Court File No.: T-2030-13

#### FEDERAL COURT

BETWEEN:

NEIL ALLARD TANYA BEEMISH DAVID HEBERT SHAWN DAVEY

Plaintiffs

and

# HER MAJESTY THE QUEEN IN RIGHT OF CANADA

Defendant

#### AFFIDAVIT OF LYNN WHIPKEY MEHLER

I, LYNN WHIPKEY MEHLER, a partner in the law firm of Hogan Lovells US LLP, 555 Thirteenth Street, NW Washington, D.C., 20004, United States of America, being duly sworn, hereby SWEAR:

- I am a partner in Hogan Lovells US LLP, resident of the firm's Washington D.C. office. I am an attorney admitted to practice law in the State of Virginia and the District of Columbia. I have personal knowledge of the matters testified to in this affidavit.
- I make this affidavit at the request of the Respondent Attorney General of Canada with respect to the above-captioned proceeding.
- 3. In particular, BJ Wray, Legal Counsel, Department of Justice, British Columbia Regional Office, as counsel for the Respondent Attorney General of Canada in this matter, has asked me to report on the federal and state regulation of medical marijuana in the United States. Specifically, she has asked me to briefly discuss the United States federal law with respect to medical marijuana. She has asked that I list all of the state medical marijuana laws in the United Sates that permit individual use of medical marijuana (other than through clinical trials alone). Among those states, Ms. Wray has asked me to discuss those that permit the personal production of medical marijuana and the number of plants an individual is permitted to grow in those states. For states that do not permit such personal production,

Ms. Wray has asked me to describe how medical marijuana is obtained by individuals in those states. Further, she has asked me to identify the states that permit the personal production of medical marijuana and also provide for other sources of obtaining medical marijuana. Last, Ms. Wray has asked that I discuss any restrictions in state laws on the form of marijuana that may be consumed for medical purposes. Ms. Wray's instruction letter is attached to this affidavit as Exhibit A. In addition, my Certificate of Expert, is attached as Exhibit B.

### My Background and Relevant Experience

- 4. I have practiced law in the United States for more than 17 years. For 12 of those years, I represented the United States Food and Drug Administration ("FDA"), in the agency's Office of Chief Counsel, most recently as a Senior Counsel for Drugs. In that capacity, I counseled the agency on all controlled substances matters and liaised with the United States Drug Enforcement Administration ("DEA").
- 5. As counsel for the FDA, I worked on a number of matters related to the federal and state regulation of marijuana including the provision of marijuana for clinical research, analysis and recommendations regarding the control of marijuana under the federal Controlled Substances Act ("CSA"), and litigation against the United States Government related to marijuana.
- 6. As a lawyer in private practice, I have counseled numerous pharmaceutical, research, and institutional clients on their responsibilities under the CSA, the federal Food, Drug, and Cosmetic Act, and state law regarding the handling of controlled substances. In particular, I have provided counsel to these clients regarding the federal and state regulation of marijuana.
- I was awarded a Bachelor of Arts degree, *Phi Beta Kappa*, from the College of Wooster in Wooster,
   Ohio in 1994. I was awarded a J.D. degree, *Order of the Coif*, from the College of William and Mary in Williamsburg, Virginia in 1997.
- 8. Exhibit C to this affidavit is a true copy of my curriculum vitae.

### Federal Regulation of Marijuana

Marijuana is a Schedule I Substance under the Federal Controlled Substances Act ("CSA")

