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High Times: Is The Federal Legalization of Marijuana Next? What the Food and Drug Administration Could Learn from its Existing Regulations

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Cover Page Footnote

J.D. Candidate, 2016, American University Washington College of Law; B.A., Dickinson College . I would like to thank Professor Lewis Grossman for his invaluable guidance and insight. Any errors are the author's and the author's alone.

HIGH TIMES: IS THE FEDERAL LEGALIZATION OF MARIJUANA NEXT? WHAT THE FOOD AND DRUG ADMINISTRATION COULD LEARN FROM ITS EXISTING REGULATIONS

CHRISTOPHER B. ERLY*

I.Introduction	660
II.Background	662
A. The FDCA Gives the FDA Vast Regulatory Authority over Food, Drugs, Biologics, Dietary Supplements, Tobacco, and Medical Devices	662
1. Defining “Drug”	662
2. Defining “New Drug”	663
3. The NDA Process	663
4. The FDCA Gives the FDA Authority to Regulate Tobacco Products.....	666
III.Analysis	668
A. Marijuana Could Not Be Regulated as a Drug Because the FDA Would Not Approve an NDA Proposing Marijuana Be Used for a Medical Purpose	668
1. Marijuana Fits Firmly into the FDCA’s Definition of a Drug, Which Would Require Marijuana Be Regulated Under the “Drug” Statutes.....	668
2. Marijuana Is a “New Drug” Because It Lacks an Approved NDA.....	669
3. Marijuana Would Likely Not Be Approved in the NDA Process Because as a Botanical Drug It Is Difficult to Standardize Marijuana to Ensure Consistent Dosing and Active Constituents.....	670
a. IND Approval for Phase I and Phase II Studies	671

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660 JOURNAL OF GENDER, SOCIAL POLICY & THE LAW [Vol. 23:4

- b. IND Approval for Phase III Studies674
- c. NDA Review676
- B. Marijuana Regulated Under the Tobacco Provisions of the FDCA677
 - 1. Premarket Approval for “New Tobacco Products” Could Not Be Used to Regulate New Marijuana Products Because the Analysis Is based on Previously Marketed Products680
- IV. Conclusion.....682

I. INTRODUCTION

The majority of Americans support the legalization of marijuana, suggesting that future policy will reflect the views of the democratic majority.¹ Polls show that the support of legalizing marijuana is increasing over time.² The upward trend of Americans favoring legalization is not a recent phenomenon, but a trend that has grown steadily since 1985.³ The substantial increase in political support for legalizing marijuana does not match the minute increase of marijuana users in the United States.⁴ There has only been a 5% increase in Americans’ usage of marijuana since 1985, which was the turning point of the upward trend in favoring the legalization of marijuana.⁵ A 5% increase in marijuana use does not explain a 35% change in support for legalization.⁶ Indeed, national polls show that public support for the legalization of marijuana is ahead of most elected officials’ support.⁷ Nonetheless, marijuana policy reform is occurring throughout the United States.⁸

1. See Art Swift, *For First Time, Americans Favor Legalizing Marijuana*, GALLUP (Oct. 22, 2013), <http://www.gallup.com/poll/165539/first-time-americans-favor-legalizing-marijuana.aspx> (finding that 58% of Americans favor legalizing marijuana).

2. See *id.* (illustrating that support for legalizing of marijuana has risen from 12% since 1969 to 58% as of 2013).

3. See *id.* (showing that 23% of Americans favored legalization of marijuana in 1985).

4. See Lydia Saad, *In U.S., 38% Have Tried Marijuana, Little Changed Since ‘80s*, GALLUP (Aug. 2, 2013), <http://www.gallup.com/poll/163835/tried-marijuana-little-changed-80s.aspx>; Swift, *supra* note 1.

5. See Saad, *supra* note 4 (displaying marijuana usage change from 33% to 38% between 1985 and 2013).

6. See *id.*; Swift, *supra* note 1.

7. See MARIJUANA POLICY PROJECT, SUPPORT FOR MARIJUANA POLICY REFORM 1 (2014) available at <http://www.mpp.org/assets/pdfs/library/State-Polling.pdf>.

8. See *State Marijuana Laws Map*, GOVERNING, <http://www.governing.com/gov->

Currently, twenty-three states and the District of Columbia have legalized possession of marijuana in some form.⁹ As of November 2014, Alaska, Oregon, and the District of Columbia have pushed their legalization efforts beyond medicinal use joining Colorado and Washington in legalizing marijuana for recreational use.¹⁰ The District of Columbia's recreational marijuana initiative, Initiative 71, took effect on February 26, 2015.¹¹ Colorado is collecting millions of dollars per month in revenue from marijuana taxes, fees, and licensing, which may encourage states that have legalized medicinal marijuana to legalize recreational marijuana.¹² Indeed, 2014 was a substantial year for marijuana legalization efforts.¹³ However, analysts suggest that multiple more state ballot initiatives are likely to follow in the coming years, which could make the legalization of marijuana a platform issue in the 2016 presidential election.¹⁴

This Comment argues that marijuana could not be regulated under the Food and Drug Administration (FDA) drug regime easily, and would rather be best regulated under a new Food, Drug, and Cosmetic Act (FDCA) statutory section resembling the FDCA's tobacco section. Part II examines the FDA's regulatory models that could be used to regulate marijuana.¹⁵ Part III applies marijuana to existing regulatory models.¹⁶ Part IV

data/state-marijuana-laws-map-medical-recreational.html (last visited Nov. 9, 2014) [hereinafter *Marijuana Map*] (discussing the fact that November 2014 elections resulted in Alaska, Oregon, and District of Columbia legalizing recreational marijuana).

9. *Id.*

10. *See id.*

11. *See id.* (comparing the 2014 ballot initiatives to Colorado and Washington's ballot initiatives legalizing recreational marijuana in 2012); *Press Release, Marijuana Prohibition Ends in DC as Initiative 71 Takes Effect*, DCMJ (Feb. 26, 2015), available at <http://dcmj.org/press-release-marijuana-prohibition-ends-dc-initiative-71-takes-effect/>.

12. *See Colorado Marijuana Tax Data*, COLORADO DEPT. OF REVENUE, <https://www.colorado.gov/pacific/sites/default/files/0215%20Marijuana%20Tax%2C%20License%2C%20and%20Fees%20Report.pdf> (last visited May 8, 2015) (reporting \$9 million in state revenue from marijuana for March 2015).

13. *See Marijuana Map*, *supra* note 8 (explaining that the number of states legalizing recreational marijuana doubled in 2014).

14. *See* Nick Wing, *These States Are Most Likely To Legalize Next. Will You Have A Happier 4/20 In 2015?*, HUFFINGTON POST (Apr. 18, 2014), http://www.huffingtonpost.com/2014/04/18/states-legalize-weed_n_5162737.html (last updated Apr. 23, 2014).

15. *See infra* Part II (outlining the FDA's regulatory scheme of drugs and tobacco).

16. *See infra* Part III (analyzing marijuana regulation under the FDCA's drug section and tobacco section).

concludes that marijuana has the potential to be regulated under either a drug model or tobacco model, but that the tobacco model is preferable because of its ability to incorporate the recreational use of marijuana and its lack of standardization.¹⁷

II. BACKGROUND

A. *The FDCA Gives the FDA Vast Regulatory Authority over Food, Drugs, Biologics, Dietary Supplements, Tobacco, and Medical Devices*

The FDCA empowers the FDA to exercise national authority in regulating food (including dietary supplements), drugs, medical devices, tobacco, cosmetics, and biologics.¹⁸ In giving the FDA broad regulatory power with regards to these categories, Congress intended to provide the FDA with federally mandated authority.¹⁹ The FDA is responsible for making sure that the regulatory schemes constructed by the FDCA are followed, which first requires the product in question be classified under one of the FDCA's definitions such as a cosmetic or supplement.²⁰ After the product is classified, it is regulated under the product's corresponding section in the FDCA.²¹

1. *Defining "Drug"*

Congress enacted the FDCA with the intention of it being liberally construed and interpreted "as broad as its literal language indicates."²² The FDCA defines "drug" as:

(A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of

17. See *infra* Part IV (concluding that federal regulation of marijuana is coming and its regulation will look more like a tobacco regime than a drug regime).

