.gov/Programs/DO/letstalkcannabis/Pages/responsibleuse.aspx (last visited May 3, 2019).

176. *How Big Alcohol Abuses "Drink Responsibly" to Market its Products*, ALCOHOL JUSTICE (May 2012), https://alcoholjustice.org/images/stories/DrinkResponsiblyFinal.pdf.

As an additional precaution, manufacturers can contract with dispensaries to mandate "talking points" to coincide with the edible sale.[177] Dispensaries could place additional custom warning labels on edibles to further articulate expected effects, which the CDPH recommends but does not require. 'Budtenders' should be required to give additional instructions upon purchase about potential effects and articulate both the 10mg standard and first-time dosage recommendation. [178] Currently, the City of San Francisco requires all cannabis retailers to make a handout titled "Safe Consumption of Cannabis Products" available to customers, detailing possible effects of cannabis.[179] Various dispensaries have met this requirement by simply posting a link on their website, however, is inadequate. This safe consumption handout needs to be visibly posted in stores, placed inside the opaque packaging, by checkout counters, in the display next to the products, and pointed out by the budtenders. Although there is already an individual daily purchase limit, a shared statewide system to track the daily limit sold to each consumer might also help mitigate the risk of dispensaries being "held liable for a potential 'overdose' or an improper sale."[180]

3.6 POSSIBLE IMPOSITION OF GRAM SHOP LAWS AND CALIFORNIA CIVIL CODE § 1714.45

Notably, in California, liquor stores and licensed liquor establishments do not face liability for serving an individual, unless the individual is an obviously intoxicated minor.[181] Yet, we currently hold cannabis product manufacturers liable for placing an unreasonably dangerous product on the market.[182] Though not currently in place, California may choose to impose "gram shop" laws for cannabis, thus protecting dispensaries from liability for injuries suffered by customers.[183] Under these statutes, "selling to a

177. Campbell & Singh, *supra* note 4, at 364.

178. *Id.*

179. *Safe Consumption of Cannabis Products*, SAN FRANCISCO OFFICE OF CANNABIS (Jan. 4, 2018), https://www.sfdph.org/dph/files/csl/SAFE-CONSUMPTION-OF-CANNABIS-PRODUCTS-FACT-SHEET.pdf.

180. Persons 21 and older, can buy and possess up to 28.5 grams of cannabis, up to 8 grams of cannabis concentrate and up to 6 live plants. Alex Wigglesworth, *Legal Weed in California: A Consumer's Guide*, LOS ANGELES TIMES (April 20, 2018), https://www.latimes.com/politics/la-pol-ca-cannabis-consumer-guide-20180420-htmlstory.html; *see also* Burton & May, *supra* note 15, 10.

181. CAL. BUS & PROF. CODE § 25602.1 (2019).

182. Burton & May, *supra* note 15, at 10, 26.

183. Campbell & Singh, *supra* note 4, at 379; Ken Stratton, *"Gram Shop" Laws – What They Are and Why We Need Them in California*, ROGOWAY LAW GROUP (Jan. 9, 2019), https://www.rogowaylaw.com/gram-shop-laws-cannabis-california/.

clearly-intoxicated person is considered negligent," but dispensaries would otherwise be protected from "civil liability flowing from the bad behaviors of intoxicated customers."[184] Extending these laws to cover cannabis would not be difficult, as shown by the recent extension of immunity to alcohol-infused energy drinks.[185] However, causation for intoxication is difficult to prove, given that THC remains in a person's system long after their "high" is over.[186]

Additionally, the cannabis industry is not currently privy to the immunity provided by California Civil Code section 1714.45, which shields manufacturers and sellers from product liability if both of the following apply:

"(1) The product is inherently unsafe and the product is known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community;" and (2) the product "is a common consumer product intended for personal consumption, such as sugar, castor oil, alcohol, and butter."[187]

