

# MUCH ADO ABOUT NOTHING: WHY RESCHEDULING WON'T SOLVE ADVOCATES' MEDICAL MARIJUANA PROBLEM

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## I. INTRODUCTION

Recently, the federal government has expanded its enforcement actions against commercialized “medical marijuana” operations. In the wake of those enforcement efforts, the governors of Washington, Rhode Island, and Colorado have petitioned the Drug Enforcement Administration (DEA) to reschedule marijuana.<sup>1</sup> Specifically, the petition

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asks the DEA to reclassify marijuana from Schedule I to Schedule II under the Federal Controlled Substances Act (CSA).<sup>2</sup> The governors contend that such rescheduling will eliminate the conflict between state and federal law and enable states to establish a “regulated and safe system to supply legitimate patients who may need medical cannabis.”<sup>3</sup>

The current petition takes a unique approach. It seeks to move marijuana and also all tetrahydrocannabinols, including delta-9-THC—the primary psychoactive component of marijuana—to Schedule II “for medicinal purposes only.”<sup>4</sup> In other words, the petition requests that “marijuana and related items [be] removed from Schedule I and rescheduled as ‘medical cannabis in Schedule II.’”<sup>5</sup> Marijuana advocacy organizations, such as the Marijuana Policy Project (MPP) and Americans for Safe Access (ASA) are urging other governors around the country to join onto the petition. The petition has garnered considerable publicity, but, as MPP acknowledges, “[r]escheduling is not a cure-all.”<sup>6</sup> This is an understatement. Indeed, for the reasons described below, it is not even a significant step in the direction that the governors, MPP, and ASA hope to move.

This Article begins with a brief background of the Controlled Substances Act and then discusses the process of rescheduling, the

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1. John Ingold, *Colorado Asks DEA To Reschedule Marijuana*, DENVER POST, Dec. 29, 2011, available at [http://www.denverpost.com/news/marijuana/ci\\_19636149](http://www.denverpost.com/news/marijuana/ci_19636149).

2. *Id.* See The Controlled Substances Act, 21 U.S.C.A. §§ 801-971 (West 2009).

3. Jonah Spangenthal-Lee, *Legislators Back Gregoire, Ask Feds to Reclassify Pot*, PUBLICOLA (Jan. 27, 2012), <http://publicola.com/2012/01/27/legislators-back-gregoire-ask-feds-to-reclassify-pot/>.

4. The proposal also seeks to move tetrahydrocannabinols’ synthetic equivalents and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant to Schedule II. Gov. Lincoln D. Chaffee, Rhode Island & Gov. Christine O. Gregoire, Washington, *Letter of Petition to the DEA: Rulemaking petition to reclassify cannabis for medical use from a Schedule I controlled substance to a Schedule II* (Nov. 30, 2011), available at [http://www.governor.wa.gov/priorities/healthcare/petition/combined\\_document.pdf](http://www.governor.wa.gov/priorities/healthcare/petition/combined_document.pdf), [hereinafter the Petition].

5. *Id.* at Exhibit A.

6. MARIJUANA POLICY PROJECT, *Form Message to Governors to Support Efforts to Reclassify Marijuana*, available at <https://secure2.convio.net/mpp/site/Advocacy?cmd=display&page=UserAction&id=1079>.

meaning of Schedule II drugs (which is the classification called for by the governors), the legal definition of a drug with “medical use,” and Schedule II implications on both research and state and federal regulations. The conclusion states that despite the vociferous calls for a federal marijuana reclassification, such a move would still not allow marijuana to be legally prescribed and distributed as a drug with medical use and that it is unnecessary for the legitimate claim of the need for more research into the drug. Instead, calling for rescheduling is a misguided effort that will only serve to increase the stridency of the political rhetoric in this debate. The proposal ignores the fact that the current provisions of the CSA and the Food, Drug, and Cosmetic Act (FDCA)<sup>7</sup> together already restrict the availability of controlled substances products to such medical purposes. Moreover, the petition offers no alternate means or criteria for identifying such legitimate medical use.

## II. BACKGROUND

### *A. The Controlled Substances Act*

Congress enacted the Controlled Substances Act in 1970 as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, replacing the previous patchwork of federal legislation governing psychoactive and potentially addictive substances.<sup>8</sup> Congress acted for a dual purpose: (1) to control and regulate the licit and illicit trade in, and use of, such substances; and (2) to implement the U.S. obligations under the Single Convention on Narcotic Drugs 1961, and subsequently, the Convention on Psychotropic Drugs 1971.<sup>9</sup> As a signatory to these treaties, the U.S. is required by federal legislation to establish a range of requirements and prohibitions seeking to ensure that all psychoactive substances are used solely for legitimate medical and scientific purposes.<sup>10</sup> Therefore, the CSA already requires that controlled substances be used only for such purposes. As discussed more fully below, the CSA and FDCA contain coordinated provisions designed to ensure that properly manufactured, tested, and standardized medications are made available by qualified and licensed practitioners to patients.

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7. The Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301-399D (West 2009).

8. Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C.A. §§ 801-971 (West 2009)).

9. 21 U.S.C.A. § 801a (West 2009).

10. *Id.* § 811.

State laws that conflict with the CSA (or with the treaties) are invalid, preempted by the Supremacy Clause of the Federal Constitution.<sup>11</sup>

The CSA governs all aspects of the handling of covered substances (“controlled substances”), including import/export, manufacturing, distribution, dispensing, individual possession, and research.<sup>12</sup> The CSA divides such substances into five categories or “schedules,” depending on a substance’s usefulness as a modern medication on the one hand, and its potential for abuse/addiction on the other.<sup>13</sup> The CSA also requires that each person or entity who handles a controlled substance (until it reaches the ultimate consumer) be licensed or registered with the DEA, and each registrant must adhere to specific measures designed to ensure that controlled substances are manufactured, distributed, and dispensed only (1) for legitimate medical or scientific purposes, and (2) to patients legitimately in need of the substance.<sup>14</sup>

### *B. How Are Drugs Rescheduled?*

A substance may be rescheduled in several ways. First, an “interested party” may initiate an administrative action by filing a petition with the DEA,<sup>15</sup> as did the governors of Washington and Rhode Island.<sup>16</sup> Second, the DEA itself can initiate such an action.<sup>17</sup> Third, a product containing a controlled substance will be scheduled as part of the

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11. U.S. CONST. art. VI, cl. 2.

