

SMOKE AND MIRRORS: CANNABIS SAFETY COMPLIANCE TESTING IN MICHIGAN AND THE NEED FOR CONSUMER PROTECTION

EMMA FLANIGAN[†]

I. INTRODUCTION	757
II. BACKGROUND	760
A. <i>Marijuana's Illegal Status on the Federal Level</i>	760
1. <i>The Federal Approach to Cannabis</i>	760
2. <i>The Consequences of the Federal Approach</i>	762
B. <i>The History of Michigan's Marijuana Regulatory Regime</i>	765
C. <i>Are Michigan's Safety Measures Enough?</i>	767
D. <i>Implications for Consumers</i>	772
E. <i>Implications for the Industry</i>	776
III. SOLUTIONS FOR PROTECTING CONSUMERS AND THE INDUSTRY....	777
A. <i>Standardize Testing Procedures</i>	777
B. <i>Create Additional Recall Procedures</i>	783
C. <i>A Note on the Role for the Federal Government</i>	787
IV. CONCLUSION	792

I. INTRODUCTION

Cannabis has taken Michigan by storm since Michigan voters legalized it by ballot initiative in 2018.¹ Michigan was the first state in the Midwest to do so,² and it now boasts a \$3 billion cannabis market and the highest per capita spending on cannabis in the country.³ With social acceptance of cannabis increasing and the stigma surrounding it dissipating like smoke in the air, the new sentiment in popular culture is that weed is a fun, safe, and harmless substance.⁴

[†] B.A., 2018, *summa cum laude*, Oakland University; J.D., expected 2024, Wayne State University Law School.

1. *Michigan Proposal 1, Marijuana Legalization Initiative (2018)*, BALLOTPEdia, [https://ballotpedia.org/Michigan_Proposal_1_Marijuana_Legalization_Initiative_\(2018\)](https://ballotpedia.org/Michigan_Proposal_1_Marijuana_Legalization_Initiative_(2018)) [<https://perma.cc/KF6X-UJV3>].

2. *Id.*

3. *Michigan's Total Marijuana Sales Reach \$3 Billion in 2023*, MJBIZDAILY (Jan. 17, 2024), <https://mjbizdaily.com/michigan-total-marijuana-sales-reach-3-billion-in-2023/> [<https://perma.cc/8RJ9-UEZ6>].

4. See Ted Van Green, *Americans Overwhelmingly Say Marijuana Should Be Legal for Medical or Recreational Use*, PEW RSCH. CTR. (Nov. 22, 2022), <https://www.pewresearch.org/fact-tank/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use/> [<https://perma.cc/964A->

Yet there are many unknowns about the safety and efficacy of cannabis. Scientific research about its harms, benefits, and impact on society is lacking.⁵ This Note will look into one aspect of these unknowns: cannabis safety compliance testing.⁶ In Michigan, private companies called “safety compliance facilities” are tasked with conducting laboratory testing on marijuana produced in the state for potency and contaminants.⁷ Because cannabis is still illegal federally⁸ and the federal government has taken a hands-off approach to state cannabis legalization,⁹ traditional federal regulators—namely, the Food and Drug Administration (FDA)—have little say in the way states roll out their cannabis regulatory regimes.¹⁰ Far from the strict manufacturing and processing controls one would expect under an FDA-regulated regime,¹¹ Michigan’s safety compliance companies face only an inexperienced state regulator (the Cannabis Regulatory Agency)¹² and have significant leeway to develop their own testing procedures to apply to the cannabis they test.¹³

Despite its few short years of existence, Michigan’s system of safety compliance regulation has already faced controversy.¹⁴ In 2021,

LAS2]; see also David V. Patton, *A History of United States Cannabis Law*, 34 J.L. & HEALTH 1, 18–19 (2020).

5. See generally NAT’L ACADS. OF SCIS., ENG’G, AND MED., *THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS* (2017) for a comprehensive overview of the current state of scientific knowledge about cannabis. See also Joëlle Anne Moreno, *Half-Baked: The Science and Politics of Legal Pot*, 123 PENN ST. L. REV. 401, 411–13 (2019).

6. See MICH. COMP. LAWS § 333.27953(p) (2021) (a “‘marihuana safety compliance facility’ means a person licensed to test marihuana, including certification for potency and the presence of contaminants.”).

7. See MICH. ADMIN. CODE r. 420.301–308 (2022) (Michigan’s safety compliance requirements).

8. 21 U.S.C. § 812(c), Schedule I(c)(10) (2018).

9. See Rachel LaBruyere & Slates Veazey, *Attorney General Garland Reconfirms the DOJ’s Hands-Off Approach Toward Federal Marijuana Prosecution*, JDSUPRA (May 3, 2022), <https://www.jdsupra.com/legalnews/attorney-general-garland-reconfirms-the-9983989/> [<https://perma.cc/A9EZ-R8MJ>].

10. Eric N. Lindblom, *How FDA Could Use Its Existing Authorities to Make State Legalization of Cannabis More Safe and Effective*, 74 FOOD & DRUG L.J. 191, 194 (2019).

11. See generally Sean M. O’Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823 (2019).

12. Barton Morris, *5 Fast Facts and Updates About the MRA*, CANNABIS LEGAL GRP. (May 6, 2019), <https://michigan-marijuana-lawyer.com/5-fast-facts-and-updates-about-the-mra/> [<https://perma.cc/2JSZ-9TK5>] (noting that Michigan’s Cannabis Regulatory Agency became functional on April 30, 2019). Note that the Cannabis Regulatory Agency used to be called the Marijuana Regulatory Agency (MRA). See Exec. Order No. 2022-1, MICH. COMP. LAWS § 333.27002 (2022) (renaming the agency the Cannabis Regulatory Agency).

13. MICH. ADMIN. CODE r. 420.305(2) (2021).

14. See Adrienne Roberts, *Michigan’s Cannabis Testing Industry Like ‘Wild Wild West’: What It Means for Consumers*, DET. FREE PRESS (Aug. 25, 2022),

Michigan's Cannabis Regulatory Agency (CRA) recalled 64,000 pounds of marijuana, worth \$229 million, all tested at two laboratories in the state.¹⁵ The CRA claimed that the recall was to protect consumers from unreliable test results and certain contaminants.¹⁶ But the CRA's action resulted in a heated legal battle between the labs and the agency that ultimately ended in a court partially enjoining the CRA's recall in favor of the labs.¹⁷ As a result, a portion of the recalled marijuana—which was contaminated, according to the CRA—returned to dispensary shelves.¹⁸

After the public blunder of the recall, Michiganders have come to question whether Michigan's cannabis safety compliance industry is really safe.¹⁹ This issue is especially pressing given the far-reaching consumer implications of inaccurate safety compliance testing, such as exposure to harmful contaminants and inability to trust dosing labels.²⁰ Federal regulation of cannabis would likely be the most effective approach to protecting consumers, given the FDA's experience, access to resources, and ability to conduct the large-scale research on cannabis that is desperately needed.²¹ Yet, cannabis' Schedule I status makes research and regulation particularly difficult.²² Under the FDA's existing authorities, the FDA would face obstacles crafting a regulatory regime that fits the unique aspects of the cannabis industry.²³ Until Congress and the FDA decide their path forward on cannabis, the obligation falls on Michigan to protect its cannabis consumers.

<https://www.freep.com/story/news/marijuana/2022/08/25/michigans-cannabis-testing-industry-its-like-the-wild-wild-west/10097178002/> [https://perma.cc/56J6-BXHR] [hereinafter Roberts, *Wild Wild West*].

15. Gus Burns, *64,000-pound, \$229 Million Michigan Marijuana Recall Is the Result of Bureaucratic 'Abuse,' New Lawsuit Claims*, MLIVE (Nov. 24, 2021), <https://www.mlive.com/public-interest/2021/11/64000-pound-229-million-michigan-marijuana-recall-is-the-result-of-bureaucratic-abuse-new-lawsuit-claims.html> [https://perma.cc/R5BZ-ATRQ] [hereinafter Burns, *\$229 Million Marijuana Recall*].

16. See *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024 (Mich. Ct. Cl. Dec. 3, 2021).

17. *Id.*

18. Adrienne Roberts, *Moldy Marijuana Could Be On Store Shelves, Michigan Agency Says*, DET. FREE PRESS (Dec. 15, 2021), <https://www.freep.com/story/news/marijuana/2021/12/15/moldy-marijuana-store-shelves-agency-says/8914306002/> [https://perma.cc/HP2L-E52U] [hereinafter Roberts, *Moldy Marijuana*].

19. See Roberts, *Wild Wild West*, *supra* note 14; Gus Burns, *How Safe Is Michigan's \$2 Billion Marijuana Industry?*, MLIVE (Mar. 9, 2022), <https://www.mlive.com/public-interest/2022/03/how-safe-is-michigans-2-billion-marijuana-industry.html> [https://perma.cc/WNX7-DHPC] [hereinafter Burns, *How Safe?*].

20. See *infra* Part II.D for an in depth discussion of potential consumer harms.

21. Rebecca S. Eisenberg & Deborah B. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD & DRUG L.J. 246, 250–51 (2019).

22. See *infra* Part II.A.

23. See *infra* Part III.C.

This Note argues that, in the face of lacking federal oversight and regulatory assistance, the CRA should strengthen its safety compliance regulatory regime by standardizing cannabis testing procedures and promulgating additional recall procedures.²⁴ Taking these steps will secure consumers' safety by ensuring testing consistency, eliminating opportunities and market forces that compel laboratories to manipulate test results, helping the CRA engage in more consistent regulation and enforcement, and preventing contaminated products from ever reaching consumers.²⁵

Part II outlines the current federal and state divide in cannabis law,²⁶ the problems with Michigan's safety compliance regulatory system and the 2021 CRA recall,²⁷ and the resulting dangers to consumers.²⁸ Part III argues that Michigan should standardize testing procedures and adopt additional recall procedures to make its regulatory regime more effective,²⁹ and briefly discusses the impediments to federal regulation and a possible path forward.³⁰ Part IV concludes.³¹

II. BACKGROUND

A. Marijuana's Illegal Status on the Federal Level

1. The Federal Approach to Cannabis

Despite the growing number of states where medicinal and recreational marijuana is legal on the state level,³² it remains illegal as a Schedule I drug under the federal Controlled Substances Act (CSA).³³ As defined by the Act, Schedule I drugs have a high potential for abuse and no currently accepted medical use in the United States.³⁴ Such a

24. *See infra* Part III.

25. *Id.*

26. *See infra* Part II.A–B.

27. *See infra* Part II.C.

28. *See infra* Part II.D–E.

29. *See infra* Part III.A–B.

30. *See infra* Part III.C.

31. *See infra* Part IV.

32. *Where Marijuana Is Legal in the United States*, MJBIZDAILY, <https://mjbizdaily.com/map-of-us-marijuana-legalization-by-state/> [https://perma.cc/FUG4-5ULS].

33. 21 U.S.C. § 812(c), Schedule I(c)(10).

34. 21 U.S.C. § 812(b)(1)(A)–(C); *see also Drug Scheduling*, U.S. DRUG ENF'T ADMIN., <https://www.dea.gov/drug-information/drug-scheduling> [https://perma.cc/2GPS-DZRV].

classification puts marijuana in the same Schedule as heroin,³⁵ LSD,³⁶ and psilocybin.³⁷ It also puts marijuana at a *higher* Schedule than other potent drugs, such as opium³⁸ and cocaine.³⁹ This classification stands in stark contrast to the sweeping marijuana legalizations occurring at the state level, and the current cultural conception of marijuana as a medicinal or otherwise harmless substance.⁴⁰

In deference to the states that have legalized marijuana, however, the Department of Justice has mostly taken a hands-off approach to marijuana enforcement.⁴¹ In October 2009, Attorney General David W. Ogden directed U.S. attorneys in states where marijuana is legal not to spend investigative or prosecutorial resources on individuals whose actions are in “clear and unambiguous compliance” with those states’ marijuana laws.⁴² Later, in 2013, Attorney General James M. Cole released a memorandum that outlined a list of certain enforcement priorities related to marijuana but otherwise advised U.S. attorneys not to spend investigative or prosecutorial resources on lower-level or localized activity.⁴³

During the Trump administration, however, Attorney General Jeff Sessions rescinded this prior guidance about marijuana enforcement from the past Attorneys General.⁴⁴ Instead, he stated that U.S. attorneys should weigh all relevant considerations when deciding to prosecute marijuana crimes, as they do with all other crimes.⁴⁵ Yet Congress responded by passing the Rohrabacher-Blumenauer Amendment—an appropriations bill rider that prohibits the DOJ from using congressionally-appropriated funds to prevent states from implementing their own laws regarding the

35. 21 U.S.C. § 812(c), Schedule I(b)(10).