"This statute has never been applied to cannabis, [so] it is unclear whether cannabis qualifies as either an 'inherently unsafe' product or a "common consumer product."[188]

Additionally, if sued under current federal law, retailers' defense could be that the CSA does not create a "substantive private right to invoke."[189] However, cannabis "companies can further insulate themselves if they are able to prove to a jury that they went beyond adherence to just state laws."[190] Given the lack of precedent, product liability issues will surely be one of the most challenging compliance issues for cannabis companies, because California's strict liability products standards subject all those integral to the manufacturing and distribution process to liability. Addressing product liability issues for edibles, in view of FDCA complaints, is particularly relevant given that this burgeoning area of law is still in its infancy. Because of the current state by state legal quagmire, edible manufacturers should continue to provide information about the continued federal illegality of cannabis and the lack of FDA and DEA approval on all cannabis products.[191]

184. Campbell & Singh, *supra* note 4, at 379; Stratton, *supra* note 181.
185. Stratton, *supra* note 184.
186. Campbell & Singh, *supra* note 4, at 379.
187. CAL. CIVIL CODE § 1714.45 (2019).
188. Stratton, *supra* note 184.
189. *Id.* at 381.
190. *Id.* at 386.
191. Campbell & Singh, *supra* note 4, at 383.

CONCLUSION

In short, the rise in consumption of cannabis edible products poses unique challenges for cannabis companies. Public safety relations for edible consumption is going to be best served by continued consumer education. *Start low and slow*. Complicated product liability issues are certainly foreseeable for manufactured cannabis edibles. Manufacturing defects can result from tainted flowers, falsified testing results, and not using clean, quality products. Manufacturing defects may occur, however, and defective products can get on the market. Nevertheless, zealous recall processes and consumer notification procedures can likely lessen this impact of consumer harm. Design defects will likely arise due to a lack of a community standard as to what is truly a "reasonable design." Consumer education is key to having an informed consumer and to lessen over consumption—10mg is the standard dosage. Failure to warn issues will also likely arise due to an edible's slow onset, and often deceiving appearance and taste resembling candy. Failure to warn issues could be lessened by mandating budtender talking points at sale, such as drawing attention to the dosages and handing out warnings about effects of consumption. Ultimately, cannabis needs to be *de-scheduled* from the CSA, and properly funded federal studies on the effect of cannabis must be conducted, particularly concerning edible products, just as California is currently doing.[192] The FDA states that they remain committed to "exploring an appropriate, efficient and predictable regulatory framework" for cannabis-derived products, so the future is optimistic.[193] Frankly, in order to set proper federal regulations of edible products, an act of Congress may be needed. As this Note has articulated, it is possible to properly regulate edible cannabis products as either a food additive or a dietary supplement to ensure safe, enjoyable consumption and lessen exposure to product liability issues. Adult-use cannabis is here to stay—your move, Congress.

192. The bureau contracted with the California Cannabis Research Program (as known as the Center for Medicinal Cannabis Research) pursuant to § 11362.9 of the H&S Code to develop a study that identifies the impact that cannabis has on motor skills. CAL. BUS & PROF. CODE § 26190.5 (2019). The Medical Cannabis Research Act of 2019 was recently introduced to the House of Representatives, which would force the DEA to issue three registrations "to manufacture cannabis for legitimate research purposes within a year." Despite the fact that cannabis will remains a Schedule I drug, this bill is a step in the right direction. Currently, federal researchers obtain their medical cannabis from one subpar source and if this bill passed at least the studied product would potentially be of better quality, improving the studies themselves. John A. Gilbert & Larry K. Houck, *Medical Cannabis Research Act Stirs DEA Marijuana Registration Pot,* FDA Law Blog (Apr. 10, 2019), http://www.fdalawblog.net/2019/04/medical-cannabis-research-act-stirs-dea-marijuana-registration-pot/.

193. Gottlieb, *supra* note 43.

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