18. See generally 21 U.S.C. §§ 301-399f (2012) (containing all statutory provisions giving FDA regulatory authority).

19. See *What does FDA Do?*, FDA, <http://www.fda.gov/aboutfda/transparency/basics/ucm194877.htm> (last visited Oct. 20, 2014).

20. See § 321 (providing various definitions of products that fall within the FDA's regulatory authority).

21. See, e.g., §§ 341-50 (regulating food); §§ 351-60 (regulating drugs and devices); § 387 (regulating tobacco).

22. See *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (stating that definition of "drug" within FDCA was meant to be broadly interpreted).

man or other animals.²³

However, even if a product is not specifically intended to diagnose, cure, mitigate, treat, or prevent a disease; if the manufacturer makes a claim that its product can diagnose, cure, mitigate, treat or prevent a disease, then the product would be construed as a drug by the FDA.²⁴

2. *Defining “New Drug”*

Once a product is determined to be a “drug,” one would have to consider whether it is a “new drug.”²⁵ A drug is considered a new drug if it is not generally recognized by scientific experts as safe and effective for its intended use.²⁶ New drugs are prohibited from being introduced into commerce until they are deemed safe and effective.²⁷ The FDA interprets the FDCA to mean that a drug is not generally recognized as safe and effective, and thus a “new drug,” if it is marketed without an FDA-approved New Drug Application (NDA).²⁸ The Supreme Court affirmed this interpretation of the FDCA and has held that without an approved NDA a drug cannot be generally recognized as safe and effective, no matter the validity of the claim.²⁹ Minus a few narrow exceptions, an approved NDA is a required part of a drug being recognized as safe and effective in the United States.³⁰

3. *The NDA Process*

Prior to submitting an NDA, the sponsor of the NDA must submit an

23. See § 321(g)(1).

24. See, e.g., *General Mills, Inc. Warning Letter*, FDA (May 5, 2009), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2009/ucm162943.htm> (warning the makers of Cheerios® Toasted Whole Grain Oat Cereal that its health claims regarding Cheerios® reducing cholesterol made Cheerios® an unapproved new drug).

25. See § 321(p)(1) (requiring a product to first be a drug as defined by the FDCA, before considering whether the FDA has approved the product).

26. See *id.*

27. See § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed. . .”).

28. See *Weinberger v. Hynson*, 412 U.S. 609, 629 (1973).

29. See *id.* (holding “the hurdle of ‘general recognition’ of effectiveness requires at least ‘substantial evidence’ of effectiveness for approval of an NDA.”).

30. See *New Drug Application*, FDA, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/newdrugapplicationnda/default.htm> (last visited Nov. 9, 2014) (stating that every new drug since 1938 has been subject to an approved NDA before United States commercialization).

Investigational New Drug Application (IND), which primarily focuses on development of the drug's pharmacological profile and determination of its toxicity.³¹ The IND must demonstrate that the drug product is safe for testing in humans and that the clinical protocol is properly designed for its intended objectives.³² The IND requires a description of the proposed clinical studies (to assure studies would be acceptable for NDA consideration); product chemistry, manufacturing, and controls data (CMC); as well as summaries of the toxicological effects and biological disposition of the drug in animals and, if known, in humans (including non-clinical data and data from foreign studies).³³

After the FDA is satisfied with the sponsor's IND, the sponsor will begin Phase I clinical studies.³⁴ Phase I typically involves using a small volunteer group to determine metabolic and pharmacological actions associated with increasing doses allowing for preliminary evidence of the drug's effects.³⁵ Once Phase I is concluded, Phase II begins with clinical studies composed of larger subject groups, which now include subjects with the condition that the drug is proposed to treat.³⁶ The sponsor begins to collect preliminary data on effectiveness of the drug by looking at biological evidence that the drug is doing what it is supposed to do, while still examining the safety of the drug.³⁷ If the drug is still producing evidence of effectiveness, and the adverse effects are tolerable, FDA allows the sponsor to move on to Phase III clinical studies.³⁸ Phase III studies are

31. See 21 C.F.R. § 312.21.

32. See *id.* § 312.22 (stating the general principles of IND); *IND Application Reporting: Protocol Amendments*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm362503.htm> (last visited Dec. 5, 2014) (allowing sponsor to progress from Phase I to Phase II to Phase III by submitting "protocol amendments" instead of a new IND for each phase).

33. See § 312.23 (describing the contents required in IND); GUIDANCE FOR INDUSTRY BOTANICAL DRUG PRODUCTS 7, 18, FDA (June 2004) [hereinafter BOTANICAL GUIDANCE] available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070491.pdf>.

34. See § 312.2 (requiring approval of IND application before clinical testing can begin).

35. See *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last visited on Oct. 18, 2014) [hereinafter *Drug Review Process*] (providing that Phase I testing groups are generally 20 to 80 subjects).

36. See *id.* (explaining Phase II groups have 100 to 300 subjects).

37. See *id.*

38. See *id.* (stating that effectiveness must be shown in Phase II trials before a drug sponsor may move on to Phase III trials).

typically expensive multi-year studies involving thousands of subjects with the sponsor studying different doses and population groups.³⁹ After many years of research and, often the expenditure of more than a billion dollars, the sponsor can submit an NDA to the FDA to determine whether the drug will be marketable.⁴⁰

NDA regulations require the sponsor to provide the FDA with in-depth information regarding the drug, which includes the drug's components, dosages, proposed labeling, and full reports of investigations into whether the drug is safe and effective.⁴¹ The FDA will withhold approval of a new drug unless the sponsor provides substantial evidence that the drug will have the effect it purports to have under conditions of use prescribed, recommended, or suggested on the labeling.⁴² An NDA must contain substantial evidence of effectiveness derived from adequate and well-controlled clinical studies, evidence of safety, and adequate information of the product's CMC, all submitted in the format that the FDA requires.⁴³ The FDA will approve the drug for sale if, after evaluation, the FDA determines that the drug's benefits outweigh its risks.⁴⁴

However, even after approval of an NDA, the FDA monitors adverse event reports involving the approved drug, which could result in the drug being removed from the market if an unforeseen risk arises.⁴⁵ Additionally, drug approval may be contingent on the sponsor's inclusion of a voluntary

39. *See id.* (explaining Phase III clinical studies generally range from a few hundred to 3,000 participants); *see also* Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, MEDSCAPE (2001), http://www.medscape.com/viewarticle/405869_1 (estimating 10% of medication fail in Phase III trials).

40. *See* Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/> (finding that the average cost of bringing a drug to market is \$1.3 billion).

41. *See* 21 U.S.C. § 355(b) (providing a detailed list of the contents that the drug sponsor is responsible for providing within the NDA).

42. *See id.* §355(d) (providing a detailed list of factors that can result in approval being withheld besides general safety and effectiveness data, including lack of patent information and manufacturing details).

43. *See id.* § 355 (providing the less specific statutory requirements required by Congress); 21 C.F.R. part 314.50 (providing regulations promulgated by FDA concerning a NDA's content and format requirements, which is much more specific than what was originally provided by FDCA).