12. 21 U.S.C.A. §§ 821-831.

13. *Id.* § 812.

14. *Id.* § 822.

15. *Id.* § 811(a)(2).

16. Several rescheduling petitions have been filed since the enactment of the CSA in 1970. The most recent petition was denied in July 2011. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40552-1 (July 8, 2011) (to be codified at 21 C.F.R. pt. 1308). That denial is currently being appealed. See Steve Elliott, *Appeal Challenges DEA Denial to Reschedule Medical Marijuana*, TOKE OF THE TOWN (Jan. 26, 2012), available at [http://www.tokeofthetown.com/2012/01/appeal\\_challenges\\_dea\\_denial\\_to\\_reschedule\\_medical.php](http://www.tokeofthetown.com/2012/01/appeal_challenges_dea_denial_to_reschedule_medical.php).

17. 21 U.S.C.A. § 811(a)(2). The DEA also has the authority temporarily to schedule substances on an emergency basis because they pose an imminent threat to public health. 21 U.S.C.A. § 811(h). The DEA has recently taken this step with regard to certain synthetic cannabinoids. Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids into Schedule I, 75 Fed. Reg. 71635 (Nov. 24, 2010). The DEA also has the power to schedule a substance without adhering to the administration procedure if such scheduling is required by the U.S.’s obligations under international treaties. 21 U.S.C.A. § 811(d).

Food and Drug Administration (FDA) approval process.<sup>18</sup> Finally, Congress may reschedule or schedule a substance by legislation, although this has very rarely occurred in the past.<sup>19</sup>

The scheduling process examines eight factors:

- (1) The drug's actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the drug or other substance;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under [the CSA].<sup>20</sup>

Both the FDA and DEA analyze these factors, although the FDA's recommendations on any scientific and medical issues are binding on the DEA.<sup>21</sup>

When enacting the CSA in 1970, Congress placed marijuana in Schedule I, along with other psychoactive substances of botanical origin, such as psilocybin, ibogaine, mescaline, and peyote.<sup>22</sup> Substances in Schedule I have: (1) "a high potential for abuse[;]" (2) no "currently accepted medical use" in the U.S.; and (3) lack "accepted safety for use . . . under medical supervision."<sup>23</sup> Schedule I substances may only be used in research studies that are supervised by the FDA and licensed by the DEA.<sup>24</sup>

By contrast, Schedule II substances have: (1) "a high potential for abuse" (as with Schedule I); (2) "a currently accepted medical use" in the U.S. or "a currently accepted medical use with severe restrictions[;]" and (3) abuse "may lead to severe psychological or physical dependence."<sup>25</sup>

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18. 21 U.S.C.A. § 355 (2009). See also Nicholas Reuter, M.P.H., *Food and Drug Administration, Testimony before Congress on the Scheduling of Drugs Under the Controlled Substances Act* (Mar. 11, 1999), available at <http://www.fda.gov/newsevents/testimony/ucm115087.htm>.

19. See *Gonzales v. Raich*, 545 U.S. 1, 22, 125 (2005).

20. 21 U.S.C.A. § 811(c).

21. *Id.* § 811(b)-(c).

22. *Id.* See also *Controlled Substances Schedules*, DOJ, DEA, OFFICE OF DIVERSION CONTROL, <http://www.deadiversion.usdoj.gov/schedules/> (last visited Sept. 18, 2012).

23. 21 U.S.C.A. § 812(b)(1).

24. *Id.* § 827(f).

25. *Id.* § 829(a).

Schedule II substances may be prescribed by physicians and dispensed by pharmacists *only when incorporated into specific FDA-approved products*.<sup>26</sup> Interpreting this statutory language as meaning “Schedule II substances may be prescribed,” however, is dangerously incomplete and may result in significant confusion. Such confusion underlies the governors’ current petition.

### *C. Schedule II Substances Are Not Directly Prescribed*

Part of the confusion over the actual significance of Schedule II status stems from a misunderstanding of the interrelated, but distinct, functions of the CSA and the FDCA. The CSA and FDCA work together to ensure that medications meet exacting standards of quality, safety, and efficacy and that, when these medications contain controlled substances, they are handled in a manner that will ensure access to legitimate patients while minimizing abuse and diversion.<sup>27</sup>

The CSA classifies substances into categories or schedules, generally by the International Nonproprietary Name (INN) or generic name of the active chemical ingredient (Active Pharmaceutical Ingredient or API).<sup>28</sup> Each substance has a separate drug code.<sup>29</sup> Generally, all such medical products, when approved for marketing by the FDA and scheduled by the DEA, are placed in the same schedule as the substance they contain.<sup>30</sup>

By contrast, under the FDCA, the FDA approves *specific medical products* produced by a particular “innovator” (for branded products) or generic manufacturers.<sup>31</sup> For example, oxycodone, an opioid, is classified as a Schedule II substance.<sup>32</sup> Specific products, such as OxyContin® (an extended release form), are also in Schedule II. Physicians prescribe a specific branded or generic product, in a particular dose and dosage form.

In some cases, a more complex or “differential” scheduling occurs. That is, the pure or even “street” version of an API may be scheduled separately from a substance comprised of an FDA-approved formulation

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26. See *id.* §§ 351-360, 801-890; see also Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for A Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 86 (2004).

27. See Dilcher, *supra* note 26, at 86.

28. See 21 U.S.C.A. § 812.

29. See DEA, RESOURCE GUIDE: DRUGS OF ABUSE (2011), available at [http://www.umsl.edu/~keelr/180/dea\\_drugsofabuse\\_2011.pdf](http://www.umsl.edu/~keelr/180/dea_drugsofabuse_2011.pdf).

30. Branded products (such as Opana® or Embeda®) are not listed in the CSA or its implementing regulations, although such individual products are themselves scheduled.

31. 21 U.S.C.A. § 355.