36. *Id.* Schedule I(c)(9).

37. *Id.* Schedule I(c)(15).

38. *Id.* Schedule II(a)(1).

39. *Id.* Schedule II(a)(4).

40. Moreno, *supra* note 5, at 405–08.

41. *See, e.g.,* LaBruyere & Veazey, *supra* note 9.

42. Memorandum from U.S. Deputy Att’y Gen. David W. Ogden on Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana (Oct. 19, 2009), <https://www.justice.gov/sites/default/files/opa/legacy/2009/10/19/medical-marijuana.pdf> [<https://perma.cc/A43T-BCDD>].

43. Memorandum from U.S. Deputy Att’y Gen. James M. Cole on Guidance Regarding Marijuana Enforcement to All United States Attorneys (Aug. 29, 2013), <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> [<https://perma.cc/X3FQ-XZZC>].

44. Memorandum from U.S. Att’y Gen. Jefferson B. Sessions on Marijuana Enforcement to All United States Attorneys (Jan. 4, 2018), <https://www.justice.gov/opa/press-release/file/1022196/download> [<https://perma.cc/FBZ2-UETU>].

45. *Id.*

use, distribution, possession, or cultivation of medical marijuana.⁴⁶ Congress has consistently reapproved this bill rider.⁴⁷

2. *The Consequences of the Federal Approach*

Notwithstanding tacit federal acceptance of state legalization of marijuana, its illegality on the federal level still poses obstacles.⁴⁸ One significant consequence of marijuana's federal illegality is the lack of research about its health effects, both good and bad.⁴⁹ Because of its Schedule I status, research on marijuana is strictly regulated, and the federal government severely limits the ability to acquire or provide cannabis for studies investigating possible therapeutic or harmful effects.⁵⁰ Researchers seeking to conduct clinical trials on cannabis must file an Investigational New Drug application with the Food and Drug Administration (FDA), obtain a Schedule I license from the Drug Enforcement Administration (DEA), and obtain approval from the National Institute on Drug Abuse (NIDA).⁵¹ Until recently, only cannabis grown at the University of Mississippi under a NIDA contract with DEA approval could be used in clinical research.⁵² This only changed in 2021 when the DEA began issuing licenses to grow research-grade marijuana to other growers.⁵³

Due to these historical and continuing restrictions on conducting marijuana research, "cannabis policy has raced ahead of cannabis

46. O'Connor & Lietzan, *supra* note 11, at 857.

47. *Id.*; Consolidated Appropriations Act, Pub. L. No. 117-103, § 531, 136 Stat. 49, 150–51 (2022).

48. See Aubree L. Walton et al., *Cultivating Evidence-Based Pathways for Cannabis Product Development: Implications for Consumer Protection*, 57 AM. BUS. L.J. 773, 775–76 (2020).

49. Moreno, *supra* note 5, at 428–29.

50. Charles W. Webb & Sandra M. Webb, *Therapeutic Benefits of Cannabis: A Patient Survey*, 73 HAW. J. PUB. HEALTH 109, 109 (2014).

51. *Cannabis and Cannabinoids (PDQ)—Health Professional Version*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/treatment/cam/hp/cannabis-pdq#cit/section_2.2 [https://perma.cc/RMU9-V925].

52. Some researchers have criticized the marijuana grown at the University of Mississippi as too low in potency to be effective to research marijuana's public health effects, given that the marijuana being consumed by medicinal and recreational users consists of stronger and more variable strains. See Tom Hesse, *Weak Weed and Red Tape: Marijuana Research Is Slow Going*, CHRON. OF HIGHER EDUC. (Feb. 28, 2017), <https://www.chronicle.com/article/weak-weed-and-red-tape-marijuana-research-is-slow-going/> [https://perma.cc/6QFV-Z8XZ]. See also O'Connor & Lietzan, *supra* note 11, at 849.

53. *DEA Awards Seventh Cannabis Cultivation License for Research*, MJBIZDAILY (Aug. 19, 2022), <https://mjbizdaily.com/dea-awards-seventh-cannabis-cultivation-license-for-research/> [https://perma.cc/R9PB-HCFX].

science.”⁵⁴ Cannabis has become ubiquitous in most of the United States, yet current scientific knowledge lacks critical information about short and long-term brain effects (especially to the developing brain), respiratory and cardiac implications, fertility, safe pregnancy, and breastfeeding concerns, and more.⁵⁵ Furthermore, because the federal government has taken a hands-off approach to state legalization of marijuana, federal agencies that protect the health and safety of consumers have not been involved in ensuring that cannabis legalized under state law is safe or effective.⁵⁶ The FDA, for instance, has had little oversight over the marijuana produced and consumed at the state level.⁵⁷ The FDA derives its authority from the Commerce Clause of the United States Constitution,⁵⁸ which is typically interpreted expansively.⁵⁹ This authority includes promulgating regulations on food, drugs, and cosmetics⁶⁰ and conducting examinations and investigations on businesses producing these items.⁶¹ However, the FDA has rarely used its authority to interfere with legal cannabis products in states.⁶² And because of marijuana’s Schedule I status, the FDA has not approved any non-purified cannabis plant products for medical or recreational use.⁶³

The result is that the cannabis being sold and consumed at the state level does not undergo the rigors of FDA regulations for drugs, food

54. Paul J. Larkin, Jr., *Cannabis Capitalism*, 69 BUFF. L. REV. 215, 217 (2021) (quoting Archie Bleyer & Brian Barnes, Comment & Response, *Opioid Death Rate Acceleration in Jurisdictions Legalizing Marijuana Use*, 178 JAMA INTERNAL MED. 1280 (2018)).

55. Moreno, *supra* note 5, at 411.

56. See Lindblom, *supra* note 10, at 193–94 (discussing how the FDA does not regulate cannabis to ensure its safety and efficacy); see also Nate Seltenrich, *Into the Weeds: Regulating Pesticides in Cannabis*, 127(4) ENV’T HEALTH PERSPS. 1, 2 (2019) (discussing how the EPA does not regulate the use of pesticides on cannabis).

57. Lindblom, *supra* note 10, at 194.

58. U.S. CONST. art. I, § 8, cl. 3.

59. The connection with interstate commerce, and therefore the jurisdiction of the FDA, is presumed to exist under 21 U.S.C. § 379a (2009). See also *Gonzales v. Raich*, 545 U.S. 1, 22 (2005) (holding that the Commerce Clause gives Congress the authority to regulate cannabis that is produced and consumed completely intrastate under federal drug laws).

60. 21 U.S.C. § 371(a).

61. *Id.* § 372(a)(1)(A).

62. Lindblom, *supra* note 10, at 194.

63. Eisenberg & Leiderman, *supra* note 21, at 247–48. The FDA has approved a few drugs that contain *purified* cannabinoids. Specifically, it has approved purified CBD in the drug Epidiolex, and dronabinol (synthetic THC) in the drugs Marinol and Syndros. *FDA and Cannabis: Research and Drug Approval Process*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process#main-content> [<https://perma.cc/N4BY-JRKK>] [hereinafter FDA and Cannabis].

products, or dietary supplements.⁶⁴ Most cannabis would likely be considered a “drug” under the Food, Drug, and Cosmetic Act (FDCA).⁶⁵ The FDCA defines “drug[s]” as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or function of the body.”⁶⁶ Drugs are strictly regulated by the FDA and must undergo stringent clinical testing in multiple phases before making it to the market.⁶⁷ Once a drug reaches the public, the FDA continues to scrutinize its manufacturing process closely.⁶⁸

These measures are in place to ensure that products sold to consumers as medicinal truly have medicinal value, that their benefits outweigh their risks, and that they are manufactured consistently and safely.⁶⁹ As it currently stands, the marketing of cannabis in legal-cannabis states misleads consumers about its safety and efficacy for a variety of ailments.⁷⁰ Scientists have not verified claims of marijuana’s medical benefits⁷¹ and there is a dearth of research on any of its long-term effects, medicinal or not.⁷²

Similarly, given marijuana’s Schedule I status, the Environmental Protection Agency (EPA) has not promulgated any rules or guidelines about which pesticides are safe for use on marijuana crops or what amounts of residues on crops are considered safe for consumption.⁷³ Like all other crops, marijuana is vulnerable to damage by mold and pests, and growers use pesticides and other harsh chemicals to combat them.⁷⁴ The use of pesticides on cannabis poses a unique problem because most research on pesticide toxicity focuses on oral ingestion, whereas marijuana is commonly smoked.⁷⁵ The application of heat (in order to smoke the marijuana) may create pesticide compounds through pyrolysis⁷⁶ with

64. See generally O’Connor & Lietzan, *supra* note 11.

65. See 21 U.S.C. § 321(g)(1); see also O’Connor & Lietzan, *supra* note 11, at 861.

66. 21 U.S.C. § 321(g)(1); see also 21 C.F.R. § 201.128 (2021).

67. O’Connor & Lietzan, *supra* note 11, at 861–84.

68. See *id.* at 863.

69. *Id.* at 861–84.

70. See Moreno, *supra* note 5, at 460–62.

71. Lindblom, *supra* note 10, at 199.

72. See Moreno, *supra* note 5, at 411.

73. Seltenrich, *supra* note 56, at 2.

74. RODGER VOELKER & MOWGLI HOLMES, CANNABIS SAFETY INST., PESTICIDE USE ON CANNABIS 3 (2014), <https://www.thefarmer.com/attachments/csi-pesticides-white-paper-pdf.632208/> [<https://perma.cc/J57Z-FDAY>].

75. *Id.* at 3.

76. “Pyrolysis” is a chemical reaction created through the application of heat. See Sarah E. Boslaugh, *pyrolysis*, ENCYC. BRITANNICA (Dec. 11, 2023), <https://www.britannica.com/science/pyrolysis> [<https://perma.cc/5BFE-LJCL>].

unknown toxicities.⁷⁷ As such, inhaled chemicals tend to be present at higher levels than those ingested orally.⁷⁸

The EPA sets tolerances and limits for pesticide usage on crops based on thorough data specific to each crop, each application site, and each pesticide compound.⁷⁹ Pesticide manufacturers must apply to the EPA to register a new pesticide and supply intensive data about its use, safety, and formula.⁸⁰ If the EPA approves the pesticide, it strictly regulates the product's use according to its scientific findings on the product's applicability and safety.⁸¹ No such data-driven guidance exists for the cannabis industry.⁸² The result is that states have enacted highly variable and “arbitrary” regulations for pesticide usage on cannabis that are not backed by science.⁸³ Again, the way cannabis is marketed in legal-cannabis states misleads consumers to believe that the products they purchase have the safety guarantees against harsh, potentially carcinogenic chemicals that they are accustomed to having with other products.⁸⁴

B. The History of Michigan's Marijuana Regulatory Regime

In 2016, Michigan enacted the Medical Marihuana Facilities Licensing Act (MMFLA) in what may now be seen as a stepping stone to full legalization two years later.⁸⁵ The MMFLA created a licensing and regulatory framework for growers, processors, safety compliance facilities, secure transporters, and dispensaries in the business of medical marijuana.⁸⁶ Then, in 2018, Michigan voters decided by ballot initiative to legalize the recreational use and sale of marijuana in the Michigan Regulation and Taxation of Marihuana Act (MRTMA), which retained much of the same framework established under the MMFLA.⁸⁷ After the enactment of MRTMA in 2019, Governor Gretchen Whitmer created the Cannabis Regulatory Agency (CRA)—at the time operating under the

77. VOELKER & HOLMES, *supra* note 74, at 3.

78. *Id.*

79. *Id.*

80. Jenna Hardisty Bishop, Note, *Weeding the Garden of Pesticide Regulation: When the Marijuana Industry Goes Unchecked*, 65 DRAKE L. REV. 223, 227–28 (2017).

81. *Id.* at 228.

82. Seltenrich, *supra* note 56, at 2.

83. *Id.*; see also Hardisty Bishop, *supra* note 80, at 240–41.