44. *See* *How FDA Evaluates Regulated Products: Drugs*, FDA, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm269834.htm> (last visited Oct. 18, 2014).

45. *See id.* (describing the MedWatch database used to catalog adverse events involving drugs).

or involuntary restriction, or on the contingency that the sponsor continues Phase IV clinical studies after approval for further data.⁴⁶

4. *The FDCA Gives the FDA Authority to Regulate Tobacco Products*

The FDA's regulatory authority is vast reaching beyond the regulation of drugs to include such products as tobacco.⁴⁷ In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (TCA) giving the FDA authority to regulate the manufacturing, marketing, and sale of tobacco products.⁴⁸ Congress enacted TCA with the understanding that tobacco is a legal product that poses some health risks and is only for adults.⁴⁹ However, the FDA does not regulate tobacco like drugs under the strict safe and effective standard, but instead regulates tobacco under the new standard of "appropriate for the protection of the public health."⁵⁰

The TCA creates multiple restrictions on the sale of tobacco: the purchaser must be at least eighteen years of age, purchases of tobacco products must be made face-to-face, and purchases are limited by quantity.⁵¹ Tobacco advertisements have extensive regulations, which attempt to eliminate any advertisements directed toward those under eighteen years of age.⁵² Additionally, tobacco products are misbranded if packaging makes unapproved "reduced harm" claims or the warning labels do not follow the specific visibility requirements.⁵³ Regulations require

46. See Food and Drug Administration Amendments of 2007, Pub. L. No. 110-85, 121 Stat 922 (authorizing Risk Evaluation and Mitigation Strategies (REMS) post NDA approval, which provides that the FDA may require the drug sponsor to take additional actions regarding the labeling or dispensing of its drug in order to minimize potential risks).

47. See generally 21 U.S.C. § 387 (2012) (providing the statutory framework for FDA's regulation over tobacco).

48. See generally Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat 1776.

49. See *Overview of the Family Smoking Prevention and Tobacco Control Act*, FDA [hereinafter TCA Overview], <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM336940.pdf> (last visited Oct. 19, 2014) (recognizing a goal of tobacco regulation is to prevent those under eighteen from using an addictive and potentially harmful substance before fully understanding the consequences).

50. See § 387f (authorizing Secretary to promulgate rules appropriate for the protection of the public health).

51. See TCA Overview, *supra* note 49.

52. See, e.g., *id.* (banning tobacco advertisements within 1,000 feet of a school or playground, as well as banning tobacco advertisement from sporting and entertainment events).

53. See § 387c (providing that any tobacco product that does not comply with all labeling regulations may be misbranded); § 387k (restricting the use of "reduced risk")

tobacco manufactures to register with the FDA and be subject to inspections.⁵⁴ Further, the tobacco industry must disclose all research on health, toxicological, behavioral, or physiologic effects of tobacco use.⁵⁵ The FDA may implement standards for tobacco products to regulate such things as nicotine levels, pesticide use, and manufactures discloser of all tobacco product components.⁵⁶ Additionally, if the product contains an extraneous component that is harmful it is adulterated, and the FDA may seize it.⁵⁷ Pre-market review may also be required for new tobacco products if they present a significant variation from currently marketed tobacco products.⁵⁸ Manufacturers of all new tobacco products must file a substantial equivalence report with the FDA, and the new tobacco products can be legally marketed without premarket review only if the FDA determines the new products are substantially equivalent to a predicate tobacco product.⁵⁹

However, while the TCA provides the FDA with significant regulatory power over tobacco, there are still restraints on the FDA's authority over tobacco.⁶⁰ The FDA cannot ban certain classes of tobacco products, require zero nicotine, require prescriptions to purchase tobacco, establish a minimum age older than 18 years old, or ban face-to-face sales in any particular category of retail outlets.⁶¹

terms on labeling, such as light, low, or mild); § 387h (extending FDA recall authority to misbranded or adulterated products).

54. *See* § 387e (listing specific annual registration requirements for tobacco manufacturers, including facilities and products).

55. *See* § 387d (b) (requiring data submissions relating to research activities of tobacco manufacturer); § 387e (listing specific annual registration requirements for tobacco manufacturers, including facilities and products); § 387i (requiring manufacturers to keep specified records, which Secretary may request).

56. *See* § 387d (a)(1) (requiring disclosure of tobacco product compounds); § 387g (banning the use of artificial or natural flavors as a component of cigarettes; requiring tobacco producer to abide by set pesticide levels).

57. *See* § 387b (defining adulterated tobacco products as those that are filthy, poisonous, and/or deleterious); § 387h (extending FDA recall authority to adulterated products).

58. *See* § 387j (requiring an application attesting that the new tobacco product has the same characteristics as a predicate tobacco product, or provide clinical data to support differing characteristics pose no threat to public health).

59. *See id.* (defining "predicate tobacco product" as a tobacco product that was commercially marketed (other than in a test market) as of February 15, 2007, or a product previously found to be substantially equivalent by the FDA and in compliance with the requirements of the FDCA).

60. *See generally* §§ 387f (d), 387g (d).

61. *See* §§ 387f (d), 387g (d) (providing safeguards to insure at least a minimum level of access to standard tobacco products).

Tobacco presents addictive and dangerous qualities, which, surprisingly, has only brought it under the FDA's regulation relatively recently.⁶² Tobacco has a long history in the United States: economic forces coupled with consumer needs provided the tobacco industry with political influence and the ability to silence the anti-tobacco movements.⁶³ Scientific findings and political leadership led to the tobacco industry's objection to regulation and liability.⁶⁴

III. ANALYSIS

A. Marijuana Could Not Be Regulated as a Drug Because the FDA Would Not Approve an NDA Proposing Marijuana Be Used for a Medical Purpose

As a botanical product, marijuana faces a variety of challenges regarding standardization and CMC data that regular synthetic or highly purified drugs do not encounter because they are created in a lab versus grown from the ground.⁶⁵ Currently, only two botanical drug products have met the strict NDA requirements and received FDA approval.⁶⁶

1. Marijuana Fits Firmly into the FDCA's Definition of a Drug, Which Would Require Marijuana Be Regulated Under the "Drug" Statutes

Without a federal statute expressly defining marijuana as something other than a drug, marijuana squarely fits within the FDCA's definition of a drug.⁶⁷ FDCA defines "drug" as any article listed in a major

62. See TCA Overview, *supra* note 49 (discussing 2009 amendment allowing FDA regulation of tobacco products).

63. See Paul Verkuil, "A Leadership Case Study of Tobacco and its Regulation", PUBLIC TALK, <http://www.upenn.edu/pnc/ptverkuil.html> (last visited Nov. 15, 2014) (explaining first anti-tobacco movements began in 1604, but were overcome by profit motives).

64. See *id.* (discussing the Clinton Administration's involvement in warning the public of tobacco's health risks, which helped decrease tobacco industry's political power).

65. See BOTANICAL GUIDANCE, *supra* note 33, at 2, 5 (defining "botanical product" for purposes of FDA guidance and discussing possible issues within drug approval process).

66. FDA approves first anti-diarrheal drug for HIV/AIDS patients, FDA, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701.htm> (last visited Oct. 19, 2014) (stating that the FDA has only approved two botanical drugs, Fulyzaq in 2012 and Veregen in 2006).