32. See *id.* § 812.

containing that active ingredient.<sup>33</sup> For example, gamma hydroxybutyric acid or sodium oxybate (“GHB”), the “date rape” drug, is a Schedule I substance.<sup>34</sup> However, a separate substance or drug code has been created for all GHB-containing formulations that have passed through the FDA approval process.<sup>35</sup> This separate substance is in Schedule III,<sup>36</sup> as is any product containing it, such as Xyrem®. Similarly, tetrahydrocannabinols are in Schedule I, but a separate substance comprising an FDA-approved formulation of synthetic THC (called dronabinol) is in Schedule III.<sup>37</sup> Specific products containing that substance are Marinol® and its generics.<sup>38</sup> The DEA has recently proposed to create a separate category or drug code (and hence, substance) for “marihuana extract,” although at present this substance remains in Schedule I.<sup>39</sup>

In short, the fact that a substance is in Schedule II (or even III-V) does not mean that the substance itself (as contrasted with specific branded or generic products containing it) can be directly prescribed and dispensed.<sup>40</sup> This is particularly true for botanical raw plant material, for several reasons. First, botanical raw material can vary significantly in its composition. For example, depending on the strain, the opium poppy can produce differing amounts of morphine, codeine, thebaine, or oripavine.<sup>41</sup> A prescription designating “opium” or even “concentrate of

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33. See, e.g., JOINT MEETING OF THE ARTHRITIS DRUGS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE, FDA, SODIUM OXYBATE ORAL SOLUTION, (2010), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/UCM222888.pdf>.

34. 21 U.S.C.A. § 812. See also, *Drug Fact Sheet: GHB*, DOJ [http://www.justice.gov/dea/druginfo/drug\\_data\\_sheets/GHB.pdf](http://www.justice.gov/dea/druginfo/drug_data_sheets/GHB.pdf) (last visited Sept. 18, 2012).

35. See DOJ *supra* note 34.

36. *Id.*

37. 21 U.S.C.A. § 812.

38. The agency has issued a Notice of Proposed Rulemaking (NPRM) proposing to amend the existing regulations to allow certain generic products referencing the Marinol NDA, containing naturally derived dronabinol, and/or hard gelatin capsules to be placed automatically in Schedule III upon FDA approval. See, Listing of Approved Drug Products Containing Dronabinol in Schedule III, 75 Fed. Reg. 67054, 67054 (Nov. 1, 2010); see also Ruth C. Stern & J. Herbie DiFonzo, *The End of the Red Queen's Race: Medical Marijuana in the New Century*, 27 QUINNIPAC L. REV. 673, 694 (2009).

39. Establishment of a New Drug Code for Marihuana Extract, 76 Fed. Reg. 39039, 39038 (July 5, 2011). The governors' petition, however, does not address or consider the significance of this DEA NPRM.

40. See FRIENDS OF THE DEA, MARIJUANA DISPENSARIES AND THE FEDERAL GOVERNMENT: RECOMMENDATIONS TO THE OBAMA ADMINISTRATION (2009), available at [http://norml.org/pdf\\_files/Marijuana\\_Dispensaries\\_Recommendations.pdf](http://norml.org/pdf_files/Marijuana_Dispensaries_Recommendations.pdf).

41. MARTIN BOOTH, OPIUM: A HISTORY 8 (1996).

poppy straw”<sup>42</sup> would not indicate the precise formulation of active ingredients (and, therefore, the dose) that the physician intends the patient to use in treatment.<sup>43</sup> Second, raw plant material can be contaminated by fungi and other dangerous microbes, depending on the cultivation, harvesting and storage practices employed (including storage by a wholesaler or retailer).<sup>44</sup> These and other contaminants can be more reliably identified and removed during various processes of manufacturing, extraction, and formulation. Third, there is currently no method of administering raw plant material, which ensures that the patient receives a reproducible dose of active ingredients each time, in a manner that does not create any toxic byproducts.<sup>45</sup> Indeed, no raw plant material has ever been approved by the FDA for sale by prescription, although a number of psychoactive plant and other botanical raw materials are listed in Schedule II of the CSA.<sup>46</sup>

The governors’ petition contends that, “with modern DNA analysis” using polymerase chain reaction (PCR) and gel electrophoresis testing,

42. Most opiate APIs are now derived from poppy straw or concentrate of poppy straw, rather than from the opium pod. BOOTH, *supra* note 41, at 349.

43. See Lyle E. Craker; Denial of Application, 74 Fed. Reg. 2101, 2104 (DOJ & DEA Jan. 14, 2009) [hereinafter Lyle Craker Denial]; see also JANET E. JOY, STANLEY J. WATSON & JOHN A. BENSON, INST. OF MED., MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 177-78 (1999) (stating that “[d]efined substances, such as purified cannabinoid compounds, are preferable to plant products, which are of variable and uncertain composition. Use of defined cannabinoids permits a more precise evaluation of their effects, whether in combination or alone.”).

44. See Priyanka Singh, Bhawana Srivastava, Ashok Kumar & N.K. Dubey, *Fungal Contamination of Raw Materials of Some Herbal Drugs and Recommendation of Cinnamomum camphora Oil as Herbal Fungitoxicant*, 56 MICROBIAL ECOLOGY 555, 555 (2008); see also John L. Pauly & Geraldine Paszkiewicz, *Cigarette Smoke, Bacteria, Mold, Microbial Toxins, and Chronic Lung Inflammation*, 2011 J. ONCOLOGY Article ID 819129 (2011), available at <http://www.hindawi.com/journals/jo/2011/819129/>.

45. Plant material can be vaporized. However, there are many types of vaporizers available for purchase, but none has been approved or reviewed by the FDA. Many of them, depending on their construction and the temperature at which they can be set, produce toxic by-products. Dale Gieringer, Joseph St. Laurent & Scott Goodrich, *Cannabis Vaporizer Combines Efficient Delivery of THC with Effective Suppression of Pyrolytic Compounds*, 4 J. CANNABIS THERAPEUTICS 7, 7-27 (2004), available at <http://webpages.charter.net/lenny49684/volcano.pdf>. Even the Volcano®, believed by many marijuana advocates to be the “gold standard” of vaporizers, at higher temperatures does not eliminate all polycyclic hydrocarbons, and has been shown to produce significant amounts of ammonia. Roger N. Bloor, Tianshu S. Wang, Patrik Spanel & David Smith, *Ammonia Release From Heated ‘Street’ Cannabis Leaf and Its Potential Toxic Effects on Cannabis Users*, ADDICTION, Oct. 2008, at 1671-77.