84. Seltenrich, *supra* note 56, at 2.

85. MICH. COMP. LAWS § 333.27101 *et seq.* (2016); see MICH. COMP. LAWS § 333.27951 *et seq.* (2018).

86. MICH. COMP. LAWS § 333.27102(ff)(i)–(v) (2021).

87. Compare MICH. COMP. LAWS § 333.27951 *et seq.* (2018), with MICH. COMP. LAWS § 333.27101 *et seq.* (2016).

name Marijuana Regulatory Agency⁸⁸—which oversees all the licensing and regulatory affairs of the cannabis industry in Michigan.⁸⁹ It is the CRA that promulgates rules regarding safety standards in the cultivation, testing, and sale of marijuana in the state.⁹⁰

Cannabis testing laboratories, known under MMFLA and MRTMA as safety compliance facilities, are the facilities where all retail marijuana is tested for potency and other contaminants before making it to the market.⁹¹ The CRA's rules give labs leeway to determine the testing procedures they use on the cannabis they test.⁹² Specifically, labs are free to choose any methods to test product, so long as those methods are based on published, peer-reviewed techniques that have been validated by an independent third party and verified by the Association of Analytical Collaboration (AOAC) International.⁹³ In addition, laboratories have the option, but not the requirement, to become certified in Good Manufacturing Practices (GMP) and Good Agricultural and Collecting Practices (GACP).⁹⁴

Labs are tasked with testing marijuana for its potency.⁹⁵ In addition to testing the potency of tetrahydrocannabinol (THC),⁹⁶ the CRA requires labs to test periodically for tetrahydrocannabinolic acid (THC-A), cannabidiol (CBD), cannabidiolic acid (CBD-A), and additional cannabinoids as specified by the CRA.⁹⁷ The potency of these psychoactive constituents of cannabis determines the character of the “high” the user will experience.⁹⁸ Test results for cannabinoids,

88. See Exec. Order No. 2022-1; MICH. COMP. LAWS § 333.27002 (2022) (renaming the “Marijuana Regulatory Agency” the “Cannabis Regulatory Agency”). For clarity of the reader, this Note will refer to the agency as the Cannabis Regulatory Agency or CRA.

89. MICH. COMP. LAWS § 333.27001 (2019) (vesting the CRA with authority over all cannabis affairs in the state).

90. *Id.*

91. MICH. COMP. LAWS § 333.27953(r) (2021).

92. MICH. ADMIN. CODE r. 420.305(2) (2021).

93. *Id.*

94. *Id.* (4)–(5).

95. MICH. COMP. LAWS § 333.27953(r) (2021).

96. THC is the main cannabinoid in marijuana that produces psychoactive effects. U.S. DRUG ENF'T ADMIN., DRUG FACT SHEET: MARIJUANA/CANNABIS (2020), https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf [<https://perma.cc/BA9P-H4FA>].

97. MICH. ADMIN. CODE r. 420.305(3)(a)(i)–(iii) (2022). These additional chemical substances, like THC, are also cannabinoids and may contribute to the drug effects a user experiences. See Emma Stone, *What is a Cannabinoid?*, LEAFLY (Feb. 17, 2022), <https://www.leafly.com/news/cannabis-101/what-is-cannabinoid> [<https://perma.cc/6R9B-8U5D>].

98. *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, NAT'L INSTS. OF HEALTH (Nov. 2019), <https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know> [<https://perma.cc/Z5H9-HR6T>]; Roberts, *Wild Wild West*, *supra* note 14.

particularly for THC, are the biggest determinant of the market price for marijuana or a marijuana-derived product.⁹⁹ The CRA limits how much of these psychoactive chemicals may be present in a batch sold on the market.¹⁰⁰

More than just testing for potency, these labs are on the front lines of ensuring that the cannabis sold in Michigan is safe for consumption.¹⁰¹ Michigan requires safety compliance facilities to test for foreign matter, such as organic and inorganic material; to conduct microbial screening for yeasts, molds, and pathogens; to test for chemical residues of certain pesticides, residual solvents, and heavy metals; to check for water activity; and occasionally to test for mycotoxins and other target analytes as prescribed by the CRA.¹⁰² The CRA sets limits for the amounts of these substances and foreign materials that may be found in cannabis before it deems the cannabis unsafe for sale.¹⁰³

Of course, the CRA has the authority to enforce the rules it promulgates.¹⁰⁴ It may perform investigations, inspections, and may take disciplinary action where it deems necessary.¹⁰⁵ It may also place administrative holds on marijuana products, issue safety warnings, and recall marijuana products.¹⁰⁶

C. Are Michigan's Safety Measures Enough?

A growing concern in virtually all legal cannabis states is that some cannabis laboratories inflate THC potency results, report inaccurate contamination profiles, or otherwise manipulate data on the cannabis they test.¹⁰⁷ This phenomenon is largely prompted by what is known as “lab

99. Gus Burns, *It's Not Just THC, Marijuana Labs Are Testing for Metals, Pesticides, and Even Insects*, MLIVE (Mar. 9, 2022), <https://www.mlive.com/public-interest/2022/03/its-not-just-the-marijuana-labs-are-testing-for-metals-pesticides-and-even-insects.html> [https://perma.cc/6J6B-BFB3] [hereinafter Burns, *It's Not Just THC*].

100. MICH. CANNABIS REGUL. AGENCY, SAMPLING AND TESTING TECHNICAL GUIDANCE FOR MARIJUANA PRODUCTS VERSION 5.1 (2022), https://www.michigan.gov/cra/-/media/Project/Websites/cra/bulletin/5Technical/Sampling_and_Testing_Technical_Guidance_for_Marijuana_Products_694124_7.pdf [https://perma.cc/2YBX-RPVP] [hereinafter CANNABIS REGUL. AGENCY, SAMPLING AND TESTING].

101. See MICH. COMP. LAWS § 333.27953(p) (2023) (defining a safety compliance facility as the facility at which marijuana is tested for contaminants).

102. MICH. ADMIN. CODE r. 420.305(b)–(i) (2022); Burns, *It's Not Just THC*, *supra* note 99.

103. See CANNABIS REGUL. AGENCY, SAMPLING AND TESTING, *supra* note 100.

104. MICH. COMP. LAWS § 333.27957 (2018).

105. *Id.*

106. MICH. ADMIN. CODE r. 420.502(2) (2022).

107. David Downs, *40% THC Flower?! How Lab Shopping and THC Inflation Cheat Cannabis Consumers*, LEAFLY (Jan. 26, 2021), <https://www.leafly.com/news/strains->

shopping.”¹⁰⁸ Lab shopping is when cannabis producers send out cannabis samples to several labs for testing, and when they receive results back, they choose to do business with the lab that returned the most financially favorable test results.¹⁰⁹ This often involves results indicating a very high THC content, since THC content is the biggest driver of cannabis sales.¹¹⁰ As a result, in order to compete and ultimately stay in business, lab companies face pressure to produce satisfactory test results for their clients.¹¹¹

Michigan’s cannabis testing companies are not exempt from this pressure.¹¹² Public concern has been developing about the prevalence of lab shopping in the state and the deleterious effect it has on the integrity of the industry.¹¹³ One former Michigan cannabis lab owner decided to close her lab in the face of the current business climate, stating that “growers and processors must shop for testing laboratories that give them the highest THC numbers. This causes accurate labs to lose their business and patients in Michigan to be at risk.”¹¹⁴ Ultimately, she stated that she refuses to compete in an industry “that only cares about money going into its pocket.”¹¹⁵ Another Michigan cannabis lab owner called the problem of lab shopping and test result manipulation an “epidemic” that needs a good regulatory system to check and stop it.¹¹⁶ Yet, industry insiders are left wondering why “the CRA is struggling to enforce its own rules.”¹¹⁷

In 2021, these growing concerns about the safety of cannabis lab testing in Michigan came to the forefront in the controversial *Viridis*

products/lab-shopping-the-inflation-marijuana-2019-leafly-review
[<https://perma.cc/4GWU-V69J>].

108. Roberts, *Wild Wild West*, *supra* note 14.

109. Gus Burns, *Super Potent Weed Spurs Distrust in Michigan Marijuana Industry*, MLIVE (June 22, 2022), <https://www.mlive.com/public-interest/2022/06/super-potent-weed-spurs-distrust-in-michigan-marijuana-industry.html> [<https://perma.cc/ZHL9-VFNS>] [hereinafter Burns, *Super Potent Weed*].

110. *Id.*

111. Kate Carlson, ‘Lab Shopping’ Accusations Create Tough Environment For Cannabis Testing Facilities, MIBIZ (Aug. 14, 2022), <https://mibiz.com/sections/economic-development/lab-shopping-accusations-create-tough-environment-for-cannabis-testing-facilities> [<https://perma.cc/4FCR-H4A6>].

112. See Roberts, *Wild Wild West*, *supra* note 14; Burns, *How Safe?*, *supra* note 19.

113. See Roberts, *Wild Wild West*, *supra* note 14; Burns, *How Safe?*, *supra* note 19.

114. Roberts, *Wild Wild West*, *supra* note 14 (statement of Linda Palmatier, owner of The Spott Laboratory in Kalamazoo).

115. *Id.*

116. Burns, *Super Potent Weed*, *supra* note 109 (statement of Lev Spivak-Birndorf, founder and chief science officer for PSI Labs in Ann Arbor).

117. Carlson, *supra* note 111.

Laboratories case.¹¹⁸ Viridis Laboratories and Viridis North are separate LLCs licensed by the state of Michigan to perform safety compliance testing, with the former in Lansing and the latter in Bay City.¹¹⁹ The labs were highly competitive, accounting for 60–70% of the market share of cannabis testing in the state.¹²⁰ In November 2020, the CRA began investigating the companies’ “Viridis Method” of potency testing after receiving complaints that Viridis was inflating THC numbers.¹²¹ The CRA audits THC potency test results in excess of 28%, and Viridis-tested cannabis achieved those numbers seven times more frequently than other labs in the state.¹²² Notably, however, the CRA had previously approved Viridis’ method of THC testing.¹²³

In October 2021, about a year after the initial investigation on THC potency inaccuracies began, the CRA informed Viridis that it would be conducting on-site investigations at the Viridis facilities.¹²⁴ In addition to the on-site investigations, the CRA also had other private labs re-test random samples of cannabis products originally tested at Viridis Laboratories; however, the CRA failed to include any samples from the Viridis North facility in the random re-tests.¹²⁵ Thereafter, the CRA posted a bulletin formally recalling nearly all of the products tested by both companies over a span of three months.¹²⁶ This recall affected 64,000 pounds of marijuana, most already on the shelves of dispensaries, worth over \$229 million.¹²⁷

Despite the apparent gravity of the situation, the CRA surprisingly did not make the reasoning for the recall clear.¹²⁸ The recall bulletin simply indicated that the MRA had identified inaccurate or unreliable results of the products tested by Viridis Labs and Viridis North.¹²⁹ The CRA had no

118. *Viridis Lab’s, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024 (Mich. Ct. Cl. Dec. 3, 2021).

119. *Id.* at *1.

120. Roberts, *Wild Wild West*, *supra* note 14.

121. Gus Burns, *Super Potent Weed*, *supra* note 109.

122. *Id.*

123. *Viridis Lab’s, LLC*, 2021 WL 8014024, at *1.

124. *Id.*

125. *Id.* at *5.

126. *Id.* at *1.

127. Burns, *\$229 Million Marijuana Recall*, *supra* note 15.

128. See MICH. CANNABIS REGUL. AGENCY, PUBLIC HEALTH AND SAFETY BULLETIN: NOTIFICATION OF MARIJUANA PRODUCT RECALL (2021), https://www.michigan.gov/cra/-/media/Project/Websites/cra/bulletin/1Public-Health-an-Safety-Advisory/111821_Notification_of_Marijuana_Product_Recall_Viridis_Bulletin_Update_741566_7.pdf [<https://perma.cc/P6WX-E9F5>] [hereinafter CANNABIS REGUL. AGENCY, RECALL].

129. *Id.*

internal documents outlining specific reasons for the recall.¹³⁰ Additionally, the CRA had no published or internal standards for when it should issue recalls.¹³¹ Later, the Manager of the Scientific and Legal Enforcement Division of the CRA, though not involved in the decision to implement the recall, testified that she was under the impression that the recall was based on ten failed random sample re-tests for aspergillus and that the labs lacked incubation logs for the cannabis they tested.¹³² Aspergillus is a common fungus that grows on marijuana, which can cause life-threatening aspergillosis, especially in immunocompromised individuals.¹³³ Incubation logs are typically used when marijuana is put in an incubator to test for yeasts, molds, and other pathogens.¹³⁴ Without an incubation log, it is harder to track when a sample is placed in an incubator, and it may be more likely to pass testing if it has not been stored for the full incubation period.¹³⁵

Against the potentially devastating recall and the lack of coherent reasons that the CRA provided, both Viridis labs sued the CRA in the Michigan Court of Claims.¹³⁶ The labs pursued eleven causes of action, with one being an injunction against the CRA prohibiting enforcement of the recall.¹³⁷ To support their request for an injunction, the labs argued that the recall was in violation of Michigan's Administrative Procedures Act

130. In the eventual court opinion, the judge notes that the CRA did not have any internal documents about the Viridis recall. *Viridis Lab 'ys, LLC*, 2021 WL 8014024, at *1–2.

131. In the eventual court opinion, the judge notes that a CRA official testified that the agency has no internal guidelines to govern recalls. *Id.* at *5 n.10.

132. *Id.* at *2.