67. See generally 21 U.S.C. §§ 351-361 (2012) (creating the regulatory framework for drugs and devices).

pharmaceutical compendium, intended to treat, mitigate, or diagnose a medical condition; or is intended to affect the structure or function of its consumer.⁶⁸ The *United States Pharmacopeia* (USP) and the *National Formulary* (NF) both listed marijuana in their publications from 1850 until 1942, at which time marijuana was prescribed for various conditions including labor pains, nausea, and rheumatism.⁶⁹ Today, the use of medical marijuana is recognized in multiple states, allowing the medicinal use of marijuana for treating Alzheimer's disease, anorexia, AIDS, arthritis, cachexia, cancer, Crohn's disease, epilepsy, glaucoma, HIV, migraines, multiple sclerosis, nausea, pain, spasticity, and wasting syndrome.⁷⁰ Additionally, marijuana is commonly smoked by users for its stimulating effect on the brain causing the release of dopamine, which produces a euphoric sensation, or "high."⁷¹ Marijuana's prescribed use for treating diseases and conditions, and its effect on the brain's function clearly make marijuana a "drug" as defined by the FDCA.⁷²

2. *Marijuana Is a "New Drug" Because It Lacks an Approved NDA*

Marijuana's inclusion in the broadly defined drug category does not automatically require preapproval before marketing; however, it does make marijuana subject to a "new drug" analysis, which requires premarket approval if the article is a new drug.⁷³ Not only is marijuana a "drug," but it is also a "new drug."⁷⁴ Marijuana is a new drug because it is not

68. See § 321(g)(1); Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1127 (July 2008) (stating that, despite the language of the FDCA, the FDA and the courts do not regard inclusion of a substance in the compendia as in and of itself sufficient for drug classification).

69. See Gerald Gianutsos, *Medical Marijuana: Therapeutic Uses and Legal Status*, US PHARMACIST (Oct. 1, 2010), http://www.uspharmacist.com/continuing_education/ceviewtest/lessonid/106975/ (stating marijuana has been cultivated in the United States since 1611).

70. See UNITED STATES GENERAL ACCOUNTING OFFICE, MARIJUANA EARLY EXPERIENCES WITH FOUR STATES' LAWS THAT ALLOW USE FOR MEDICAL PURPOSES, 51-53 (2002), available at <http://www.gao.gov/assets/240/236305.pdf>.

71. See *How does marijuana produce its effects?*, NAT'L INST. ON DRUG ABUSE, <http://www.drugabuse.gov/publications/research-reports/marijuana/how-does-marijuana-produce-its-effects> (last viewed May 12, 2014).

72. See *id.* (discussing marijuana's effects on brains regulation of balance, posture, coordination, and reaction time).

73. See 21 C.F.R. § 310.100 (2014) (explaining that some drugs marketed before 1938 are covered under a grandfather clause allowing those drugs to be marketed without premarket approval as long as drug has not changed in formulation, manufacture control, or labeling in a way that may significantly affect safety of drug).

74. See generally 21 U.S.C. § 355 (2012) (proving the statutory regulations for

generally recognized by scientific experts as safe and effective for use under the conditions prescribed or recommended.⁷⁵ Without having been deemed safe and effective, “new drugs” are prohibited from being introduced into commerce.⁷⁶ While marijuana has been in society and used medicinally for a long time, the FDA states that a drug is a “new drug” if marketed without an FDA approved New Drug Application (NDA), and marijuana has no uses that have been approved through the NDA process.⁷⁷ Currently, the FDA’s position on the medicinal use of marijuana is clear; it explicitly concluded in 2011 that marijuana has a high potential for abuse, is not currently recognized for medical use, and is unsafe to use under medical supervision.⁷⁸ Marijuana has not been subjected to the NDA process, nor has it been generally recognized as safe and effective for treating and conditions, so it is a “new drug” under the FDCA that would be illegal to sell.⁷⁹

3. *Marijuana Would Likely Not Be Approved in the NDA Process Because as a Botanical Drug It Is Difficult to Standardize Marijuana to Ensure Consistent Dosing and Active Constituents*

For marijuana to become recognized as safe and effective for a particular use, FDA would have to approve a New Drug Application (NDA) proposing marijuana be used to treat a specific condition or disease.⁸⁰ An NDA requires the sponsor to provide the FDA with in-depth information regarding the drug, including the drug’s components, dosages, proposed labeling, and full reports of investigations into whether the drug is safe and effective.⁸¹ The FDA will withhold approval of a new drug unless the sponsor provides substantial evidence that the drug will have the effect it purports to have under conditions of use prescribed, recommended, or

new drugs).

75. See *id.* § 321(p)(1) (defining “new drug”).

76. See *id.* § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug,” unless the new drug’s NDA has been approved).

77. See *FDA and Marijuana*, FDA, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm> (last visited May 8, 2015) [hereinafter *FDA and Marijuana*] (stating that “FDA has not approved marijuana as a safe and effective drug for any indication.”).

78. See 76 Fed. Reg. 40552 (July 8, 2011) (denying petition to reschedule marijuana).

79. See § 321(p)(1) (stating that a drug is a new drug is not generally recognized as safe and effective among experts); *FDA and Marijuana*, *supra* note 96 (stating that marijuana has not been generally recognized as safe and effective among experts).

80. See § 355(b) (requiring an NDA to provide reports of the drugs effective use).

81. See *id.*

suggested on the labeling.⁸² As discussed above, substantial evidence of effectiveness and safety ordinarily must be proven by three stages of well-controlled clinical studies.⁸³

a. IND Approval for Phase I and Phase II Studies

Before marijuana could be tested in clinical studies, the sponsor would have to submit an IND providing an overview of marijuana's chemical constituents, manufacturing and processing, safety data, and details on the proposed clinical studies.⁸⁴ Providing marijuana's chemical constituents would be the first difficulty when submitting an IND because scientists continue to have difficulty identifying some of the hundreds of chemical constituents in.⁸⁵ In a guidance document, however, the FDA has recognized that in many cases the active constituent in a botanical drug is not identified, nor is its biological activity well characterized, and thus has suggested that active constituents need not be completely identified during the IND process.⁸⁶

Nevertheless, the FDA would evaluate other factors of the IND more critically because of the lack of knowledge concerning marijuana's active constituents.⁸⁷ The FDA's general guidance on botanicals, as applied to marijuana, suggest a combination of tests and controls would need to be implemented in order to ensure the identity, purity, quality, strength, potency, and consistency of marijuana.⁸⁸ The manufacturing process will need to be well-defined within the CMC portion of the IND including

82. See § 355(d)-(e) (stating NDA approval will be withdrawn upon finding imminent hazard to public health).

83. See *Drug Review Process*, *supra* note 35 (overviewing FDA's drug review process: animal testing, IND, Phase I-III testing, review meeting, NDA submission, NDA review).

84. See *id.*; 21 C.F.R. § 312.22 (2014) (stating that IND must contain sufficient information to demonstrate that drug product is safe for testing in humans and that clinical protocol is properly designed for its intended objectives).

85. *What Chemicals Are in Marijuana and Its Byproducts?*, PROCON, <http://medicalmarijuana.procon.org/view.answers.php?questionID=636> (last updated Aug. 8, 2009, 6:11 PM) (discussing composition of marijuana and difficulties with determining all of its compounds).

86. See BOTANICAL GUIDANCE, *supra* note 33, at 5 (suggesting that constituents do not need to be fully identified during IND, but will need to be further identified for ultimate NDA approval).

87. See *id.* (suggesting more stringent manufacturing controls to insure consistent product is constituents cannot be identified).