46. FDA, GUIDANCE FOR INDUSTRY, BOTANICAL FOOD PRODUCTS, 2004 WL 3199015 (F.D.A.), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070491.pdf> [hereinafter Botanical Food Products Guidance].



among other validated analytical techniques, a “compounding pharmacist could easily and inexpensively quantify the levels of cannabinoids.”<sup>47</sup> Indeed, it avers that “[a]ccurate analytical kits are available” to enable “extremely accurate characterization[s] of a plant’s genetic make-up.”<sup>48</sup> However, the petition provides no evidence (nor even any citations) that such technology exists and that the results of such testing would provide proof of quality and batch-to-batch consistency that would meet the standards of modern medicine and be satisfactory to the FDA.<sup>49</sup> A recent documentary on the Discovery Channel examined the practices of Harborside Health Center in Oakland, California—by its own admission, the largest marijuana dispensary on the planet—revealed that the buds (which are distributed directly to member-patients) are merely examined visually using a microscope.<sup>50</sup> The documentary noted that Steep Hill Laboratory tests some plant material, but there was no evidence that Steep Hill’s instrumentation and techniques are “validated,” that its operators are properly trained and educated, that its reference standards are accurate, or that its results are replicable by other laboratories.<sup>51</sup>

The FDA has established extremely high standards in the area of Chemistry, Manufacturing, and Controls (CMC) to ensure that a medication is consistent in composition, stable over a reasonable period of time, and not contaminated with excessive impurities.<sup>52</sup> Recently, a company seeking to develop a generic to Marinol® was forced to abandon one of its product development programs because of CMC issues.<sup>53</sup> In light of the challenges faced even by pure synthetic cannabinoids products, it is unlikely that an individual testing raw botanical material would be able to demonstrate this exacting level of consistency. Furthermore, herbal plant materials would likely be administered through smoking or vaporization. The FDA has also

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47. *The Petition*, *supra* note 4, at 3.

48. *Id.* at 42.

49. *Id.*

50. The buds are also handled by employees who do not use gloves or face masks. Steve Elliott, *World’s Largest Marijuana Dispensary Offers Bonus for Activism*, *TOKE OF THE TOWN* (Apr. 7, 2010), [http://www.tokeofthetown.com/2010/04/worlds\\_largest\\_marijuana\\_dispensary\\_offers\\_bonus\\_f.php](http://www.tokeofthetown.com/2010/04/worlds_largest_marijuana_dispensary_offers_bonus_f.php); *see also* HARBORSIDE HEALTH CENTER, <http://www.harborsidehealthcenter.com/serv-labanalyze.html>.

51. Steve DeAngelo, *Weed Wars on Discovery Channel*, available at <http://dsc.discovery.com/tv/weed-wars/steve-deangelo.html>.

52. 21 C.F.R. § 314.50(c)(2)(iv) (2011).

53. Insys Therapeutics, Inc., Registration Statement (Form S-1), at 88 (Aug. 17, 2007), available at <http://www.sec.gov/Archives/edgar/data/1516479/000119312511081792/0001193125-11-081792-index.htm>.

established extremely rigorous CMC criteria for inhaled products.<sup>54</sup> Metered dose inhalers must meet demanding standards in order to ensure that they maintain “consistent dosing and particle size distribution. . . throughout the expiration dating period.”<sup>55</sup> Notably, virtually all inhaled products have been approved only for pulmonary conditions, such as asthma.<sup>56</sup> Vaporized products for non-pulmonary conditions have faced considerable concern from FDA.<sup>57</sup> It is therefore not surprising that crude botanical opiate or other materials are not prescribed and dispensed.

Marketed medications containing pure opiate APIs (morphine, codeine, etc.) were available at the time the CSA was enacted.<sup>58</sup> Therefore, the crude raw botanical materials from whence they were derived—opium (latex), poppy straw, and concentrate of poppy straw—were placed in Schedule II along with those APIs.<sup>59</sup> However, their Schedule II status does not allow physicians to prescribe dried opium or poppy straw, or even the pure APIs derived from them, but rather only specific products containing those APIs.<sup>60</sup>

The same would apply to marijuana, even if the plant material were reclassified to Schedule II, along with poppy straw. Imagine for a moment that the “medical marijuana” advocates were instead “medical opium” advocates and that various states passed laws decriminalizing (or affirmatively authorizing and regulating) the cultivation and distribution of opium plant material, i.e., opium latex or poppy straw. Even though opium latex and poppy straw are each in Schedule II, there would still be a conflict between such state laws and both the CSA and the FDCA. As a well-known drug reform advocacy website states, “[i]f poppies are

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54. FDA, DRAFT GUIDANCE FOR INDUSTRY, METERED DOSE INHALER (MDI) AND DRY POWDER INHALER (DPI) DRUG PRODUCTS, CHEMISTRY, MANUFACTURING, AND CONTROLS DOCUMENTATION, 1998 WL 34327459 (F.D.A.), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070573.pdf>.

55. *Id.* at 6.

56. *Id.* at 2.

57. In 2010, the FDA turned down the marketing application for a vaporized anti-psychotic product (not containing controlled substances) because of concerns relating to pulmonary side effects in certain patients. The company submitted an updated Risk Evaluation and Mitigation Strategy (REMS) and is awaiting further decision by the FDA. See *FDA Extends Review of Alexza Product, Shares Fall*, REUTERS (Jan. 23, 2012), <http://www.reuters.com/article/2012/01/23/us-alexza-idUSTRE80M16E20120123>.

58. Indeed, thebaine is a Schedule II substance, but it is not directly used therapeutically. Instead, it is converted into a variety of other substances, including oxycodone, oxymorphone, naltrexone, and buprenorphine, which in turn are formulated into FDA-approved products. See DEPARTMENT OF JUSTICE, *Drug Fact Sheets*, (last visited July 1, 2012), [http://www.justice.gov/dea/druginfo/concern\\_thebaine.shtml](http://www.justice.gov/dea/druginfo/concern_thebaine.shtml).