- 9. The CSA lists both marijuana<sup>1</sup> and the psychotropic components of marijuana, tetrahydrocannabinols ("THC"), as Schedule I substances.<sup>2</sup> Schedule I is the most restrictive CSA schedule.<sup>3</sup>
- 10. Under the CSA, a Schedule I substance is one for which there is "no currently accepted medical use in treatment in the United States," "a lack of accepted safety for use of the drug or other substance under medical supervision," and a "high potential for abuse." Except as otherwise provided for in the CSA, there are both criminal and civil penalties for cultivating, manufacturing, distributing or possessing any amount of a controlled substance. 5
- 11. Since the original categorization of marijuana as a Schedule I substance by Congress in 1970, there have been several petitions filed requesting the federal government to change its schedule through the administrative process set forth in the CSA.<sup>6</sup> To move a substance to a different schedule, or out of the schedules entirely, the DEA must initiate a rulemaking process.<sup>7</sup> If a rescheduling petition is filed with DEA, the DEA must request a scientific and medical evaluation and a scheduling recommendation from the U.S. Department of Health and Human Services ("HHS").<sup>8</sup> FDA has administrative responsibility for drafting the HHS evaluation and recommendation, with concurrence from the HHS National Institute on Drug Abuse (NIDA). Such an evaluation and scheduling

The term marijuana is also commonly spelled "marihuana" in the U.S. There is no meaningful distinction between the two spellings. This affidavit will use the spelling "marijuana" consistently throughout for ease of reading.

<sup>21</sup> U.S.C. § 812(c). The CSA defines marijuana as "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin." 21 U.S.C. § 802(16). The Schedule I listing also applies to "any material, compound, mixture, or preparation, which contains" any quantity of marijuana or THC, including "any of their salts, isomers, and salts of isomers." 21 U.S.C. § 812(c).

<sup>&</sup>lt;sup>3</sup> See 21 U.S.C. § 812(b).

<sup>&</sup>lt;sup>4</sup> 21 U.S.C. § 812(b)(1).

See 21 U.S.C. §§ 844, 844a.

The CSA grants authority to the U.S. Attorney General to make changes to the schedules through a specified procedure. See 21 U.S.C. § 811(a). The Attorney General has delegated this authority to the U.S. Drug Enforcement Administration ("DEA"). See 28 C.F.R. § 0.100(b); 28 C.F.R. § 0.104.

<sup>&</sup>lt;sup>7</sup> See 21 U.S.C. § 811(a).

<sup>8</sup> See 21 U.S.C. § 811(b).

recommendation requires FDA to perform a substantial and in-depth review of available data and information on the substance that touches on all facets of abuse, medical use, and public health effects.

12. In response to the number of requests to reschedule marijuana that have triggered an evaluation and scheduling recommendation from HHS, HHS has consistently recommended that marijuana remain in Schedule I. DEA has agreed and denied the rescheduling requests after its own analysis of available data. Several of these decisions were appealed to the U.S. Court of Appeals for the D.C. Circuit, and in no case did the court overturn the DEA's ruling.<sup>10</sup>

# Possessing, Cultivating, Manufacturing or Distributing Marijuana without a DEA Registration Violates the CSA

- 13. The CSA prohibits possessing, cultivating, manufacturing or distributing any controlled substance without annually registering with the DEA. 11 However, DEA does not provide a registration for marijuana for non-research uses such as for medical treatment.
- 14. Federal law permits research on marijuana, but only if certain conditions are met.<sup>12</sup> To conduct research on marijuana, the researcher must first obtain a registration under the CSA from DEA.<sup>13</sup> To receive such a registration, HHS must determine that the researcher is qualified and competent and the proposed research must be determined to have merit.<sup>14</sup> Applying for such a registration requires submission of a detailed protocol to the DEA describing, among other things, the location where the research will take place and the security provisions for storing and dispensing the controlled substance

When assessing the scheduling of a substance, HHS and DEA are required to consider the following factors before making findings related to potential for abuse, currently accepted medical use in the U.S., and safety or dependence liability: (1) Its 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. See 21 U.S.C. § 811(c).

See, e.g., Americans for Safe Access v. DEA, 706 F.3d 438 (D.C. Cir. 2013); Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C. Cir. 1994); Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936 (D.C. Cir. 1991); NORML v. DEA, No. 79-1660 (D.C. Cir. Oct. 16, 1980); NORML v. DEA, 559 F.2d 735 (D.C. Cir. 1977); NORML v. Ingersol, 497 F.2d 654 (D.C. Cir. 1974).