88. See *id.* (including (1) multiple tests for drug substance and drug product, (2) raw material and process controls, and (3) process validation).

adequate in-process controls.⁸⁹

Consistency could be the biggest challenge because variations in soil, geographical region, water, light, harvesting, and storage condition magnify the inconstant chemical makeup of marijuana and make marijuana standardization nearly impossible.⁹⁰ If the drug sponsor cannot show the ability to consistently produce a single formulation and dose of marijuana from batch-to-batch the FDA would likely deny the NDA because inconsistencies between batches would cause uninterpretable results in the clinical trial.⁹¹ IND approval only permits the drug sponsor to conduct clinical trials with the new drug, which will provide the data that is ultimately submitted for NDA consideration.⁹² If the clinical trials do not conform to clinical standards the FDA will likely deny the drug sponsor's NDA because the results of the studies are not credible.⁹³ The dosage and composition of the marijuana will be very important during clinical trials to ensure credible results for the NDA.⁹⁴ However, marijuana plants do not need to be produced perfectly identical.⁹⁵ "Different plant strains and batches vary radically in their levels of psychoactive substances and in the contaminants — fungi, bacteria, pesticides, heavy metals and other substances — they contain."⁹⁶ The drug sponsor must state in the IND how it would control all of these factors in order to produce a standardized product.⁹⁷ Although lack of standardization would not prevent approval of the IND for initial clinical trials, it could hinder IND proposals for Phase

89. See § 312.23(a)(7)(iv).

90. See Claire Frezza, *Medical Marijuana: A Drug Without A Medical Model*, 101 *Geo. L.J.* 1117, 1135 (2013) (quoting Suzanne D. McGuire, Comment, *Medical Marijuana: State Law Undermines Federal Marijuana Policy—Is the Establishment Going to Pot?*, 7 *SAN JOAQUIN AGRIC. L. REV.* 73, 74-75 (1997)).

91. See BOTANICAL GUIDANCE, *supra* note 33, at 11-12 (recommending the sponsor outline its ability to produce batch-to-batch consistency within the CMC data).

92. See *Drug Review Process*, *supra* note 35.

93. See generally § 314.125 (stating reasons for NDA refusal, including, inadequate methods for controls).

94. See BOTANICAL GUIDANCE, *supra* note 33, at 11-12 (recommending a single formulation and a single dosage form be used throughout different states of the clinical trials unless impossible).

95. See *id.* (suggesting samples be retained from Phase I and Phase II trials for product comparison with the product used in Phase III trials to ensure batch consistency).

96. See Henry I. Miller, *The Real Dope On Medical Marijuana*, *FORBES* (Mar. 28, 2012, 10:56 AM), <http://www.forbes.com/sites/henrymiller/2012/03/28/the-real-dope-on-medical-marijuana/>.

97. See BOTANICAL GUIDANCE, *supra* note 33, at 10-12 (discussing CMC requirements of § 312.23(a)(7)).

III clinical studies and, ultimately, the approval of its NDA.⁹⁸

Showing that marijuana can be standardized through testing and controls is important for IND approval, but a showing that marijuana is safe for human studies is more important.⁹⁹ The drug sponsor must provide pharmacological and toxicological information within the IND.¹⁰⁰ The proposed dose of marijuana to be tested must be shown to be safe through clinical and nonclinical data, which may include studies not conducted by the sponsor (e.g. foreign studies).¹⁰¹ The sufficiency of data required for Phase I and Phase II testing is relatively low compared to what is necessary for Phase III testing.¹⁰²

Moreover, the extensive use of marijuana in humans already may provide sufficient information to support initial clinical studies, forgoing the standard in vivo or in vitro experiments testing articles under laboratory conditions which the FDA generally requires.¹⁰³ Currently, there are a variety of peer-reviewed studies weighing in on the safety and efficacy of marijuana that provide data for the FDA's consideration.¹⁰⁴ Arguably, the largest safety concern of marijuana is the delivery method: smoking presents issues of pulmonary disease and lung cancer.¹⁰⁵ The safety of

98. See 21 U.S.C. §355(d) (2012) (requiring NDA to contain substantial evidence of effectiveness derived from adequate and well-controlled clinical studies); BOTANICAL GUIDANCE, *supra* note 33, at 11-12 (explaining the importance of product consistency for Phase III trials).

99. See 21 C.F.R. §312.22 (2014) (requiring IND to contain sufficient information to demonstrate that drug product is safe for testing in humans).

100. See *id.* § 312.23(a)(8) (describing content and format of pharmacological and toxicological information to be provided in IND).

101. See BOTANICAL GUIDANCE, *supra* note 33, at 13 (stating less safety data is necessary for initial clinical trials than what is expected from by synthetic or highly purified drugs).

102. See *id.*; *Drug Review Process*, *supra* note 35 (explaining that Phase I testing is used to determine safety and side effects on healthy individuals).

103. See BOTANICAL GUIDANCE, *supra* note 33, at 25-26 (comparing herbal products with extensive human use that require less safety testing to synthetic drugs with little to no human use that require more extensive nonclinical safety testing).

104. See 60 *Peer-Reviewed Studies on Marijuana*, PROCON, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000884> (last updated Feb. 27, 2015) (providing medical studies involving cannabis and cannabis extracts, from 1990-2014).

105. See Jenny Hope, *Cannabis 'kills 30,000 a year'*, DAILY MAIL, <http://www.dailymail.co.uk/health/article-179264/Cannabis-kills-30-000-year.html> (last visited Oct. 24, 2014) (speculating that marijuana smokers suffer from lung disease at same rates as cigarette smokers); MARIJUANA AND MEDICINE ASSESSING THE SCIENCE BASE 6, IOM (1999), available at http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf (recommending marijuana not be smoked because of

marijuana is widely debated; however, due to the low threshold of safety data required for initial studies, marijuana would be safe enough to progress to clinical studies.¹⁰⁶ Upon IND approval for Phase I and Phase II studies, the drug sponsor would further identify marijuana's constituents, continue to develop safety data, and begin to establish an effective dose of marijuana.¹⁰⁷

b. IND Approval for Phase III Studies

IND approval for Phase III studies of marijuana will be much more difficult to obtain because the sponsor is expected to provide more detailed information of CMC and safety than when conducting a Phase I or Phase II study.¹⁰⁸ The FDA would require additional safety data in order to support marijuana's use among a much larger subject population size.¹⁰⁹ As in Phase I and Phase II, past human and animal studies will be considered; however, further systematic toxicological evaluations could be needed to supplement available knowledge on the general toxicity, teratogenicity, mutagenicity, and carcinogenicity of the final marijuana product.¹¹⁰

Further detail regarding CMC data is required to ensure the reproducibility of the substance.¹¹¹ If the marijuana cannot be standardized through manufacturing and controls, the Phase III trials are unlikely to produce consistent data supporting the use of marijuana for the chosen

harmful effects of smoking).

106. See *Deaths from Marijuana v. 17 FDA-Approved Drugs*, PROCON, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000145> (last visited Oct. 24, 2014) (demonstrating that there are fewer marijuana related deaths than compared to many FDA approved drugs). But see Roxanne Khamsi, *How Safe Is Recreational Marijuana?*, SCIENTIFIC AMERICAN (May 14, 2013), <http://www.scientificamerican.com/article/how-safe-recreational-marijuana/?page=2> (describing marijuana's negative effects to cognitive and motor function).

107. *Drug Review Process*, *supra* note 35 (stating Phase I testing focuses on safety, and Phase II testing examines effectiveness).

108. See 21 C.F.R. § 312.22(b) (2014) (stating that information required for IND approval is based on which Phase is being approved); BOTANICAL GUIDANCE, *supra* note 33, at 27 (presenting guidance that more detailed information is required for Phase III studies).

109. See BOTANICAL GUIDANCE, *supra* note 33, at 27 (requiring additional toxicology data to support the product's wider use within Phase III); *Drug Review Process*, *supra* note 35 (explaining that in Phase III trials the subject group is generally between several hundred and 3,000 people).

110. See BOTANICAL GUIDANCE, *supra* note 33, at 34-35 (depending on indication, route of administration and duration of recommended drug exposure, and other requirements, nonclinical animal studies can vary).