133. Yousef Gargani et al., *Too Many Mouldy Joints—Marijuana and Chronic Pulmonary Aspergillosis*, 3 MEDITERRANEAN J. OF HEMATOLOGY AND INFECTIOUS DISEASES (2011).

134. Gus Burns, *Michigan Lab Fights Back in Court After Becoming Target of \$230 Million Marijuana Recall*, MLIVE (Dec. 2, 2021), <https://www.mlive.com/public-interest/2021/12/michigan-lab-fights-back-in-court-after-becoming-target-of-230-million-marijuana-recall.html> [<https://perma.cc/DZQ6-HLR5>] [hereinafter Burns, *Michigan Lab Fights Back*].

135. *Id.*

136. See Complaint, *Viridis Lab 'ys, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024 (Mich. Ct. Cl. Dec. 3, 2021).

137. *Id.* at 29–60 (alleging due process violations, equal protection violations, tortious interference with business relationships, abuse of process, civil conspiracy, and seeking various types of declaratory and injunctive relief). Many of these claims were later dismissed either through the parties' agreement or by the court. See *Viridis Lab 'ys, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2022 WL 1055238, at *3–7 (Mich. Ct. Cl. Feb. 3, 2022). The only claim that the court upheld was a substantive due process violation as to Viridis North, which allowed the court to issue a permanent injunction against the CRA from enforcing the Viridis North recall. *Id.* at *5–6.

(APA) and was arbitrarily applied to Viridis North.¹³⁸ First, they argued that any recall instituted under these circumstances, where the agency has no published or internal standards guiding when it requires a recall, is tantamount to promulgating a new rule outside of required APA procedures.¹³⁹ Second, they argued that the recall against Viridis North was arbitrary, because no product from its facility was re-tested, yet failed re-tests for aspergillus were one of the reasons given for the recall.¹⁴⁰ The only other reason for the recall was the companies' lack of incubation logs, but neither a statute nor rule required incubation logs.¹⁴¹

On the first argument, the court determined that although no guidelines exist for when recalls are necessary, the CRA has broad power to issue recalls under state law.¹⁴² The court deferred to the CRA's judgment that one of the purported reasons for the recall, failed re-testing for aspergillus, would be a sufficient justification under Michigan's APA and is not equivalent to a new rule.¹⁴³ On the second argument, however, the court held that the recall of Viridis North's products was arbitrary for two reasons.¹⁴⁴ First, because none of the random samples that the CRA re-tested came from Viridis North.¹⁴⁵ Second, because the lack of incubation logs alone was *not* a sufficient reason to sustain a recall against Viridis North.¹⁴⁶ No statute or rule required companies to use incubation logs, and the CRA had previously approved Viridis' standard operating procedures that specifically lacked the use of incubation logs.¹⁴⁷ Ultimately, despite the rarity with which courts issue preliminary injunctions against state agencies, the court issued a preliminary injunction against CRA enforcement of the Viridis North recall because the recall was arbitrary.¹⁴⁸

138. *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024, at *4 (Mich. Ct. Cl. Dec. 3, 2021).

139. *Id.* Under the Michigan APA, agencies must give the public notice of a proposed rule and the opportunity to comment before promulgating it. MICH. COMP. LAWS § 24.241 (2018). Any "rule" promulgated without such process would be unlawful. *Id.*

140. *Viridis Lab's, LLC*, 2021 WL 8014024, at *4. Under the Michigan APA, one of the reasons a court can overrule an agency decision is if it is "arbitrary, capricious, or clearly an abuse or unwarranted exercise of discretion." MICH. COMP. LAWS § 24.306(e) (1969).

141. *Viridis Lab's, LLC*, 2021 WL 8014024, at *5.

142. *Id.*; see MICH. ADMIN. CODE r. 420.502(2) (2020).

143. *Viridis Lab's, LLC*, 2021 WL 8014024, at *5.

144. *Id.* at *5–6.

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.* at *6, *7.

After the court granted the preliminary injunction for Viridis North, the CRA re-tested the product from Viridis North and found that about 26% of the product failed re-testing for microbials—including aspergillus.¹⁴⁹ In light of these findings, the CRA filed a motion to reconsider the injunction in the Court of Claims, seeking to reinstate the recall against Viridis North.¹⁵⁰ The court denied this motion, noting that the CRA based its motion on evidence gathered *after* the original recall.¹⁵¹ Thus, the court required the CRA to send the Viridis North cannabis back to the market.¹⁵² Two months later, the court granted a permanent injunction in favor of Viridis North for the same reasons as given for the preliminary injunction.¹⁵³

Notably, there were eighteen documented adverse health complaints from consumers potentially (but not definitively) linked to the recalled cannabis from both labs, including emergency visits, increased seizure activity, and allergic reactions after using the product.¹⁵⁴

D. Implications for Consumers

The Viridis cannabis recall and the subsequent court case between Viridis Labs and the CRA sent shockwaves through Michigan's budding cannabis industry, causing industry insiders and outsiders alike to question the reliability and safety of cannabis on the market.¹⁵⁵ With cannabis producers free to pick and choose the labs that give them the most beneficial test results, labs free to test products their *own* way, and unclear

149. Roberts, *Moldy Marijuana*, *supra* note 18.

150. *Viridis Lab's, LLC*, 2021 WL 8014022, at *1.

151. *Id.* At least on the federal level, a court may not accept an agency's "post hoc rationalizations" for agency action; the justification for an agency action must be upheld on the same basis articulated in the agency's original order. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168–69 (1962) (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196 (1947)). Michigan courts have not squarely addressed this issue. *See, e.g., Mich. Farm Bureau v. Dep't of Env't Quality*, 292 Mich. App. 106, 145, 807 N.W. 866, 892 (2011) ("It is true, *at least in the federal context*, that an agency must typically defend its actions on the basis of justifications contained in the administrative record, rather than post hoc rationalizations." (emphasis added)). However, the Michigan APA does require that judicial review be confined to the record. *See MICH. COMP. LAWS* § 24.304(3) (1969).

152. Roberts, *Moldy Marijuana*, *supra* note 18.

153. *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2022 WL 1055238, at *7 (Mich. Ct. Cl. Feb. 3, 2022).

154. Gus Burns, *Read 18 Health Complaints Linked to Massive Michigan Marijuana Recall*, MLIVE (Dec. 21, 2021), <https://www.mlive.com/politics/2021/12/read-18-health-complaints-linked-to-massive-michigan-marijuana-recall.html> [https://perma.cc/V3K4-5D5R].

155. Roberts, *Wild Wild West*, *supra* note 14.

CRA rules governing the whole industry, the most pressing concern is consumer safety.¹⁵⁶ As mentioned, laboratories do more than simply quantify the THC content of cannabis—they test for molds, pesticides, residual solvents, heavy metals, and more.¹⁵⁷ There are abounding health implications for consumers of cannabis tainted by these substances,¹⁵⁸ and as such, a cohesive and strong regulatory scheme for testing cannabis is necessary.

By design, pesticides are harmful to living creatures, including humans.¹⁵⁹ There is little research on which pesticides are safe for use on cannabis,¹⁶⁰ and certain pesticides reaching consumers could result in long-term harm. For example, the fungicide myclobutanil was the subject of a class action lawsuit in Colorado, when cannabis consumers discovered that a local dispensary had sold marijuana treated with it.¹⁶¹ Myclobutanil breaks down into hydrogen cyanide when heated (such as when smoked) and is toxic to humans.¹⁶² In another example, studies have reported the presence of the fungicide imazalil on cannabis crops.¹⁶³ Imazalil is a known endocrine disruptor in mammals and can cause genetic mutations that carry into subsequent generations.¹⁶⁴ Notably, THC concentrates exacerbate dangers from pesticide contamination because the THC concentration and extraction process also concentrates and extracts pesticides.¹⁶⁵ One study showed that THC concentration techniques concentrate pesticides at a rate of about ten times the amount originally on the cannabis flower.¹⁶⁶

Similarly, some residual solvents—which cannabis companies use to extract THC, CBD, and other therapeutic compounds from cannabis flower in order to concentrate them into oil or wax—can be harmful to human health if individuals consume them.¹⁶⁷ Common solvents used or

156. *Id.*

157. MICH. ADMIN. CODE r. 420.305(b)–(i) (2022).

158. *See infra* notes 159–92 and accompanying text.

159. Steven B. Perlmutter, *High Times Ahead: Products Liability in Medical Marijuana*, 29 HEALTH MATRIX: J. L.-MED. 225, 257 (2019).

160. Seltnerich, *supra* note 56, at 4.

161. John Campbell & Sahib Singh, *Budding Torts: Forecasting Emerging Tort Liability in the Cannabis Industry*, 30 LOY. CONSUMER L. REV. 338, 357–58 (2018).

162. *Id.*

163. Zackary Montoya et al., *Cannabis Contaminants Limit Pharmacological Use of Cannabidiol*, 11 FRONTIERS PHARMACOLOGY 1, 6–7 (2020).

164. *Id.*

165. VOELKER & HOLMES, *supra* note 74, at 10.

166. *Id.*

167. Aimee O’Driscoll, *When You Should Worry About Leftover Solvents in Cannabis Oil*, LEAFLY (Jan. 29, 2020), <https://www.leafly.com/news/science-tech/when-you-should-worry-about-leftover-solvents-cannabis-oil> [<https://perma.cc/69GV-G9FM>].

produced in the extraction process include ethanol, methanol, benzene, butane, propane, xylenes, and more.¹⁶⁸ Depending on the solvents present and the way a person consumes the cannabis, the cannabis may affect users in different ways.¹⁶⁹ For example, long-term exposure to butane may cause lung injury;¹⁷⁰ benzene is a known carcinogen and can cause dizziness, headache, rapid heartbeat, and confusion in the moments after inhalation;¹⁷¹ and xylenes can cause nausea, headache, dizziness, and vomiting.¹⁷²

Likewise, heavy metals present in cannabis plants can cause harm to humans.¹⁷³ Cannabis plants are phytoremediators, meaning that they absorb heavy metals from soil.¹⁷⁴ Heavy metals such as lead, mercury, cadmium, and chromium are known carcinogens, and they can build up in the body, causing damage to enzymes, proteins, lipids, and nucleic acids, and leading to neurological deterioration.¹⁷⁵ In one incident in Germany, cannabis users who consumed cannabis contaminated with high levels of lead developed severe symptoms such as nausea, acute colic, peripheral neuropathy, loss of appetite and weight, and chronic fatigue.¹⁷⁶ However, children are at the greatest risk for harm from cannabis with heavy metals, since heavy metals tend to affect them more severely than adults.¹⁷⁷ This includes children with epilepsy who use CBD to treat their symptoms.¹⁷⁸

Moreover, fungi and bacteria found on cannabis also present human health hazards.¹⁷⁹ Those with weakened immune systems are highly vulnerable to infections from consuming cannabis contaminated with

168. CANNABIS REGUL. AGENCY, SAMPLING AND TESTING, *supra* note 100.

169. O'Driscoll, *supra* note 167.

170. Ryan P. Anderson & Katie Zechar, *Lung Injury From Inhaling Butane Hash Oil Mimics Pneumonia*, 26 RESPIRATORY MED. CASE REPS. 171 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6327978/> [<https://perma.cc/ZHF2-9Q57>].

171. *Facts About Benzene*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://emergency.cdc.gov/agent/benzene/basics/facts.asp> [<https://perma.cc/Y8X6-8ZS2>].

172. O'Driscoll, *supra* note 167.

173. Sarah LaJeunesse, *Cannabis May Contain Heavy Metals and Affect Consumer Health, Study Finds*, PENN STATE UNIV. (Dec. 14, 2021), <https://www.psu.edu/news/research/story/cannabis-may-contain-heavy-metals-and-affect-consumer-health-study-finds/> [<https://perma.cc/DW7Q-GBXX>].

174. *Id.*

175. *Id.*

176. Montoya et al., *supra* note 163, at 5.

177. *Id.*; see also Muwaffak Al Osman et al., *Exposure Routes and Health Effects of Heavy Metals on Children*, 32 BIOMETALS 563 (2019) (describing the effect of various types of heavy metal exposure on child development and health).