59. *Id.*

60. *Id.*

grown as sources for opiates, there is no question that it violates the CSA.”<sup>61</sup> Furthermore, physicians would not be authorized to prescribe, nor pharmacists to dispense, dried opium latex or poppy straw.<sup>62</sup> In order to be prescribed, a specific product containing opiate APIs would have to pass muster in the FDA approval process.<sup>63</sup> Therefore, the mere act of placing herbal marijuana in Schedule II would not make it available to patients nor address the conflict between state and federal law.

#### *D. Pharmacist Compounding*

The petition appears to rely heavily on the premise that, if marijuana were moved to Schedule II, pharmacists could blend and dispense raw marijuana plant material upon the prescription of a physician.<sup>64</sup> However, under the FDCA, a pharmacist’s compounding authority is quite limited.<sup>65</sup> The FDA generally permits “traditional” compounding, which involves the preparation of a medication that is tailored to the specific needs of a particular patient, based on an unsolicited physician’s prescription.<sup>66</sup> It does not include wide scale manufacturing of products by pharmacists; this runs afoul of the FDCA:

The drugs that pharmacists compound are not FDA-approved and lack an FDA finding of safety and efficacy. However, FDA has long recognized the important public health function served by traditional pharmacy compounding. FDA regards traditional compounding as the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a

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61. THE VAULTS OF EROWID, [http://www.erowid.org/plants/poppy/poppy\\_law.shtml](http://www.erowid.org/plants/poppy/poppy_law.shtml) (last visited July 1, 2012).

62. Both Laudanum and Paregoric (tinctures of opium) pre-existed the original Food and Drugs Act of 1906. Recently, the FDA has taken enforcement action against these products as “unapproved drugs” that have not undergone FDA trials to prove safety and efficacy, as well as for violations of Good Manufacturing Practices. See FDA, Warning Letter, Hi-Tech Pharmacal Co., Inc. (June 28, 2010), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm219984.htm>. See also FDA, GUIDANCE FOR FDA STAFF AND INDUSTRY, MARKETED UNAPPROVED DRUGS – COMPLIANCE POLICY GUIDE SEC. 440.100 MARKETED NEW DRUGS WITHOUT APPROVED NDAS OR ANDAS, 2006 WL 1720638 (F.D.A.), *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070290.pdf>.

63. See 21 U.S.C.A. §§ 301-399d.

64. See *The Petition*, *supra* note 4.

65. FDA, COMPLIANCE POLICY GUIDES MANUAL, HUMAN DRUGS, SUB CHAPTER 460.200 - PHARMACY ISSUES, 2004 WL 3363379 (F.D.A.), *available at* <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM118050.pdf>.

66. See *id.*

physician's prescription to create a medication tailored to the specialized needs of an individual patient. *Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.*

Through the exercise of enforcement discretion, FDA historically has not taken enforcement actions against pharmacies engaged in traditional pharmacy compounding. Rather, FDA has directed its enforcement resources against establishments whose activities raise the kinds of concerns normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA.<sup>67</sup>

Therefore, it is unlikely that rescheduling would enable pharmacists to prepare marijuana-based products for a significant number of patients.<sup>68</sup>

Moreover, pharmacists are only authorized to dispense a controlled substance to a patient based on a legitimate prescription from a physician.<sup>69</sup> Under the CSA, a prescription must contain the drug name, strength, dosage form, quantity prescribed, and directions for use.<sup>70</sup> Again, there is no evidence that a pharmacist could "easily" prepare a blend of cannabis plant material that would meet these requirements and the standards of FDA-approved modern medications. Presumably, the governors' petition is referring to the testing technologies currently employed by the panoply of marijuana "testing laboratories" that provide services to some dispensaries. However, in a recent article authored by the Director of the California branch of the National Organization for the Reform of Marijuana Laws (NORML), approximately one third of laboratories examined demonstrated "unacceptable deviations of more than 25% from the mean."<sup>71</sup> The remaining laboratories were consistent

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67. FDA, Warning Letter, Hal's Compounding Pharmacy (Dec. 4, 2006), *available at* <http://www.casewatch.org/fdawarning/comp/hal.shtml> (emphasis added) (internal citations omitted).

68. See 21 U.S.C. § 353(a).

69. 21 C.F.R. § 1306.11(a) (2011).

70. 21 C.F.R. § 1306.05(a).

71. Dale Gieringer & Arno Hazekamp, *How Accurate Is Cannabis Testing? Ring Test Assesses The Labs*, O'SHAUGHNESSY'S (Sep. 26, 2011), *available at* [http://www.canorml.org/RingTestOShaughnessys\\_Aut11.pdf](http://www.canorml.org/RingTestOShaughnessys_Aut11.pdf).

only to within approximately 20%.<sup>72</sup> This might meet the standards for testing the potency of seized cannabis (which serve law enforcement and policy development purposes), but it would certainly not meet the standards of pharmaceutical testing for prescription medications administered to patients.<sup>73</sup> Furthermore, other evidence from around the country suggests that laboratory results are even less reliable.<sup>74</sup>

*E. Accepted Medical Use*

The primary difference between Schedule I and II substances lies in the phrase “currently accepted medical use in treatment in the United States.”<sup>75</sup> This phrase is not defined in the CSA.<sup>76</sup> However, the DEA has developed a five-part test for determining which substances are classified as Schedule II that has been upheld by federal courts:

- (1) The drug’s chemistry must be known and reproducible;
- (2) There must be adequate safety studies;
- (3) There must be adequate and well-controlled studies proving efficacy;
- (4) The drug must be accepted by qualified experts; and
- (5) The scientific evidence must be widely available.<sup>77</sup>

Mere anecdotal evidence (reports of specific cases), state laws, or even the policy positions of medical organizations, are not sufficient to satisfy these criteria, but rather only data from robust, controlled studies are sufficient to satisfy them.<sup>78</sup> Not surprisingly, FDA approval of a

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72. *Id.*

73. See 21 C.F.R. §§ 210-211 (2011).

74. John Ingold, *Medical Pot’s Potency Difficult To Pin Down For Colorado Dispensaries*, DENVER POST (Apr. 18, 2011), available at [http://www.denverpost.com/news/marijuana/ci\\_17870142](http://www.denverpost.com/news/marijuana/ci_17870142).