111. See BOTANICAL GUIDANCE, *supra* note 33, at 27 (stressing the importance of reproducibility in ensuring consistent data in well-controlled trials).

condition.¹¹² Standardizing marijuana requires producing batches of plants with qualitatively and quantitatively comparable chemical constituents. Batch to batch inconsistency will likely plague marijuana's approval because many strains of marijuana exist, each presenting a different variety of characteristics.¹¹³ Additionally, environmental factors would create further inconsistencies within each batch of marijuana.¹¹⁴ One could imagine that Phase III studies would produce inconsistent data if a main active constituent, say Tetrahydrocannabinol (THC), was found at different levels per unit of marijuana.¹¹⁵ However, the solution to producing consistent batches of marijuana could be the implementation of extensive manufacturing controls.¹¹⁶ The sponsor achieves quality and consistency of the final drug product by controlling the botanical source and adequate blending, in combination with other downstream CMC controls on the manufacturing processes.¹¹⁷ The final studies towards proving marijuana's effectiveness would commence upon the approval of marijuana's IND for Phase III.¹¹⁸

112. *See id.*

113. *See Cannabis Strain and Infused Product Explorer*, LEAFLY, <http://www.leafly.com/explore> (last visited Oct. 30, 2014) (documenting 1024 strains of marijuana and general characteristics of each strain); *cf.* CENTER FOR DRUG EVALUATION AND RESEARCH, CROSS DISCIPLINE TEAM LEADER REVIEW APPLICATION NUMBER 202292ORIG1S000 7-12, (2012), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202292Orig1s000CrossR.pdf (noting CMC issues Fulyzaq, the second botanical drug ever approved, faced during NDA review).

114. *See Frezza, supra* note 90, at 1135 (quoting Suzanne D. McGuire, Comment, *Medical Marijuana: State Law Undermines Federal Marijuana Policy—Is the Establishment Going to Pot?*, 7 SAN JOAQUIN AGRIC. L. REV. 73, 74-75 (1997)).

115. *See* Karl W. Hillig & Paul G. Mahlberg, A CHEMOTAXONOMIC ANALYSIS OF CANNABINOID VARIATION IN *CANNABIS* (CANNABACEAE), 91 AM. J. BOT. 966, 971-73 (June 2004), *available at* <http://www.amjbot.org/content/91/6/966.full.pdf+html> (finding that various environmental and genetic factors determine the qualitative and quantitative levels of cannabinoids within marijuana).

116. *See* BOTANICAL GUIDANCE, *supra* note 33, at 5 (suggesting the use of manufacturing controls to ensure identity, purity, quality, strength, potency, and consistency of botanical drugs).

117. *Cf.* BOTANICAL REVIEW APPLICATION NUMBER 21-202, CENTER FOR DRUG EVALUATION AND RESEARCH (Oct. 31, 2006), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021902s000_botanicalr.pdf (noting recommendations for standardizing Veregen, the first botanical drug approved by the FDA, during NDA review).

118. *See Drug Review Process, supra* note 35 (noting Phase III studies further test safety and effectiveness among different patient populations and dosages).

c. *NDA Review*

While the duration of clinical studies vary, the process of clinical testing and NDA review for marijuana may take upwards of fifteen years to complete.¹¹⁹ It will be up to marijuana's sponsor to successfully show that marijuana is safe and effective for treating a specific condition or disease.¹²⁰ There is no specific number or value that all drugs are compared to when determining safety and effectiveness.¹²¹ Instead, the FDA applies a risk-benefit analysis.¹²² Marijuana does not need to be more effective than existing treatments for approval; marijuana only needs to be proven effective through clinical testing.¹²³ The FDCA does not clearly define "safe," and thus the FDA would base its determination on whether the benefits of marijuana outweigh the potential risks.¹²⁴ The technical requirements are equally important, such as demonstrating that the manufacturer can produce a standardized marijuana product and that the clinical trials supporting marijuana's effectiveness were conducted in accordance to good clinical practice (GCP).¹²⁵ If marijuana's NDA is

119. *How long does it take for a new drug to go through clinical trials?*, CANCER RESEARCH UK, <http://www.cancerresearchuk.org/about-cancer/cancers-in-general/cancer-questions/how-long-does-it-take-for-a-new-drug-to-go-through-clinical-trials> (last visited Nov. 2, 2014) (explaining time it take to complete clinical trials varies on type of disease, method of treatment, number of patients needed, length of treatment, length of follow up period required, and any problems encountered).

120. 21 U.S.C. § 355(b)(1) (2012) (requiring NDA to be filed demonstrating a new drug's safety and effectiveness).

121. Brady Dennis, *FDA's 'safe and effective' drug approvals based on widely varied data, study finds*, WASH. POST (Jan. 21, 2014), http://www.washingtonpost.com/national/health-science/fda-drug-approvals-based-on-varied-data-study-finds/2014/01/21/b12d0712-82be-11e3-8099-9181471f7aaf_story.html (discussing that FDA's determination of safe and effectiveness lacks uniformity, and that amount of data required for one drug's approval may not suffice for another's).

122. *See id.*

123. *See* 21 C.F.R. § 314.105 (2014) (stating that the FDA has flexibility in applying statutory standards, and uses its own scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards); Robert J. Temple, *Comparative Effectiveness Research*, FDA (Apr. 21, 2010), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM209270.pdf> (stating that legislative history is clear, a new drug does not have to be better than, or as good as existing treatments).

124. *Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making*, FDA (Feb. 2014), *available at* <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf> (recognizing that all drugs have the ability to cause adverse effects, and thus are examined on a benefit-risk assessment unique to each case).

125. *See* BOTANICAL GUIDANCE, *supra* note 33, at 33 (recommending that batch-to-

submitted with careful consideration to FDA guidance and regulations then the FDA's decision should follow within ten months.¹²⁶ Assuming marijuana's sponsor is able to show the necessary effectiveness and safety, the CMC issues would still have to be worked out in order to assure consistency of the product and, ultimately, approval from the FDA.¹²⁷ Additionally, if marijuana were approved, only the specific strain of marijuana that received an approved NDA would be available by prescription.¹²⁸ Any changes to the approved marijuana product would require additional FDA premarket approval.¹²⁹

B. Marijuana Regulated Under the Tobacco Provisions of the FDCA

Much like drugs, tobacco is regulated to minimize its harmful effects to society; however, tobacco regulation is much less restrictive and provides greater accessibility.¹³⁰ Marijuana should be regulated like tobacco by recognizing marijuana as a legal product that is only for adults, even

batch consistency be shown); *Clinical Trial Guidance Documents*, FDA, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122046.htm> (last visited Nov. 2, 2014) (providing documents on what the FDA considers to be good clinical practice because how clinical trials are conducted is taken into consideration during NDA review).

126. See Dhiren N. Shah, OBTAINING APPROVAL OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS FROM A CHEMISTRY, MANUFACTURING, AND CONTROLS PERSPECTIVE 406, AVENTIS PHARMACEUTICALS (2005), available at <http://www.slideshare.net/priyankagarapu/nda-anda-approval> (noting from a technical regulatory perspective, if all the work is done properly as described in sections a-h, the NDA submission should become fairly easy); Drug Review Process, *supra* note 35 (stating that 90% of NDA applications are acted upon within 10 months).

127. See 21 U.S.C. § 355(d) (2013) (stating that a NDA may be refused if the methods used, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity).

128. See § 353(b) (requiring drugs that present potential safety issues be only prescribed by a licensed practitioner, and only be dispensed by a pharmacist).