178. Al Osman et al., *supra* note 177.

179. Vladimir Vujanovic et al., *Scientific Prospects for Cannabis-Microbiome Research to Ensure Quality and Safety of Products*, 8 MICROORGANISMS 290, 293 (2020).

these substances.¹⁸⁰ *Aspergillus*, for example, is a common mold that grows on cannabis.¹⁸¹ *Aspergillus* can result in aspergillosis, a lung infection that can prove fatal, especially for immunocompromised persons.¹⁸² There have been several reported cases of immunocompromised persons—such as those undergoing chemotherapy—becoming sick or dying from aspergillosis after using contaminated marijuana.¹⁸³ Likewise, studies have shown that harmful bacterial species like *E. coli*, salmonella, and clostridium (which causes botulism) can proliferate on cannabis, whose symptoms range from diarrhea, vomiting, fever, paralysis, and even death.¹⁸⁴ Concerningly, oncologists frequently recommend their patients use marijuana to treat nausea associated with chemotherapy.¹⁸⁵ Immunocompromised persons, however, are not the only potential victims of contaminated marijuana. In one California case, for example, an immune-healthy individual was hospitalized for over three months with *Cryptococcal* meningitis that was linked to a contaminated batch of medical marijuana from her dispensary.¹⁸⁶

Even inaccurate THC and CBD measurements can harm consumers.¹⁸⁷ For example, if safety compliance labs test THC content inaccurately and there is more THC in the cannabis than the consumer expects, they are at risk for increased anxiety, brief psychosis, cardiovascular issues, and gastrointestinal issues as part of the drug effects.¹⁸⁸ These risks increase if the user is new to cannabis.¹⁸⁹ In contrast, if less THC or CBD is present than the consumer expects, the consumer may not experience the effects or medical benefits they paid for.¹⁹⁰ This issue is especially important with medical marijuana, where accurate dosing is imperative.¹⁹¹ For example,

180. *Id.*

181. Montoya et al., *supra* note 163, at 3.

182. Rosa Ruchlemer et al., *Inhaled Medicinal Cannabis and the Immunocompromised Patient*, 23 SUPPORTIVE CARE CANCER 819, 821 (2014) (describing the increased risk of respiratory infections to immunocompromised individuals, such as those with leukemia or undergoing chemotherapy, when they smoke marijuana).

183. Gargani et al., *supra* note 133.

184. Montoya et al., *supra* note 163, at 4.

185. Gargani et al., *supra* note 133.

186. Bryan Shapiro et al., *Cryptococcal Meningitis in a Daily Cannabis Smoker Without Evidence of Immunodeficiency*, BMJ CASE REPS. (Jan. 26, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5787011/> [<https://perma.cc/TS4M-GAC2>].

187. See, e.g., Steve P. Calandrillo & Katelyn Fulton, “High” Standards: The Wave of Marijuana Legalization Sweeping America Ignores the Hidden Risks of Edibles, 80 OHIO ST. L. REV. 201, 236 (2019); see also Perlmutter, *supra* note 159, at 263.

188. Calandrillo & Fulton, *supra* note 187, at 236.

189. *Id.*

190. Perlmutter, *supra* note 159, at 263.

191. See *id.*

if a medical marijuana user has a medical condition such as epilepsy, strains with higher CBD have been shown to be more efficacious than strains with lower CBD.¹⁹² Thus, a user taking CBD for epilepsy may have less protection from seizures if the CBD content of the products they use is lower than what the labels say.¹⁹³

E. Implications for the Industry

Consumers, however, are not the only ones affected by a cannabis industry that lacks adequate regulation; the industry also suffers.¹⁹⁴ Regulatory uncertainty imposes costs on businesses because they cannot shape their behavior around consistent agency action.¹⁹⁵ There are many potential drivers of regulatory unpredictability. Notably, one is the presence of weaknesses in the regulatory rules, such as where there are gaps that allow the agency too much room for discretionary interpretation that businesses cannot predict.¹⁹⁶ An example of a regulatory gap like this is the CRA's lack of guidelines about when or how to institute a recall.¹⁹⁷ Another driver of regulatory unpredictability is lack of transparency, which makes businesses lose trust in the industry.¹⁹⁸ An example of a lack of transparency is the CRA's lack of clear reasoning for the recall against Viridis.¹⁹⁹

Regardless of the reason for regulatory uncertainty, it significantly affects business behavior.²⁰⁰ A business that believes the CRA does not strictly enforce testing rules may be more willing to take risks such as skirting regulatory testing requirements, whereas a business that believes that the CRA acts arbitrarily may not allocate its costs and efforts in the most efficient, profit-maximizing way possible.²⁰¹ Moreover, regulatory

192. *Id.*

193. *Id.*

194. *See, e.g.,* Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency, No. 21-000219-MB, 2021 WL 8014024, at *7 (Mich. Ct. Cl. Dec. 3, 2021) (describing the irreparable harm that would come to Viridis from CRA's recall, along with the ramifications in the industry, before concluding that injunctive relief prohibiting the recall was warranted).

195. Jonathan S. Masur & Jonathan Remy Nash, *Promoting Regulatory Prediction*, 97 IND. L.J. 203, 210 (2022).

196. WORLD BANK, BANGLADESH DEVELOPMENT UPDATE: TOWARDS REGULATORY PREDICTABILITY 29 (Apr. 2019), <https://documents1.worldbank.org/curated/en/269241554408636618/pdf/Bangladesh-Development-Update-Towards-Regulatory-Predictability.pdf> [<https://perma.cc/9N4E-YUZK>].

197. *Viridis Lab's, LLC*, 2021 WL 8014024, at *5.

198. WORLD BANK, *supra* note 196, at 32.

199. *Viridis Lab's, LLC*, 2021 WL 8014024, at *2.

200. Alfred Marcus et al., *Firms, Regulatory Uncertainty, and the Natural Environment*, 54 CAL. MGMT. REV. 5, 5–6 (2011).

201. Masur & Nash, *supra* note 195, at 210.

uncertainty makes potential entrepreneurs and investors less likely to go into business or invest in the first place, thereby hampering the industry's growth.²⁰²

In sum, the *Viridis* case exposed the cracks in Michigan's cannabis testing industry: namely, that the CRA lacks the guidance, control, and consistency for its regulatory actions to withstand legal scrutiny.²⁰³ These regulatory cracks are pressing issues that the industry must address. Consumers exposed to contaminated cannabis can face serious adverse health effects,²⁰⁴ and poorly conceived CRA regulatory actions can cause devastation to individual businesses and even the whole industry.²⁰⁵ As such, the next Part discusses steps the CRA can take to regain legitimacy and regulate in consumers' best interests: standardizing testing procedures²⁰⁶ and promulgating additional recall procedures.²⁰⁷

III. SOLUTIONS FOR PROTECTING CONSUMERS AND THE INDUSTRY

Laboratory testing is the cannabis industry's first line of defense against bodily harms caused by common cannabis impurities.²⁰⁸ As such, it is critical that Michigan develops strong, consistent regulations to rein in the current "wild, wild west" of cannabis testing and put accuracy, safety, and stability over profit in this fledgling industry.²⁰⁹ This section discusses possible changes to the current system that could move the industry toward these aims.

A. Standardize Testing Procedures

The Cannabis Regulatory Agency (CRA) could strengthen the reliability of marijuana safety by standardizing the testing procedures it allows laboratories to use to test cannabis. As it stands now, cannabis testing laboratories are under enormous pressure to produce favorable test results for their clients.²¹⁰ Such pressures are a byproduct of the free market forces in the industry, where the market favors products with high

202. WORLD BANK, *supra* note 196, at 32.

203. *See generally Viridis Lab 'ys, LLC*, 2021 WL 8014024.

204. *See supra* Part II.D.

205. *See supra* Part II.E; *see also Viridis Lab 'ys, LLC*, 2021 WL 8014024, at *6–7 (discussing the possibility of irreparable harm to Viridis from CRA's enforcement action).

206. *See infra* Part III.A.

207. *See infra* Part III.B.

208. *See* MICH. COMP. LAWS § 333.27953(p) (2021) (defining a safety compliance facility as the facility at which marijuana is tested for contaminants).

209. Roberts, *Wild Wild West*, *supra* note 14.

210. *Id.*; NAT'L CANNABIS LAB'Y COUNCIL, STANDARDIZING CANNABIS LAB TESTING NATIONALLY 6 (Andrew Kline et al. eds., 2022).

THC content and start-up laboratories must vie for clients.²¹¹ The fact that cannabis producers, who bear all the costs associated with failed lab tests,²¹² may lab shop to find the lab that consistently provides the “best” results compounds these pressures.²¹³

Effective regulation through testing standardization would alter some of these consequences of “cannabis capitalism.”²¹⁴ By harmonizing testing methodologies, the CRA would make several gains for consumer safety and reducing market volatility. To begin, standardization would shift cannabis producers’ market incentive from finding a laboratory that produces the most favorable results to, instead, growing the highest quality product possible.²¹⁵ This outcome would result because standardization would reduce the ability of cannabis laboratories to manipulate data through their own individual test methods.²¹⁶ Thus, cannabis producers would have little use for “shopping” around for a lab that provides favorable results.²¹⁷ Cannabis producers would have no choice but to produce quality cannabis products in order to achieve the test results they desire.²¹⁸ As such, standardization would adjust the adverse market incentive to cut corners for both cannabis producers and cannabis labs.

Next, standardization would reduce the possibility of inconsistent test results from one laboratory to another on the same product. As evidenced by the current lab shopping phenomenon, cannabis producers can send a sample of a batch of cannabis to multiple labs and receive varying results back on that cannabis.²¹⁹ Moreover, it is entirely possible that a sample that fails at one lab might not fail at another, given that differences in operating procedures produce differences in results.²²⁰ These discrepancies are a result of the latitude the CRA gives laboratories to develop their own unique procedures.²²¹ The ability for labs to produce varying results ultimately means that it is possible for consumers to receive

211. Chris Casacchia, *California Rolls out Plans to Standardize Cannabis Testing Statewide*, MJBIZDAILY (Nov. 29, 2021), <https://mjbizdaily.com/california-rolls-out-plans-to-standardize-cannabis-testing-statewide/> [<https://perma.cc/26BR-GY3Q>].

212. MICH. ADMIN. CODE r. 420.306(5) (2020).

213. Bart Schaneman, *Lack of Standards, Dubious Business Practices Threaten to Upend Cannabis Testing Industry*, MJBIZDAILY (Dec. 17, 2021), <https://mjbizdaily.com/lack-of-standards-dubious-business-practices-threaten-to-upend-cannabis-testing-industry/> [<https://perma.cc/7V4R-W6LG>].

214. See Larkin, *supra* note 54 (coining the term “cannabis capitalism”).

215. See NAT’L CANNABIS LAB’Y COUNCIL, *supra* note 210, at 7.

216. See *id.*

217. See *id.*

218. See *id.*

219. Gus Burns, *Super Potent Weed*, *supra* note 109.

220. Cassachia, *supra* note 211.

221. See MICH. ADMIN. CODE r. 420.305 (2022).

inaccurate information about the cannabinoid content and safety of the products they purchase.²²² As such, consumers are unable to make an informed decision about using marijuana.²²³

Furthermore, standardization would allow the CRA to regulate Michigan laboratories more effectively. By establishing well-defined parameters that laboratories must follow, the CRA could more easily detect when a lab is engaging in illegal conduct because outlier test results could not be explained away by differences in testing methodology.²²⁴ In addition, the CRA could better educate testing licensees and engage in consistent enforcement when a laboratory deviates from acceptable practice.²²⁵ Finally, the CRA regulating in conformity with businesses' expectations would add stability to the market.²²⁶

Considering these proposed changes in light of the *Viridis* case is illuminating. First, standardization would have avoided the issue of whether *Viridis* was inflating THC numbers. The CRA had received complaints that the *Viridis* companies were inflating THC numbers and became concerned with their “*Viridis Method*” of testing THC potency,²²⁷ although it had previously approved this method.²²⁸ *Viridis*' cannabis tests exceeded 28% THC seven times more frequently than samples tested at other labs in Michigan.²²⁹ In response to these numbers, one lab, The Spott Laboratory, even went so far as to re-test a sample of *Viridis*-tested cannabis to compare THC results.²³⁰ While *Viridis* had found the cannabis sample to have 40.3% THC, Spott only found it to have 26.4%.²³¹ Regardless of whose results are more accurate, it is clear that huge discrepancies can result between different methods of testing, and some methods lead to outlier numbers.²³² Discrepancies like this would not occur if there were accurate standardized test procedures across the board,

222. See *supra* notes 93–103 and accompanying text (regarding lab shopping and test manipulation).

223. See *id.*

224. See CAL. DEP'T OF CANNABIS CONTROL, INITIAL STATEMENT OF REASONS—STANDARD CANNABINOIDS TEST METHOD 2 (June 17, 2022), https://cannabis.ca.gov/wp-content/uploads/sites/2/2022/06/DCC_Cannabinoids-Test-Method_ISOR_2022-0603_CD.pdf [<https://perma.cc/66PY-EWBM>] [hereinafter DCC, INITIAL STATEMENT OF REASONS].