75. 21 U.S.C.A. § 812(b)(1).

76. *Id.* § 812. See also *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991) (stating “neither the statute nor its legislative history precisely defines the term”).

77. See *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

78. See *id.* at 1137; see also *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 Fed. Reg. 10499-02 (Mar. 26, 1992).

product is sufficient (although not necessary) to establish that such product has an accepted medical use in the U.S.<sup>79</sup>

The governors' petition asserts that there is a "consensus of medical opinion concerning medical acceptability of cannabis amongst the largest groups of physicians in the United States."<sup>80</sup> In support of this statement, the petition states that the American Medical Association (AMA) allegedly reversed its position that marijuana should remain a Schedule I substance.<sup>81</sup> However, contrary to the governors' petition, the AMA does not believe that there has been sufficient research to justify making herbal marijuana available as a prescription medication: "Despite more than 30 years of clinical research, only a small number of randomized, controlled trials have been conducted on smoked cannabis."<sup>82</sup>

Furthermore, while the AMA's Report does state that the Schedule I status should be "reviewed," it limits the purpose of such review to the "goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods."<sup>83</sup> The AMA does not recommend that marijuana should be rescheduled in order that it can be directly prescribed and dispensed in its raw form to patients. In fact, the AMA recommendation cautions that, "[t]his should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, *or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.*"<sup>84</sup> In the body of its report, the AMA further clarified its position by stating:

The AMA supports the concept of drug approval by scientific and regulatory review to establish safety and efficacy, combined with appropriate standards for identity, strength, quality, purity, packaging, and labeling, rather than by ballot initiative or state legislative action. *The future of cannabinoid-based medicine lies in the rapidly evolving field of botanical drug substance development, as well as the design of molecules that target various aspects of the endocannabinoid system. To the extent*

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79. *Alliance for Cannabis Therapeutics*, 15 F.3d at 1137.

80. *The Petition*, *supra* note 4, at 14.

81. *Id.*

82. COUNCIL ON SCI. & PUB. HEALTH, AMA, USE OF CANNABIS FOR MEDICINAL PURPOSES, 15 (2009), available at <http://www.ama-assn.org/resources/doc/csaph/i09csaph3ft.pdf> (hereinafter AMA Report).

83. *Id.* at 16.

84. *Id.* (emphasis added).

*that rescheduling marijuana out of Schedule I will benefit this effort, such a move can be supported.*<sup>85</sup>

The term “botanical drug substance” is derived from an FDA guidance document *Guidance for Industry: Botanical Drug Products*.<sup>86</sup> It refers, not to herbal plant material, but to extracts or similar preparations of the active botanical components.<sup>87</sup> As the AMA Report states:

*The crude botanical substance can become a “botanical drug substance” through processes of extraction, blending, addition of excipients, formulation, and packaging in a defined manner. Particular attention is devoted to product composition because botanicals are complex mixtures of chemical/structural components. Similar to conventional products, a botanical drug substance must undergo animal toxicity studies, and demonstrate its safety and efficacy in randomized, double-blind, placebo-controlled trials. Additional pharmacologic and toxicologic studies are required if a non-oral route (e.g., inhalation) of administration is contemplated. If the substance is intended to treat chronic conditions, 6 to 12 months in long-term safety extension studies is considered sufficient.*<sup>88</sup>

Therefore, rather than accepting that marijuana meets the accepted standards for modern medicine, the AMA is essentially stating that research into crude marijuana plant material is a dead end.

### III. ANALYSIS

#### *A. Application of the FDCA and CSA to Intrastate Manufacturing/Cultivation and Distribution*

Under the Federal Constitution, Congress has specific enumerated powers and can only pass legislation pursuant to one of those powers.<sup>89</sup> Under the Commerce Clause, Congress has the power to regulate commerce amongst the states.<sup>90</sup> The U.S. Supreme Court has expansively

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85. *Id.* (emphasis added).

86. FDA, *supra* note 46.

87. *Id.*

88. AMA, *supra* note 82, at 10 (emphasis added).

89. U.S. CONST. art. I, § 8, cl. 18.

90. U.S. CONST. art. I, § 8, cl. 3.

defined the scope of activity that involves or affects interstate commerce.<sup>91</sup> With regard to the CSA, the Court has ruled that, under the Commerce Clause, the CSA is valid as applied to “the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes” on the advice of a physician.<sup>92</sup>

Similarly, the FDA broadly interprets the reach of the FDCA, which applies to products in, or that are introduced or delivered for introduction into, or received in, interstate commerce.<sup>93</sup> A product is a “drug,” subject to the quality, safety, and efficacy requirements<sup>94</sup> of the FDCA if it is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or is “intended to affect the structure or any function of the body.”<sup>95</sup> A “new drug”<sup>96</sup> cannot be introduced or delivered for introduction into interstate commerce unless approved by the FDA.<sup>97</sup>

In light of the interconnectedness of many aspects of the national economy, it is highly likely that any marijuana medical product would be deemed to affect interstate commerce, particularly if the transaction has a commercial aspect.<sup>98</sup> The use of the internet or other publication method to advertise a product creates an additional connection to the channels of interstate commerce. Therefore, intrastate manufacture and distribution of marijuana products would not avoid the requirements and restrictions of the CSA and FDCA.<sup>99</sup> Accordingly, a physician would not be able to prescribe, or a pharmacist to dispense, a marijuana medical product unless that product had secured FDA marketing approval.

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91. James L. Buchwalter, *Construction and Application of Dormant Commerce Clause*, U.S. Const. Art. I, § 8, cl. 3—*Supreme Court Cases*, 41 A.L.R. FED. 2d 1 (2009).

92. *Gonzales v. Raich*, 545 U.S. 1, 1 (2005).

93. 21 U.S.C.A. § 355(a).

94. In order to obtain approval for a new drug, including for its labeling and advertising, the sponsor must demonstrate “substantial evidence” of safety and efficacy. *Id.* § 355(b). Substantial evidence is “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have.” 21 U.S.C.A. § 355(d).

95. 21 U.S.C.A. § 321(g)(1).