129. See GUIDANCE FOR INDUSTRY CHANGES TO AN APPROVED NDA OR ANDA, FDA (Apr. 2004), available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm077097.pdf> (explaining changes to an approved drug that effect its identity, strength, quality, purity, or potency must be submitted to FDA for approval before further marketing).

130. See, e.g., § 387f (d) (preventing the promulgation of rules that would require a prescription for tobacco). *But see Drugs Applications for Over-the-Counter (OTC) Drugs*, FDA, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm> (last viewed Dec. 4, 2014) (explaining OTC drugs are safe and effective for use by general public without seeking treatment by a health professional).

though it poses potential health risks.¹³¹ The Secretary of HHS would also possess the authority to promulgate rules, upon Congress specifically giving the FDA authority over marijuana, appropriate to minimizing the potential risks of marijuana, while still allowing society to access it with great ease as compared to drug regulations.¹³² The FDA would regulate almost every aspect of the marijuana industry, including manufacturing, labeling, advertising, and sale.¹³³

The manufacturing of marijuana could be regulated in multiple ways similar to how tobacco is regulated, which would ensure that consumers get the safest product possible.¹³⁴ Manufacturers would have to disclose all components of the marijuana products, and the FDA could regulate the amounts of each component, such as THC.¹³⁵ Additionally, the FDA would have the authority to impose strict quality standards to assure nothing is introduced into the marijuana that could present additional risks to the consumer, such as intentional or unintentional chemical additives.¹³⁶

Restrictions on labeling and advertisement would allow the FDA to control the information consumers get about marijuana, as well as which consumers are targeted with that information.¹³⁷ Like the FDA's goal in regulating tobacco, the goal with marijuana will be ensuring people are aware of its risks, and preventing marijuana use among minors.¹³⁸ Labeling

131. See TCA Overview, *supra* note 49 (explaining a goal of tobacco regulation is to prevent use of a potentially harmful substance before fully understanding risks).

132. See § 387f (giving HHS Secretary authority to create rules promoting public health with regards to tobacco).

133. See generally § 387 (imposing regulations upon tobacco sales, advertising, labeling, and manufacturing).

134. See § 387d (b) (requiring data submissions relating to research activities of tobacco manufacturer); § 387e (listing specific annual registration requirements for manufacturers, including facilities and products); § 387i (requiring manufacturers to keep and present specified records on request); § 387t(2) (allowing promulgation of rules related to inspection).

135. See § 387d (a)(1) (requiring disclosure of tobacco product compounds); § 387g (stating tobacco product standards); *Drug Facts: Marijuana*, NATIONAL INSTITUTE ON DRUG ABUSE (January 2014), <http://www.drugabuse.gov/publications/drugfacts/marijuana> (arguing increase of THC in marijuana creates adverse effects).

136. See § 387b (defining tobacco products that are filthy, poisonous, or deleterious as adulterated); § 387h (explaining FDA's recall authority of misbranded or adulterated products).

137. See TCA Overview, *supra* note 49 (banning tobacco advertisements within 1,000 feet of a school or playground, as well as banning tobacco advertisement from sporting and entertainment events).

138. See *id.* (explaining a goal of tobacco regulation is to prevent use of a potentially harmful substance before fully understanding risks).

restrictions would effectively eliminate manufacturers from marketing their products as safe, and would impose visibility requirements on any health warnings the Secretary of HHS deems necessary.¹³⁹ Marijuana manufacturers under such a regime could not market their products as safe because marijuana has side effects, including diminished cognitive performance and many of the same respiratory illnesses associated with smoking tobacco.¹⁴⁰

Furthermore, sales regulations on marijuana could reduce access to the substance for minors.¹⁴¹ The Secretary of HHS could impose an age restriction on sales of marijuana.¹⁴² An age restriction would mean that no business, in any state, could sell marijuana to an individual under a specific age.¹⁴³ Equally important, the Secretary is restricted from making the minimum age greater than eighteen years old for tobacco, and thus still maintaining access for the adult population.¹⁴⁴ By using the tobacco model as the framework for marijuana regulation, a minimum age should be imposed, but experts may want to impose a different age than that of tobacco because of marijuana's effects on brain development.¹⁴⁵

The tobacco provisions that are most distinguishable from the drug model are those that limit the FDA's authority to promulgate rules that would severely restrict access to tobacco, e.g., not allowing the FDA to restrict face-to-face sale, to ban certain categories of tobacco, or to require prescriptions to purchase tobacco.¹⁴⁶ These limitations decrease the FDA's

139. See § 387c (stating a tobacco product that does not have proper labeling or is misleading will be considered misbranded); § 387k (restricting use of "reduced risk" terms on labeling, such as light, low, or mild); § 387h (explaining that the FDA has authority to recall a product if it is misbranded).

140. See *Drug Facts: Marijuana*, *supra* note 135 (finding marijuana smoke to be a lung irritant causing daily cough and phlegm production, more frequent acute chest illness, and a heightened risk of lung infections).

141. See TCA Overview, *supra* note 49.

142. Cf. § 387f(d) (allowing promulgation of restrictions on sale and distribution of a tobacco products).

143. See *id.* (providing authority to promulgate rules appropriate for the protection of the public health).

144. See § 387f (d)(3)(A)(ii) (limiting the Secretary's ability to establish a minimum age older than 18 year old for tobacco products).

145. See *Drug Facts: Marijuana*, *supra* note 135 (explaining that heavy marijuana during adolescent years causes a decline in IQ); Michael Martinez, *10 things to know about nation's first recreational marijuana shops in Colorado*, CNN (Jan. 1, 2014), <http://www.cnn.com/2013/12/28/us/10-things-colorado-recreational-marijuana/> (requiring marijuana buyers to be 21 or older in Colorado).

146. See generally § 387f (d)(3)(A) (detailing restrictions on the Secretaries rule making authority).

authority enough to ensure access to tobacco products, and thus would provide easier access to marijuana, especially compared to marijuana regulated under the drug provisions.¹⁴⁷ If marijuana were regulated with these same access-promoting provisions as tobacco, it would remain regulated, but not to the point of being regulated out of the market as would happen if marijuana were regulated as a drug.¹⁴⁸

1. Premarket Approval for “New Tobacco Products” Could Not Be Used to Regulate New Marijuana Products Because the Analysis Is based on Previously Marketed Products

FDCA provides that “new tobacco products” must be pre-approved by the FDA before being marketed.¹⁴⁹ This provision would not work with marijuana because the premarket review compares the new tobacco product to tobacco products that are currently being commercially marketed.¹⁵⁰ A provision comparing new products to already marketed products works for tobacco because the industry is well established. Tobacco products have been marketed for hundreds of years, so there are standards to compare the new products to.¹⁵¹ Marijuana, on the other hand, is not legally sold in the United States, so there are no existing products to base a new product determination from.¹⁵² Since the FDA lacks the ability to compare new marijuana products to currently marketed products, the regulations requiring premarket approval for new marijuana products would not work.¹⁵³ Nevertheless, a solution for premarket review of marijuana would require further research, because without premarket review marijuana would be less regulated than tobacco.¹⁵⁴ Possible solutions that should be explored include prospective legislation that creates a predicate marijuana

147. *See id.* (providing limits to rule making as not to challenge tobacco’s recreational use).

148. *Compare* § 387f (restricting rule promulgation authority to insure access) *with* § 355 (requiring an extensive premarket approval process before a new drug can be marketed).

149. *See* § 387j (defining tobacco products not marketed before February 15, 2007, or existing tobacco products that are modified as new tobacco products).

150. *See id.* (comparing materials, ingredients, design, composition, heating source, and other features).

151. *See* § 387j (2)(A)(i)(I) (exempting product that are substantially equivalent to traditional tobacco products from new product requirements).