225. See *id.*

226. Masur & Nash, *supra* note 195, at 210.

227. Burns, *Super Potent Weed*, *supra* note 109.

228. Complaint at 8, *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024 (Mich. Ct. Cl. Dec. 3, 2021).

229. Burns, *Super Potent Weed*, *supra* note 109.

230. *Id.*

231. *Id.*

232. See *id.*

which would allow consumers to know what to expect when they purchase cannabis at a certain advertised THC quantity.

Moreover, standardization would have given the CRA a legitimate basis upon which to institute a recall against Viridis. In the CRA's recall of Viridis-tested products, one of the reasons it gave for the recall was that the companies failed to keep incubation logs for the marijuana they tested.²³³ Yet, keeping incubation logs is not a required procedure for testing facilities,²³⁴ even if it might be a best practice to do so.²³⁵ The CRA also said that Viridis' test results were "unreliable," but was unable to identify with specificity what about Viridis' procedures or process made their results unreliable.²³⁶ If there had been clearer, consistent, standardized rules about which procedures and methodologies were necessary in the process of testing cannabis, the CRA would not have struggled to find a rationale for the recall if Viridis was actually violating those procedures. Instead, the CRA was vague and inconsistent in its reasoning, which ultimately resulted in the legal challenge from Viridis that sent allegedly contaminated marijuana back to store shelves for consumers.²³⁷

Finally, standardization would have avoided the disruption and harm to Viridis' operations, its reputation, and the broader industry. Before the recall, Viridis controlled about 70% of the marijuana testing market in Michigan, and the recall affected 64,000 pounds of marijuana worth over \$229 million.²³⁸ Much of this product was already on dispensary shelves.²³⁹ Thus, Viridis anticipated that the full recall, if allowed to proceed, would result in significant economic consequences for Viridis and a domino economic effect for producers and dispensaries.²⁴⁰ The Michigan Court of Claims ultimately agreed when it granted an injunction against the CRA.²⁴¹ Moreover, Viridis needed to spend money and time litigating this issue in state court while the goodwill with its client base

233. *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024, at *2 (Mich. Ct. Cl. Dec. 3, 2021).

234. *Id.* at *5.

235. Burns, *Michigan Lab Fights Back*, *supra* note 134.

236. *Viridis Lab's, LLC*, 2021 WL 8014024, at *2.

237. Roberts, *Moldy Marijuana*, *supra* note 18.

238. Roberts, *Wild Wild West*, *supra* note 14; Burns, *\$229 Million Marijuana Recall*, *supra* note 15.

239. Roberts, *Wild Wild West*, *supra* note 14; Burns, *\$229 Million Marijuana Recall*, *supra* note 15.

240. *Viridis Lab's, LLC*, 2021 WL 8014024, at *6–7.

241. *Id.* at *7 ("The testimony and common-sense tells one that a recall against two testing corporations for ineffective testing methods could cause lasting harm to goodwill amongst its customer base who are currently damaged by not getting product to market, and that cannot all be remedied by money damages.").

suffered.²⁴² Standardization would have facilitated the industry's understanding of legal confines and helped businesses anticipate agency action, and the CRA would have had a strong, defensible basis upon which to engage in enforcement.

Notably, California has also recognized the problems that come with a lack of standardization in testing procedures for marijuana.²⁴³ In October 2021, California Governor Gavin Newsom signed Senate Bill 544, which requires its Department of Cannabis Control (DCC) to promulgate “one or more standardized cannabinoids test methods” for all testing laboratories in the state to use.²⁴⁴ Senate proponents of the bill focused on the fact that allowing labs to have different testing procedures leads to inconsistent results on marijuana products, thereby misleading and confusing consumers.²⁴⁵ Thereafter, California amended its Business and Professions Code with the requirement that DCC promulgate such standardized test methods.²⁴⁶

As a result of the passage of this bill, in June 2022, the DCC proposed rules²⁴⁷ that establish a standardized procedure for laboratories to follow when testing for cannabinoids.²⁴⁸ The DCC explained that the purpose of the rules is to reduce inconsistency in cannabinoid potency tests between labs, create uniformity and transparency in procedures, allow the Department to more easily regulate laboratories and enforce the rules, and protect consumer safety.²⁴⁹ The DCC promulgated its final rules in July 2023, which became effective in October 2023, and enforceable beginning January 1, 2024.²⁵⁰

242. See generally *id.*; see also Roberts, *Wild Wild West*, *supra* note 14 (providing a quote from the CEO of Viridis Laboratories in which he says that a “stigma” persists against the company after the recall).

243. S.B. 544, 2021 Leg., Reg. Sess. (Cal. 2021) (enacted).

244. *Id.*

245. *Id.*

246. CAL. BUS. & PROF. CODE § 26100(f)(2) (2022).

247. CAL. DEP’T OF CANNABIS CONTROL, NOTICE OF PROPOSED RULEMAKING—STANDARD CANNABINOIDS TEST METHOD AND STANDARDIZE OPERATING PROCEDURES (June 17, 2022), https://cannabis.ca.gov/wp-content/uploads/sites/2/2022/06/DCC_Cannabinoids-Test-Method_Notice_2022-0608.pdf [<https://perma.cc/5S4J-UKFT>] [hereinafter DCC, NOTICE OF PROPOSED RULEMAKING].

248. See *Standard Cannabinoids Test Method and Standardized Operating Procedures*, CAL. DEP’T OF CANNABIS CONTROL, <https://cannabis.ca.gov/cannabis-laws/rulemaking/standard-cannabinoids-test-method-and-standardized-operating-procedures/> [<https://perma.cc/K4ZX-UTN6>] [hereinafter DCC, *Standard Test Method*].

249. DCC, INITIAL STATEMENT OF REASONS, *supra* note 224, at 1–2.

250. CAL. DEP’T OF CANNABIS CONTROL, APPROVED TEXT OF REGULATIONS (July 2023), https://cannabis.ca.gov/wp-content/uploads/sites/2/2023/08/approved_text_standard_test_methods_operating_procedures.pdf [<https://perma.cc/3ZTG-872J>] [hereinafter DCC, FINAL REGULATIONS]; DCC, *Standard Test Method*, *supra* note 248.

California's proposed rules represent a step in the right direction for protecting consumers and the legitimacy of the cannabis industry, but they do not quite go far enough. Notably, California's Business and Professions Code only requires standardized test procedures when it comes to testing for cannabinoids,²⁵¹ and as such, the DCC's final rules only address the same.²⁵² While this measure ensures that consumers will have consistent and reliable THC, CBD, and other cannabidiol potency information, it does not protect consumers from testing inaccuracies regarding pesticide residue, fungi, microbes, and other impurities.²⁵³ As illuminated by the *Viridis* case—in which the absence of incubation logs and aspergillus contamination was an issue²⁵⁴—the lack of concrete rules and guidelines surrounding how to test for contaminants and prevent contamination puts consumers at risk and can lead to devastating consequences for businesses in the industry.²⁵⁵

Of course, standardizing testing procedures is not something that can occur overnight. The dearth of research on cannabis also means that the most accurate way to test cannabis is still not fully clear.²⁵⁶ But with growing scientific and industry interest across the country for standardization and current efforts by states and industry groups to come closer to the goal of standardization,²⁵⁷ it could be an achievable policy goal for Michigan. Indeed, as of 2024, Michigan is considering amending the MRTMA to give the CRA explicit authority to open a state-run “reference laboratory.”²⁵⁸ The state-run laboratory would conduct its own

251. CAL. BUS. & PROF. CODE § 26100(f)(2) (2022).

252. DCC, FINAL REGULATIONS, *supra* note 250.

253. *Id.*

254. *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024, at *5 (Mich. Ct. Cl. Dec. 3, 2021).

255. See generally Roberts, *Wild Wild West*, *supra* note 14.

256. See NAT'L CANNABIS LAB'Y COUNCIL, *supra* note 210, at 6.

257. See, e.g., *id.* at 1 (describing the goal of the National Cannabis Laboratory Council to create a unified approach to testing based on scientifically recognized standards); CAL. BUS. & PROF. CODE § 26100(d)(2) (requiring DCC to promulgate rules to standardize testing procedures); DCC, NOTICE OF PROPOSED RULEMAKING, *supra* note 247 (proposing standardized test methods for cannabinoids testing).

258. H.B. 5529, 102nd Leg., Reg. Sess. (Mich. 2024). As of this writing, this bill has only been introduced in the House, and has not yet been passed. Because MRTMA was a voter initiative, amending it will require three-fourths of the representatives in both the Senate and House to approve the bill. John Schroyer, *Michigan May Establish State-Run Cannabis Testing Lab to Aid Industry Oversight*, GREEN MKT. REP. (Mar. 7, 2024), <https://www.greenmarketreport.com/michigan-may-establish-state-run-cannabis-testing-lab-to-aid-industry-oversight/> [<https://perma.cc/YH95-JDFR>]. Notably, the state has already set aside funding for eventual development of the reference lab. Barton Morris, *Budding Opportunities: Michigan Invests \$4.4 Million in Cannabis Reference Laboratory to Elevate Industry Standards*, CANNABIS LEGAL GRP. (Aug. 2, 2023),

audits and investigations of cannabis that is tested at private facilities, with the goal of increasing accuracy and honesty throughout the testing industry.²⁵⁹ The existence of an unbiased state-run laboratory with its own testing capabilities could be an intermediate step to the development of standardized test methods that the industry needs.²⁶⁰

B. Create Additional Recall Procedures

Another solution that could protect consumers and avoid further injury to the marijuana industry would be promulgating additional recall procedures to guide when recalls are necessary. Michigan cannabis regulations permit the CRA to recall marijuana products, issue safety warnings, place products on administrative hold, and require a marijuana business to provide information or notifications to a customer at the point of sale.²⁶¹ However, as it currently stands, Michigan has no published or internal standards for determining when a recall is required or how to go about it.²⁶² Adopting clear recall procedures would ensure that when there is contaminated marijuana on the market, it can be removed on a legitimate, defensible, and predictable basis, avoiding potential harm to consumers, disruption for businesses, and costly delays from litigation.²⁶³

The federal Food and Drug Administration (FDA) rules surrounding recalls illustrate how the CRA could structure recall policy and procedures. First, the FDA has different classifications for different types of recalls, and an ad hoc committee engages in an evaluation to determine the proper classification before issuing a recall.²⁶⁴ Class I recalls are the most serious and are issued when the use or exposure to a product is reasonably likely to cause death or serious adverse health consequences.²⁶⁵ Class II recalls are issued when the use or exposure to a product may cause temporary or reversible health consequences or when the probability of serious health consequences is remote.²⁶⁶ Class III recalls are issued when the use of or exposure to a defective product is not likely to cause adverse

<https://www.linkedin.com/pulse/budding-opportunities-michigan-invests-44-million/>
[<https://perma.cc/9HPG-JJBX>].

259. Schroyer, *supra* note 258.

260. Morris, *supra* note 258.

261. MICH. ADMIN. CODE r. 420.502(2) (2022).

262. *See id.*; Viridis Lab'ys, LLC v. Mich. Marijuana Regul. Agency, No. 21-000219-MB, 2021 WL 8014024, *5 (Mich. Ct. Cl. Dec. 3, 2021).

263. *See, e.g., id.*

264. 21 C.F.R. § 7.41 (1977).

265. *Recalls Background and Definitions*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions> [<https://perma.cc/QV9V-ZG5V>] [hereinafter FDA Recalls].

266. *Id.*

health consequences.²⁶⁷ Finally, “market withdrawals” occur when a product has a minor violation that would not be subject to FDA legal action.²⁶⁸

The FDA can request that a firm voluntarily recall a product if it determines there is a risk of illness, injury, or gross consumer deception and that it is necessary to protect the public health and welfare.²⁶⁹ The FDA can make the recall mandatory if the firm does not follow the request.²⁷⁰ In such a case, the FDA must provide the responsible firm an informal hearing to state its case about whether the recall should be lifted.²⁷¹ If the arguments persuade the FDA, it can amend or vacate the recall.²⁷² In addition, the firm itself can initiate a recall if it believes its product violates FDA regulations.²⁷³ In that case, the FDA assists the firm in classifying and rolling out the recall.²⁷⁴ The firm and the FDA then engage in communications with affected businesses and the public to spread the word about the recall.²⁷⁵

Similar procedures could benefit the CRA in future cannabis recalls by avoiding confusion and contestation about the propriety of the recall. The *Viridis* case is helpful in exemplifying this point. In *Viridis*, the public reason given for the CRA’s recall was that it had identified “inaccurate and/or unreliable results of products tested” by *Viridis*.²⁷⁶ During the litigation, CRA’s manager of the Scientific and Legal Enforcement Division elaborated that the basis of the recall was that ten re-tests of *Viridis*’ tested product failed for aspergillus, and that the companies lacked incubation logs for their testing.²⁷⁷ Yet the MRA had no internal documents corroborating that basis or any other reason for the recall.²⁷⁸

If the CRA had been forced to classify the recall in a manner similar to the FDA’s classification system, it would have also justified the reasoning for the recall by backing it with evidence of the harm that could come to consumers from the products. As noted, before the FDA classifies a recall, an ad hoc group of FDA scientists engage in an evaluation that considers multiple factors tending to show the level of probable harm to

267. *Id.*

268. *Id.*

269. 21 C.F.R. § 7.45 (1977).