96. A new drug is one “the composition of which is such that [it] is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling . . . .” 21 U.S.C.A. § 321(p). This is a very rigorous standard.

97. *Id.* § 355(a).

98. *See Raich*, 545 U.S. at 27.

99. 21 U.S.C.A. § 801(3).



*B. Rescheduling Is Not Necessary To Make Marijuana Products Available For Research*

A committee of the California Medical Association recently called for the rescheduling of marijuana “so it can be tested and regulated.”<sup>100</sup> However, it is not necessary for marijuana to be rescheduled in order for legitimate research to proceed.<sup>101</sup> Schedule I status does not prevent a product from being tested and researched for potential medical use.<sup>102</sup> The FDA (and its Controlled Substances Staff) will allow an investigational product containing a controlled substance (including Schedule I substances) to be tested in a clinical (human) trial if there is adequate evidence of safety from non-human studies.<sup>103</sup> The CSA imposes stringent security, record keeping, and other requirements, but these apply equally to Schedule I and Schedule II substances.<sup>104</sup>

Under the CSA, the only differences between Schedule I and II are rather technical.<sup>105</sup> Before granting a Schedule I research registration, the DEA will separately inquire whether the FDA believes that the researcher is qualified and competent and the trial design will elicit scientifically valid data.<sup>106</sup> A Schedule I research registration must be renewed each year, whereas research registrations for other controlled substances are valid for three years.<sup>107</sup> Schedule I research registrations are protocol, as well as substance, specific.<sup>108</sup> By contrast, a Schedule II registration is valid for research into all Schedule II substances and protocols.<sup>109</sup> Physicians, if they possess registrations to prescribe and administer products containing controlled substances, may conduct research (if permitted by the FDA and the relevant ethics committee) on

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100. Shannie Lammie, *California Medical Association Recommends Cannabis Rescheduling and Legalization*, COLORADO DISPENSARY SERVS. (Oct. 18, 2011), <http://www.cdscenters.com/blog/2011/10/18/california-medical-association-recommends-cannabis-rescheduling-legalization/>.

101. See 21 U.S.C.A. §§ 811, 821, 823; 21 C.F.R. § 1301.13(e).

102. See *id.*

103. In order for any investigational product to move into advanced clinical research (and ultimately to new drug approval), many additional criteria must be met. Robust data must demonstrate a product’s pharmacological activity, quality (including consistent composition, extent of impurities, and stability), toxicity of various types, and efficacy in a particular patient population for a specific medical condition. 21 C.F.R. § 315.50 (2011).

104. *Id.*

105. See 21 U.S.C.A. § 823; see also AMA, *supra* note 83, at 9.

106. 21 U.S.C.A. § 823(f).

107. 21 C.F.R. § 1303.13(e)(1).

108. *Id.*

109. *Id.*

any Schedule II substance as a “coincident” or adjunct activity to that registration; they need not obtain a separate research registration from DEA.<sup>110</sup>

These additional Schedule I restrictions can delay a research program but are not insurmountable. Furthermore, it may be possible to make minor amendments to the CSA to “equalize” Schedule I and Schedule II research requirements without necessitating a rescheduling of marijuana. Even in the absence of such a statutory amendment, Schedule I research certainly does go forward. In a recent pharmaceutical company-sponsored human clinical study investigating a product derived from marijuana extracts, the DEA registered approximately thirty research sites in the U.S. and also registered an importer to bring the product into the U.S. from the U.K., where it was manufactured.<sup>111</sup>

### *C. Obtaining Raw Plant Material for Research*

Schedule II status would not make it easier for medical researchers to obtain marijuana plant material for purposes of research. The U.S.’s obligations under the Single Convention on Narcotic Drugs require that a national agency have exclusive control over the domestic cultivation of marijuana, as well as its importation and exportation.<sup>112</sup> The National Institute on Drug Abuse (NIDA) primarily implements the responsibilities outlined in the treaty. The NIDA contracts with the University of Mississippi’s National Center for Natural Products Research (NCNPR) to cultivate marijuana for research purposes.<sup>113</sup> Researchers who obtain grant funding from an institute of the National Institutes of Health (NIH), such as NIDA, can obtain marijuana for their studies, while researchers who are externally funded must undergo the equivalent of a grant review process (a review of their study design by an expert committee of the Public Health Service) in order to obtain such marijuana at cost from NIDA.<sup>114</sup> NCNPR has the ability to produce

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110. *Id.*

111. Importer of Controlled Substances; Notice of Application, 71 Fed. Reg. 64298 (DOJ & DEA Nov. 1, 2006); *Press Release: Sativex Commences US Phase II/III Clinical Trial in Cancer Pain*, GW PHARMACEUTICALS, (Nov. 26, 2007), <http://www.gwpharm.com/Commences%20US%20Phase%20IIIII%20Clinical%20Trial.aspx>.

112. Single Convention on Narcotic Drugs, United Nations, art. 23, 28, Mar. 30, 1961, 18 U.S.T. 1407 [hereinafter *Single Convention*].

113. Manufacturer of Controlled Substances; Notice of Application, 76 Fed. Reg. 62449 (Oct. 7, 2011). *See also* Craker, *supra* note 43, at 2012.

114. *See* Craker, *supra* note 43, at 2104-06.

standardized marijuana of varying THC potencies.<sup>115</sup> Its cultivation area of five acres has been adequate to supply all marijuana-related studies to date.<sup>116</sup>

Even if marijuana were placed in Schedule II, these treaty obligations would remain in force. This does not, however, mean that it would never be possible to conduct large scale cultivation of marijuana for purposes of commercial medication development, although such cultivation would have to be closely supervised by the NIDA or the DEA, in a manner similar to NCNPR's "farm." Furthermore, it is also possible that cultivation would take place in another country (under the auspices of that country's national agency), and extracts of the active ingredients would be imported into this country for research, just as concentrate of poppy straw is now imported into the U.S. for the development of modern opioid products. Under 100-year old international policies,<sup>117</sup> most countries, including the U.S., do not cultivate psychoactive plant material for purposes of commercial medication development, but rather import such narcotic raw material (NRM) from a short list of authorized manufacturing/cultivating countries.<sup>118</sup> Importantly, such extracts are exempt from the Single Convention's national agency mandate.<sup>119</sup> As indicated above, this is precisely how marijuana extract-derived medications are currently made available for research in the U.S.<sup>120</sup>

#### *D. State Regulation of Marijuana*

Would Schedule II status permit states to regulate the cultivation, sale, and distribution of marijuana for either medical or recreational use? As noted above, the CSA was enacted in part to implement the U.S.'s international obligation to restrict the use of psychoactive substances to legitimate medical and scientific purposes.<sup>121</sup> Schedule II substances are subject to very strict controls, given that almost all the security and other controls that govern Schedule I substances apply equally to Schedule II

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115. *Id.* at 2104.