152. § 812 (placing marijuana in the Schedule I category of illicit drugs, and thus making it a Federal crime to sell marijuana in the United States).

153. *See* § 387j (defining tobacco products not marketed before February 15, 2007, or existing tobacco products that are modified as new tobacco products).

154. *See id.* (requiring new tobacco product, that are not substantially equivalent to predicate tobacco product, to undergo premarket review).

product once marijuana has been commercially marketed for a couple of years or a mandatory premarket review that is based on a new standard.¹⁵⁵

The drug model and tobacco model both provide viable regulation schemes that could be used to regulate marijuana.¹⁵⁶ A drug model would provide the greatest control over marijuana, requiring thorough premarket review in order to demonstrate safety and effectiveness.¹⁵⁷ Premarket review for a drug is very costly and time consuming, and ultimately may not result in approval.¹⁵⁸ Additionally, the drug model would limit marijuana to medicinal use only, which would require people to obtain a prescription for lawful use, thereby restricting access.¹⁵⁹ The tobacco model is in some ways like the drug model, providing regulation over manufacturing, labeling, advertising, and sale.¹⁶⁰ However, the tobacco model would better handle the variety of marijuana strains by not requiring production to be limited to a single standardized product, unlike the drug model that requires one uniform product.¹⁶¹ The tobacco model would provide less control over marijuana, creating a balance between access and oversight by recognizing marijuana as a legal product, for adults, that poses potential health risks.¹⁶² Although the tobacco model would best accommodate the recreational use of marijuana, it would not be able to formally recognize valid medicinal uses of marijuana.¹⁶³ Any claim from a manufacturer that its marijuana product could be used to treat or mitigate some condition would instantly make that marijuana product an

155. This comment recognizes that some degree of premarket review would be critical, however, the creation of a new premarket review exclusively for marijuana is outside the purview of this comment.

156. *See generally* §§ 301 *et seq.* (providing statutes for the regulation of drugs and tobacco).

157. *See generally* § 355 (requiring the sponsor of any new drugs to demonstrate safety and effectiveness through clinical trials before commercially marketing the product).

158. *See Herper, supra* note 40 (explaining a single clinical trial can cost up to \$100 million).

159. *See* § 353(b) (requiring drugs with potential safety issues be prescribed by a licensed practitioner).

160. *See generally* § 387 (imposing regulations upon tobacco sales, advertising, labeling, and manufacturing).

161. *See* BOTANICAL GUIDANCE, *supra* note 33, at 11-12 (recommending sponsor produce batch-to-batch consistency).

162. *See* TCA Overview, *supra* note 49 (explaining a goal of tobacco regulation is to prevent use of a potentially harmful substance before fully understanding risks).

163. *See* § 321(g) (stating that claims to mitigate, treat, or prevent disease makes a product a drug).

unapproved new drug.¹⁶⁴ Regardless, physicians could still recommend a marijuana product for purposes of treatment, even if that product is not formally recognized for treating said condition.¹⁶⁵ Nevertheless, the tobacco model provides enough regulation to minimize the risks marijuana may present, such as pulmonary disease and access for minors.¹⁶⁶ The major difference between the drug model and tobacco model is that the tobacco model would provide explicit statutory language preventing FDA from issuing regulations that would greatly inhibit access to marijuana.¹⁶⁷ A tobacco model would allow for distribution similar to cigarettes or alcohol.¹⁶⁸ Because tobacco is a botanical product, the tobacco model would better incorporate marijuana, allowing the inconsistencies and variations that the drug model is not meant to handle.¹⁶⁹

IV. CONCLUSION

The majority opinion in the United States favors the legalization of marijuana.¹⁷⁰ A significant number of states have legalized marijuana for medicinal use, and a growing number of states have legalized marijuana for recreational use.¹⁷¹ When the federal government decides to follow the majority and legalize marijuana to some degree, they will have various models of regulation to choose from.¹⁷² The drug model provides the best regime for marijuana if legalized purely for medicinal purposes.¹⁷³ Even

164. See § 321(p) (stating that any drug without an approved NDA is a new drug).

165. Cf. “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet, FDA, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> (last visited Dec. 5, 2014) (recognizing physicians ability to prescribe medicine for off-label uses).

166. See § 387f (giving HHS Secretary authority to create rules promoting public health with regards to tobacco).

167. See generally § 387f (d) (detailing restrictions on the Secretaries rule making authority).

168. See *id.* (providing that face-to-face sales cannot be eliminated, nor can a prescription be required to by tobacco)

169. See BOTANICAL GUIDANCE, *supra* note 33, at 2 (defining botanical product as a finished product that contains vegetable matter).

170. See Swift, *supra* note 1 (discussing that 58% of Americans favor legalization of marijuana).

171. See Marijuana Map, *supra* note 8 (showing 23 state and the District of Columbia have legalized marijuana).

172. See generally §§ 301 *et seq.* (providing FDA with authority to regulate a variety of products accounting for about 25 cents of every dollar spent by consumers in the United States).

173. See § 355 (requiring new drugs to be generally recognized as safe and effective by experts).

though marijuana would have difficulties obtaining an NDA due to standardization issues, the drug model's safe and effective standard would ensure patients get the best marijuana product for treating their condition.¹⁷⁴ However, if recreational use of marijuana is legalized, then the tobacco model would be far superior, providing enough regulation to mitigate risk but maintain access to marijuana, while also avoiding standardization issues.¹⁷⁵ Nevertheless, the current FDA regime could incorporate both models by allowing the tobacco model to regulate recreational use, while still affording manufacturers the opportunity to submit NDAs if they wish to make drug claims or have their products covered by insurance.¹⁷⁶ Current medical marijuana markets include different strains of marijuana that are supposedly better for particular conditions.¹⁷⁷ A mature medical marijuana market almost certainly will not be one size fits all.¹⁷⁸ Producers will want to customize their products and make claims promoting specific products for specific uses.¹⁷⁹ The legalization of marijuana is coming and the FDA has the means to regulate its distribution.¹⁸⁰

174. See BOTANICAL GUIDANCE, *supra* note 33, at 11-12 (recommending a single formulation and a single dosage form be used throughout different states of the clinical trials unless impossible).

175. See TCA Overview, *supra* note 49 (explaining a goal of tobacco regulation is to prevent use of a potentially harmful substance before fully understanding risks).

176. See MEDICARE DRUG COVERAGE UNDER MEDICARE PART A, PART B, PART C, & PART D, HHS (Jan. 2014), available at <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11315-P.pdf> (requiring a medication to be FDA approved in order for Medicare Part D to cover it).

177. See *How Do You Know What Medical Marijuana Strain Is Right for You?*, UNITED PATIENTS GROUP (Jan. 31, 2012), <http://www.unitedpatientsgroup.com/blog/2012/01/31/how-do-you-know-which-medical-marijuana-strain-is-right-for-you/>.

178. Cf. Amanda Reiman, *The Fallacy of a One Size Fits All Cannabis Policy*, 35 HUMBOLDT JOURNAL OF SOCIAL RELATIONS 104, 118 (2013), available at <http://www2.humboldt.edu/hjsr/docs/fwhjsrparagraph/Issue%2035%20Seventh%20Article%20Reiman.pdf> (acknowledging that marijuana is a complex plant with many forms and uses).

179. See, e.g., *Strain Guide*, MEDICAL MARIJUANA STRAINS, <http://www.medicalmarijuanastrains.com/strain-guide/> (last viewed Apr. 22, 2015) (creating a search index for medical marijuana based on illness and desired effect).

180. See Swift, *supra* note 1 (finding that 58% of Americans favor legalizing marijuana).