270. 21 U.S.C. § 3501.

271. *Id.*

272. *Id.*

273. 21 C.F.R. § 7.46 (1977).

274. *Id.*

275. See 21 C.F.R. §§ 7.49–.50 (1977).

276. *Viridis Lab’ys, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024, at *2 (Mich. Ct. Cl. Dec. 3, 2021) (internal quotation marks omitted).

277. *Id.* at *2, *7.

278. *Id.* at *2.

the public.²⁷⁹ If it were CRA policy to consider the level of probable harm to the public and to classify a recall along similar lines, there would be less opportunity to question whether the recall was instituted for an improper purpose—which was an argument Viridis made against the recall.²⁸⁰

Moreover, FDA recall regulations are collaborative in the sense that both the FDA and the regulated entity have obligations when a recall is instituted, and both work together on developing strategy and communicating.²⁸¹ The FDA must initially allow the regulated entity to voluntarily engage in a recall at the FDA's request.²⁸² And in the case of mandatory recalls, the regulated entity has a chance to be heard at an informal hearing soon after the recall is instituted.²⁸³ Such a construct could reduce contentions between marijuana businesses and the CRA when the CRA must take enforcement action. As exemplified in *Viridis*, the “confusion”²⁸⁴ between the parties resulting from the hastily implemented recall was the driving force behind Viridis' allegation that the agency stepped outside the bounds of the Michigan APA.²⁸⁵ Creating collaborative procedures would reduce the likelihood that businesses and the CRA would become embroiled in costly litigation over enforcement actions.

Clearer recall procedures would also benefit consumers and, ultimately, the wider industry. In the *Viridis* case, the Michigan Court of Claims ultimately found that the agency's Viridis North recall was arbitrary, and as such, the marijuana tested at that facility could be sold.²⁸⁶ After this decision, however, the CRA re-tested the specific product from Viridis North and found that about twenty-six percent of the product failed for microbials.²⁸⁷ When the CRA filed a motion for reconsideration in the Court of Claims on the order for a preliminary injunction on these grounds, the court denied the motion because the re-testing was outside the scope of the original recall.²⁸⁸

279. See 21 C.F.R. § 7.41 (1977).

280. See Complaint at 3, *Viridis Lab 'ys, LLC*, No. 21-000219-MB, 2021 WL 8014024 (“[T]he record evidence set forth below strongly suggests that the Marijuana Regulatory Agency wrongfully targeted Plaintiffs for improper purposes, such as . . . a desire to ‘level the playing field’ so that all marijuana safety compliance facilities would get an equal share of the cannabis testing market.”).

281. See 21 C.F.R. §§ 7.42–.46, 7.49–.50.

282. 21 U.S.C. § 350l(a).

283. *Id.* § 350l(c).

284. See *Viridis Lab 'ys, LLC*, 2021 WL 8014024, at *2 n.5.

285. *Id.* at *2, *4.

286. *Id.* at *7.

287. Roberts, *Moldy Marijuana*, *supra* note 18.

288. *Viridis Lab 'ys, LLC*, 2021 WL 8014022, at *1.

Such a result could have been avoided if the original recall was legally justifiable on its face. Instead, incoherent agency action resulted in a court decision unfavorable to the agency, and contaminated marijuana allegedly returning to store shelves.²⁸⁹ Further instances of unsafe marijuana contaminated with microbials making it back to store shelves could foreseeably result in actual harm or even death, especially for users who have immune deficiencies.²⁹⁰ Given that there can be up to fifty pounds of marijuana in one harvest batch,²⁹¹ there is a considerable chance that one contaminated batch could reach a large number of consumers, increasing the odds that a consumer is harmed.

Certainly, the FDA's recall procedures are tailored to fit the products it regulates—food, drugs, and cosmetics across the entire country.²⁹² The CRA, as a state agency regulating a much smaller category of products, may need to tailor recall regulations to fit the setting and industry. For example, recall procedures that are too rigidly defined would not be appropriate in a brand-new industry such as this, where cannabis science is lagging.²⁹³ The agency must have the flexibility to evolve with new information and respond adequately to unforeseen scenarios.²⁹⁴ The Michigan Court of Claims acknowledged this fact in the *Viridis* case, noting that although the CRA does not have guidelines for when recalls are appropriate, it has the general power to issue recalls to protect public health, and the court would defer to its judgment on whether recalls are necessary if the action is not arbitrary.²⁹⁵

Yet, the very fact that the Michigan Court of Claims found the *Viridis* recall partially arbitrary suggests that the CRA should adopt additional recall procedures so that future recalls are based in verifiable fact that is defensible in court, and so that cannabis businesses can expect, and depend upon, consistent regulation. It could do so in a way that retains its flexibility by broadly classifying recalls and establishing concomitant recall procedures based on health risk and adopting a collaborative recall mechanism that gives the business a chance to recall voluntarily.

289. Roberts, *Moldy Marijuana*, *supra* note 18.

290. See Ruchlemer et al., *supra* note 182, at 821.

291. MICH. ADMIN. CODE r. 420.304(c) (2020).

292. *What We Do*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2023), <https://www.fda.gov/about-fda/what-we-do> [<https://perma.cc/WU37-DGJH>].

293. Moreno, *supra* note 5, at 411.

294. John T. Carnevale et al., *A Practical Framework for Regulating For-Profit Recreational Marijuana in US States: Lessons from Colorado and Washington*, 42 INT'L J. DRUG POL'Y 71, 83 (2017).

295. See *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024, at *5 (Mich. Ct. Cl. Dec. 3, 2021); see also *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2022 WL 1055238, *4–5 (Mich. Ct. Cl. Feb. 3, 2022).

C. A Note on the Role for the Federal Government

While Michigan could take these mitigating steps to make cannabis safety compliance more consistent and accurate, ultimately the most effective regulatory scheme would likely come from the federal government.²⁹⁶ Without federal regulation and guidance, states are left to make piecemeal regulatory decisions based on limited scientific understandings of cannabis and limited expertise in evaluating drugs and other products for safety and effectiveness.²⁹⁷ Moreover, large-scale research designed to satisfy the standards of a single federal regulator may be more cost-effective and illuminating than multiple smaller studies at the state level.²⁹⁸

Despite these benefits and the mounting calls for federal cannabis reform, Congress has had an historic inertia for changing cannabis policy, and it is likely that it will overcome such inertia in incremental steps rather than sweeping reforms.²⁹⁹ Additionally, there is no existing federal regulatory framework that could realistically be applied to cannabis and cannabis production. The Food and Drug Administration (FDA) would be responsible for the production and safety of cannabis, as it regulates all drugs, food, food ingredients, and dietary supplements³⁰⁰—yet, the unique features of cannabis make it unsuited for one of the FDA’s existing regulatory categories.

Under FDA’s regulatory powers, cannabis would likely be considered a drug because a “drug” is defined in the FDCA as something “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,” and “articles (other than food) intended to affect the structure or any function of the body.”³⁰¹ Moreover, FDA determines the “intended use” by looking at the producer’s “objective intent” for the item, which may be shown by labeling, advertising, oral or written statements by the

296. Eisenberg & Leiderman, *supra* note 21, at 250.

297. *Id.* at 250–51.

298. *Id.*

299. See E.K. McWilliams & Nika Arzoumanian, *Federal Cannabis Reform: Inevitable but Inevitably Piecemeal*, LAW360 (Aug. 6, 2021, 5:34 PM), <https://www.jenner.com/a/web/nubJ1XvYaaQhkn6wmgz7Mi/4HRMZQ/McWilliams%2520Arzoumanian%2520Law360%2520Aug%25206%25202021.pdf?1628610237> [https://perma.cc/8Z6D-WKQL] (predicting that cannabis reform on the federal level will be a slow and piecemeal process); see also Chris Roberts, *Marijuana Reform Faces ‘More Challenging’ Environment in Congress Under GOP*, MJBIZDAILY (Feb. 9, 2023), <https://mjbizdaily.com/marijuana-reform-faces-more-challenging-environment-in-congress-under-gop/> [https://perma.cc/Z5WR-DDH8].

300. *Laws Enforced by FDA*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/laws-enforced-fda> [https://perma.cc/Y2GV-WNFB].

301. 21 U.S.C. § 321(g)(1).

producer, and other contextual clues.³⁰² Because marijuana is typically used and marketed for medical, psychological, and emotional effects,³⁰³ most marijuana would fall under FDA's broad jurisdiction over drugs.

Furthermore, it is likely that FDA would determine that cannabis is a "new drug."³⁰⁴ Under the FDCA, a "new drug" is a distinct statutory subset of "drugs" in general.³⁰⁵ Drugs that are designated as new drugs must get premarket approval by the FDA before they can be sold to consumers.³⁰⁶ However, the premarket approval process is costly.³⁰⁷ A company seeking to develop and market a new drug must complete a New Drug Application (NDA) and provide intensive data on the manufacture, specifications, and composition of the active ingredient and the finished product.³⁰⁸ It must also undertake lengthy preclinical trials (laboratory and animal studies)³⁰⁹ before submitting an Investigational New Drug application to the FDA to

302. 21 C.F.R. § 201.128 (2021).

303. See generally Theodore L. Caputi, *The Medical Marijuana Industry and the Use of "Research as Marketing"*, 110 AM. J. PUB. HEALTH 174 (2020).

304. See O'Connor & Lietzan, *supra* note 11, at 865–68. An unapproved drug is always a new drug *unless* it is generally recognized as safe and effective ("GRASE") for its intended use and it has been used to a material extent for a material time. See 21 U.S.C. § 321(p); see also U.S. FOOD & DRUG ADMIN., FDA-2017-P-6692-0042, PETITION DENIAL LETTER FROM FDA CDER TO DRUG WATCH INTERNATIONAL (2018). This standard is difficult to meet: to be GRASE, a drug must have as much quality scientific evidence proving its safety and efficacy as would be obtained through the FDA premarket approval process. 21 C.F.R. § 314.200(e)(1). Moreover, the FDA determines which product is GRASE on a product-by-product basis, rather than on an active ingredient-by-active ingredient basis, based on what the specific product is marketed for. See *United States v. Generix Drug Corp.*, 460 U.S. 453, 460–61 (1983) (holding that the term "drug" in the FDCA is intended to mean the entire drug product, not merely active ingredients, when determining whether a product is GRASE). Thus, for example, if THC was eventually found "GRASE" this would not mean that all cannabis products would therefore be GRASE. Different cannabis strains have unique combinations and amounts of chemical compounds, and oftentimes different strains are marketed for different therapeutic purposes. See Stone, *supra* note 97; NAT'L INSTS. OF HEALTH, *supra* note 98. As such, the prerequisites for finding a cannabis product GRASE would likely not be met, and it would therefore be a new drug.

305. Compare 21 U.S.C. § 321(p) (definition of "new drug") with 21 U.S.C. § 321(g)(1) (definition of "drug").

306. See 21 U.S.C. § 355.

307. See O'Connor & Lietzan, *supra* note 11, at 884.

308. See 21 C.F.R. § 314.50(d)(1) (2016).

309. *Step 2: Preclinical Research*, U.S. FOOD & DRUG ADMIN. (Nov. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research> [<https://perma.cc/B362-2PWL>].

begin clinical trials on humans.³¹⁰ Overall, this process can cost over \$1 billion dollars and can take over a decade to complete.³¹¹

Such a process is inapt for the cannabis industry, where there are over seven hundred strains of cannabis,³¹² each of which would likely require FDA new drug approval.³¹³ The biological variability of cannabis plants, such as the differences between strains and even within strains due to growing and processing conditions, would complicate trials by making results difficult to reproduce with the precision required by the FDA.³¹⁴ Moreover, many localized cannabis businesses would not be able to compete in an industry that requires lengthy, expensive clinical trials before market approval, so FDA regulation in this manner could be a death knell for small cannabis businesses and an open invitation for big pharmaceutical companies to move in instead.³¹⁵

In addition, cannabis firms big and small would likely not benefit from market exclusivity, which the U.S. provides to drug developers as an incentive to engage in costly new drug research.³¹⁶ This is because it may not be possible to patent the cannabis plant itself,³¹⁷ and it also may not be possible to patent medical uses for cannabis that have been known to the public for some time.³¹⁸ As such, pursuing an NDA for cannabis will often be financially and pragmatically unrealistic, which is compounded by the fact that marijuana is a Schedule I drug on the federal level which further

310. *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> [<https://perma.cc/QT3H-CU9T>].