116. *Id.*

117. *See* The International Opium Convention (Jan. 23, 1921).

118. *See*, Authorized Sources of Narcotic Raw Materials, 73 Fed. Reg. 6843 (Feb. 6, 2008). Those countries are India, Turkey, France, Poland, Hungary, Australia, and Spain. *Id.* The NIDA and the DEA have exclusive jurisdiction over any importation of opium or marijuana plant material. 21 C.F.R. § 1312.11 (2011).

119. *See* Single Convention, *supra* note 112, at art. 24-25.

120. *See* Craker, *supra* note 43.

121. Single Convention, *supra* note 112.

substances.<sup>122</sup> Additionally, unlike Schedule I substances, Schedule II substances can be developed into commercialized products, and are therefore subject to production and procurement quotas determined by the DEA.<sup>123</sup> Accordingly, a state could not attempt to establish a regulatory system that undermined or otherwise conflicted with these CSA restrictions.<sup>124</sup> Again, poppy straw is a Schedule II substance, as is morphine, but a state could not create a regulatory structure that was more lenient than that established by the CSA.<sup>125</sup>

#### *E. Marijuana as a Federally-Illegal Substance*

Placing marijuana in Schedule II would not eliminate its status as an illegal substance under the CSA. While the severity of many of the CSA's criminal penalties are keyed to the schedule of the substance in question, this is not entirely true for marijuana.<sup>126</sup> There are statutes under the CSA that prescribe specific penalties for manufacturing, distributing or dispensing (or possessing with intent to do the same) of certain quantities of marijuana.<sup>127</sup> Furthermore, even considering those statutes that are keyed to a substance's schedule, the same criminal penalties apply equally to Schedule I and II substances.<sup>128</sup> Thus, none of these statutes would be directly affected by a change in marijuana's schedule. Finally, the CSA provides that it is illegal to possess any controlled substance without a valid prescription from a physician.<sup>129</sup> Again, under the FDCA, a medical product cannot be manufactured and sold (a precursor for it to be prescribed) unless the product has been approved by the FDA.<sup>130</sup> Hence, transferring crude herbal marijuana to Schedule II would have no impact on these statutes.

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122. 21 C.F.R. §§ 823, 1301.

123. 21 C.F.R. § 1301.11.

124. *Raich*, 545 U.S. at 27.

125. *Id.*

126. 21 U.S.C.A. §§ 841-65.

127. 21 U.S.C.A. §§ 841(b)(1)(A)(vii), (B)(vii), (D).

128. 21 U.S.C.A. § 841(b)(1)(C).

129. 21 U.S.C.A. § 844(a).

130. In addition, a prescription for a controlled substance must contain, amongst other things, the drug name, strength, dosage form, quantity prescribed, and directions for use. This would be very difficult to do for crude plant material. 21 C.F.R. § 1306.05(a). Moreover, a prescription can only be filled by a pharmacist. 21 C.F.R. § 1306.06. A physician may administer or dispense directly a Schedule II substance in the course of his professional practice without a prescription. 21 C.F.R. § 1306.11(b). However, the FDCA prohibits the manufacture, distribution, receipt, and sale of unapproved medical products. 21 U.S.C.A. § 355. Therefore, a cultivator could not merely cultivate marijuana and sell it to the physician, who would in turn sell and dispense it to the patient. Finally, a physician

## IV. CONCLUSION

By contrast to the careful and detailed structure of the CSA, the governors' petition offers no criteria or guidelines that would clearly identify the scope of legitimate "medical use." At present in California, and in several other states, it is widely recognized that the concept of "medical use" of marijuana is highly questionable. For payment of a small cash sum, almost anyone can obtain a physician's "recommendation" to purchase, possess, and use marijuana for alleged medical purposes. Indeed, numerous studies have shown that the most customers of these dispensaries do not suffer from chronic, debilitating conditions such as HIV, AIDS, or cancer.<sup>131</sup> Parties on both sides of the argument agree that this system has essentially legalized marijuana for recreational use—at least amongst those individuals able and willing to buy a recommendation.<sup>132</sup> The petition would potentially expand that system on a national scale, permitting any physician in any state to prescribe any form of marijuana for any medical condition. This has nothing to do with its Schedule, because placing marijuana in Schedule II would do nothing to change the fact that it could still not be prescribed—the FDA would first have to approve a specific product. Rather, vociferous calls for rescheduling like these simply muddle and confuse an already highly charged debate.

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may not issue a prescription in order to obtain controlled substances directly from a pharmacist to enable the physician to dispense such materials to her patients. 21 C.F.R. § 1306.04(b).

131. See Thomas J. O'Connell & Che B. Bou-Matar, *Long Term Marijuana Users Seeking Medical Cannabis in California (2001–2007): Demographics, Social Characteristics, Patterns of Cannabis and Other Drug Use of 4117 Applicants*, HARM REDUCTION J. (Nov. 3, 2007), available at <http://www.harmreductionjournal.com/content/4/1/1>; see also Helan Nunberg, et al., *An Analysis of Applicants Presenting to a Medical Marijuana Specialty Practice in California*, 4 J. DRUG POL'Y ANALYSIS, 1 (2011), available at <http://www.bepress.com/jdpa/vol4/iss1/art1>.

132. According to Allen St. Pierre of NORML, "in California, marijuana has also been de facto legalized under the guise of medical marijuana." *Transcript of Don Lemon CNN Television Show with Kevin Sabet and Allen St. Pierre* (Jan. 22, 2012), available at <http://transcripts.cnn.com/TRANSCRIPTS/0905/09/cnr.04.html>.