311. O'Connor & Lietzan, *supra* note 11, at 884.

312. David Gloss, *An Overview of Products and Bias in Research*, 12 NEUROTHERAPEUTICS 731, 732 (2015).

313. As explained more thoroughly in note 304, *supra*, because the FDA reviews drugs for GRASE status on a product-by-product basis, U.S. v. Generix Drug Corp., 460 U.S. 453, 460–61 (1983), each unique cannabis product would have to meet GRASE requirements independently. See Stone, *supra* note 97 (explaining the many chemical variations in cannabis products).

314. Eisenberg & Leiderman, *supra* note 21, at 263–64.

315. Mary Jane Gibson, *Is Legal Weed Doomed to Be Run by Big Business?*, VOX (Dec. 28, 2022), <https://www.vox.com/the-goods/23509642/marijuana-cannabis-legalization-prohibition-biden> [<https://perma.cc/23TA-5YM2>].

316. O'Connor & Lietzan, *supra* note 11, at 885.

317. It is possible that a cannabis plant could be patented if it is a result of a patent applicant's own "human ingenuity," such as through selective breeding or genetic engineering. Gretchen L. Temeles et al., *IP Protection and the Cannabis Industry: Strategies and Trends*, THE LEGAL INTELLIGENCER (Apr. 3, 2018), <https://plus.lexis.com/api/permalink/69c4bdf2-3adf-4a9a-bf1f-e670d07a5813/?context=1530671> [<https://perma.cc/Y6LP-XN75>].

318. O'Connor & Lietzan, *supra* note 11, at 885–86 (citing 35 U.S.C. § 102) (stating that when an invention was in public use or otherwise available to the public before the filing date for the patent, a person is not entitled to a patent).

increases the cost of research.³¹⁹ Thus, regulating cannabis in this way could have disastrous economic consequences, considering that the cannabis industry is already worth \$13.2 billion nationally as of 2022 and is expected to grow drastically in the next decade.³²⁰

Cannabis is similarly unsuited for the FDA's food and dietary supplement regulatory schemes.³²¹ Most notably, smoked products cannot be considered a "food" or a "dietary supplement" under the FDCA, thus eliminating that typical form of marijuana use.³²² Moreover, the "drug exclusion rule" applies to both foods and dietary supplements, which prevents them from using an active ingredient that is already found in an approved drug.³²³ FDA has already approved purified CBD in the drug Epidiolex, and dronabinol (synthetic THC) in the drugs Marinol and Syndros, thereby precluding these ingredients for use in food and dietary supplements.³²⁴ Any future approval of THC or other cannabinoids for medical use would have a similar preclusive effect.³²⁵ In addition, neither foods nor dietary supplements may make claims about treating disease because such claims would make the product fall under the definition of "drug" in the FDCA.³²⁶ Yet, cannabis is commonly associated with health claims.³²⁷

Given the obstacles that each of FDA's traditional regulatory pathways face for the regulation of marijuana, Congress may need to legislate a specific regulatory regime to fit the needs of the cannabis

319. Eisenberg & Leiderman, *supra* note 21, at 261–62.

320. *U.S. Cannabis Market Size, Share & Trends Analysis Report By End-use (Medical, Recreational, Industrial), By Source (Marijuana, Hemp), By Derivative (CBD, THC), and Segment Forecasts, 2023-2030*, GRAND VIEW RSCH., <https://www.grandviewresearch.com/industry-analysis/us-cannabis-market> [<https://perma.cc/KTH5-B5UX>].

321. Most notably, smoked products cannot be considered a "food" or a "dietary supplement" under the FDCA, thus eliminating that typical form of marijuana use. *See* 21 U.S.C. § 321(f) (definition of food); *id.* § 321(ff) (definition of dietary supplement). Moreover, the "drug exclusion rule" applies to both foods and dietary supplements, which prevents them from using an active ingredient that is already found in an approved drug. *See* 21 U.S.C. § 331(ll) (food); *id.* § 321(ff)(B) (dietary supplements). FDA has already approved purified CBD in the drug Epidiolex, and dronabinol (synthetic THC) in the drugs Marinol and Syndros, thereby precluding these ingredients for use in food and dietary supplements. FDA and Cannabis, *supra* note 63. In addition, neither foods nor dietary supplements may make claims about treating disease because such claims would make the product fall under the definition of "drug" in the FDCA. *See* 21 U.S.C. § 321(g)(1).

322. *See* 21 U.S.C. § 321(f) (definition of food); *id.* § 321(ff) (definition of dietary supplement).

323. *See* 21 U.S.C. § 331(ll) (food); *id.* § 321(ff)(B) (dietary supplements).

324. FDA and Cannabis, *supra* note 63.

325. *See, e.g.*, 21 U.S.C. § 331(ll) (food); 21 U.S.C. § 321(ff)(B) (dietary supplements).

326. *See* 21 U.S.C. § 321(g)(1).

327. *See generally* Caputi, *supra* note 303.

industry, thus avoiding ill-fitting existing FDA regulations. Indeed, the FDA has already called upon Congress to create a “new regulatory pathway” for CBD specifically.³²⁸ Dr. Janet Woodcock, FDA’s Principal Deputy Commissioner, described how there is not enough known about CBD’s safety to regulate it as a food product or dietary supplement up to FDA’s standards.³²⁹ Implicitly acknowledging that CBD is a product here to stay, however, she urged Congress to work with the FDA to create a unique regulatory scheme that would provide oversight and minimize risks related to CBD.³³⁰

Notably, Congress overcame a comparable hurdle when it passed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in 2009.³³¹ This Act gave the FDA express authority over the manufacture, distribution, and marketing of tobacco products³³² nine years after the Supreme Court held that the FDA lacked authority to regulate tobacco products under the FDCA.³³³ Tobacco is the only product that the FDA regulates which causes disease, disability, or death when used normally.³³⁴ As such, Congress developed a novel regulatory standard that the FDA must apply when regulating tobacco products.³³⁵ Rather than regulating to ensure the products are “safe and effective” (which is the FDA’s usual standard), instead, the FDA must determine whether its proposed regulations are “appropriate for the protection of public health . . . with respect to the risks and benefits to the population as a whole.”³³⁶ Moreover, Congress prohibited the FDA from outright banning the sale of any tobacco product in face-to-face transactions.³³⁷ Accordingly, FDA’s approach to tobacco is vastly different from its approach to other products it regulates, instead focusing on “reduc[ing] the impact of tobacco use on

328. *FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward*, U.S. FOOD & DRUG ADMIN. (Jan. 26, 2023), <https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol> [https://perma.cc/5HCX-HD56].

329. *Id.*

330. *Id.*

331. *See* 21 U.S.C. § 387 *et seq.*

332. *Id.* § 387a.

333. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

334. *Implementing the Tobacco Control Act through Policy, Rulemaking, and Guidance*, U.S. FOOD & DRUG ADMIN. (Jan. 26, 2018), <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/implementing-tobacco-control-act-through-policy-rulemaking-and-guidance> [https://perma.cc/NXY9-ENKA] [hereinafter *FDA and Tobacco*].

335. *See* 21 U.S.C. § 387 *et seq.*

336. *Id.* § 387f(d)(1).

337. *Id.* § 387f(d)(3)(A).

the nation's health" while taking into account the unique position of the tobacco industry in America.³³⁸

Similarly, a congressionally prescribed regulatory framework for cannabis, separate from the FDCA, would most likely be the most appropriate way for the federal government to bring cannabis under FDA's regulatory control. Congress would have to consider cannabis' unique features, such as the interplay between its potential medical uses and its potential social harms, and the fact that it is commonly both smoked and ingested, in crafting an appropriate regulatory standard to govern it.³³⁹ In addition, the FDA already has mechanisms that could be applied to broad cannabis regulation. The FDA Center for Drug Evaluation and Research's "Botanical Review Team" exists to facilitate drug development of plant products, despite the inherent difficulties of ensuring therapeutic consistency in plant products.³⁴⁰ This approach gives botanical drugs greater flexibility in NDA application requirements than purified drugs.³⁴¹ This existing framework, applied to novel regulatory legislation designed for cannabis, could be FDA's path forward toward comprehensive regulation of cannabis' medical and recreational development.

In sum, federal regulation of cannabis would provide benefits that piecemeal state regulation may not, such as the FDA's ability to create a unified, nationwide regulatory system backed by comprehensive large-scale research.³⁴² Congress has shown willingness to adapt regulatory schemes for products that the typical FDA regulatory pathways are ill-suited to address, as exemplified by its enactment of the FSPTCA.³⁴³ But congressional action on marijuana reform faces challenges, and it may be some time before Congress addresses the consumer protection aspects of cannabis regulation.³⁴⁴ In the meantime, Michigan should step in to fill its own regulatory gaps that could lead to consumer harm.

IV. CONCLUSION

Despite the ubiquitous presence of cannabis in Michigan's economy and culture, it should still be subject to regulation that guarantees that the

338. FDA and Tobacco, *supra* note 334.

339. See generally NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 5 (providing a comprehensive overview of the current state of research on the medical benefits and harms of cannabis).

340. CDER SMALL BUS. AND INDUS. ASSISTANCE, BOTANICAL DRUG REVIEW (2015); see also O'Connor & Lietzan, *supra* note 11, at 869.

341. See O'Connor & Lietzan, *supra* note 11, at 869.

342. Eisenberg & Leiderman, *supra* note 21, at 250–51.

343. 21 U.S.C. § 387a.

344. See McWilliams & Arzoumanian, *supra* note 299; Chris Roberts, *supra* note 299.

products reaching consumers are as safe as consumers believe they are. Inadequacies in the cultivation and production process leave cannabis plants vulnerable to contaminants and impurities that, when smoked or consumed by an unfortunate user, present a myriad of health hazards.³⁴⁵ The function of cannabis testing laboratories is to protect consumers from such impure products and to tell consumers exactly what is in the products they are using.³⁴⁶ But the leeway in Michigan's current regulatory scheme allows inaccurate and disparate test results regarding measures such as cannabinoid content and the presence of contaminants.³⁴⁷ It even gives laboratories the room to manipulate results to appease their cannabis producer clients.³⁴⁸ At the same time, the regulatory scheme fails to arm the CRA with enough teeth to fight these issues effectively.³⁴⁹ The downfalls of this regime became evident after the *Viridis* case, where the CRA's ill-conceived enforcement attempt ultimately allowed contaminated cannabis to return to store shelves.³⁵⁰

This hazy state of regulation is unacceptable in a society that tolerates, and in some cases even encourages, cannabis use.³⁵¹ Some doctors give the impression that marijuana is a safe medical remedy to relieve physical symptoms for people with chronic and debilitating illnesses.³⁵² Yet, people with illnesses are the most at risk when consuming moldy, bacteria-infested marijuana that slipped through the regulatory system's cracks.³⁵³ Moreover, they suffer the most when the cannabinoid content they rely on for dosing turns out to be inaccurate.³⁵⁴

Thus, Michigan must do more to ensure the products it produces are truly safe for use. The CRA should seek to standardize testing procedures to rein in the "wild, wild west"³⁵⁵ of the testing industry. Such a move would ensure that different laboratories could not produce different results on the same batch of cannabis, would eliminate the market force encouraging lab shopping, and would make CRA oversight of safety compliance operations more effective. The CRA should also adopt specific recall procedures outlining when a recall is necessary and the

345. See *supra* Part II.D.

346. See MICH. COMP. LAWS § 333.27953(p) (2021); see also MICH. ADMIN. CODE r. 420.305(3)(a)–(i) (2022).

347. See *supra* Part II.C.

348. See *id.*

349. See, e.g., *Viridis Lab's, LLC v. Mich. Marijuana Regul. Agency*, No. 21-000219-MB, 2021 WL 8014024 (Mich. Ct. Cl. Dec. 3, 2021).

350. *Id.*

351. See Van Green, *supra* note 4.

352. See, e.g., Gargani et al., *supra* note 133.

353. See *supra* Part II.D.

354. See *id.*

355. See Roberts, *Wild Wild West*, *supra* note 14.

resulting procedures that must be followed in such an event, allowing it to bolster its case for the recall when contaminated products make it to store shelves.

Eventually, Congress may decide that it is time to regulate cannabis on the federal level. It might craft a regulatory framework for the FDA to follow which accounts for cannabis' unique and diverse characteristics, such as the fact that it is a medicinal plant, a recreational drug, a smokable product, an ingestible product, and an ingrained part of our culture and economy. But until the federal government overcomes its inertia for cannabis, it is Michigan's duty to do what it can today to protect its people from the very substance it legalized.