<sup>11</sup> See 21 U.S.C. § 822(a).

See HHS Guidance on the Provision of Marijuana for Research (May 21, 1999), available at http://grants.nih.gov/grants/guide/notice-files/not99-091.html; see also NIH Grants Policy Statement at IIA (Oct. 2013 ed.).

<sup>&</sup>lt;sup>13</sup> 21 U.S.C. § 823(f).

<sup>&</sup>lt;sup>14</sup> *Id.*; 21 C.F.R § 1301.32.

to prevent diversion.<sup>15</sup> Certain research may also require an Investigational New Drug Application under the Federal Food, Drug, and Cosmetic Act ("FDCA"). <sup>16</sup> Researchers using Schedule I substances, including marijuana, are required to comply with DEA regulations regarding security, record-keeping and reporting (including reports of any theft or significant loss within one business day), and proper disposal of unwanted or unneeded controlled substances.<sup>17</sup> Failure to comply with federal requirements regarding research with a Schedule I controlled substance subjects the researcher and the research institution to civil and/or criminal penalties.

- 15. Since 1968, DEA has registered only a single manufacturer of marijuana for use in research activities only -- the National Center for Natural Products Research (the "Center") at the University of Mississippi operating under contract with NIDA.
- 16. The University of Massachusetts at Amherst applied to DEA for a registration to manufacture research-grade marijuana for purposes of clinical studies in 2001. In 2009 DEA denied the application on the basis that NIDA (through the Center) was capable of manufacturing an adequate quantity and quality of marijuana for meritorious scientific research. The applicant's appeal to the U.S. Court of Appeals for the First Circuit was unsuccessful inasmuch as the Court of Appeals held that DEA's decision to deny registration was entitled to deference and the applicant failed to demonstrate that the current supply of marijuana for research was inadequate.

# The Federal Government Interprets an International Treaty as Permitting Only One Source for Legal Cultivation of Marijuana in the United States

17. The United States is a signatory to the Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, <sup>18</sup> ("Single Convention"). DEA interprets the Single Convention to require each nation to designate a single official source of marijuana for research. <sup>19</sup> In the United States, NIDA has been

<sup>&</sup>lt;sup>15</sup> 21 C.F.R. § 1301.18.

<sup>&</sup>lt;sup>16</sup> 21 U.S.C. § 355(i).

<sup>&</sup>lt;sup>17</sup> 21 C.F.R. § 1301.71; 21 C.F.R. § 1301.75; 21 C.F.R. § 1301.76; 21 C.F.R. § 1304; 21 C.F.R. § 1317.05; and 21 C.F.R. § 1307.22.

<sup>&</sup>lt;sup>18</sup> 18 U.S.T. 1407.

See Brief for the Drug Enforcement Agency at 11, Craker v. Drug Enforcement Administration, No. 09-1220, 714 F.3d 17 (1st Cir. filed Mar. 22, 2012).

- designated as the responsible agency, and, as noted above, it contracts with the Center to grow marijuana as necessary for research in the United States.<sup>20</sup>
- 18. The Center is required to supply its product to meet the United States' entire need for marijuanarelated research and, as noted above, DEA has consistently found the supply to be "adequate and uninterrupted."<sup>21</sup>

# The Controlled Substances Act Requirements and Prohibitions are Unchanged by Any Contrary State Law

19. A 2005 United States Supreme Court decision makes clear that the CSA prohibitions related to marijuana are unaffected by contrary state laws. California residents challenged the reach of the CSA to regulate marijuana that was legal under California state law and that was grown, shipped, dispensed and used entirely in the state of California.<sup>22</sup> In addition to finding that the Commerce Clause permitted the CSA to reach even those who grew and consumed their own marijuana,<sup>23</sup> the Supreme Court found that the CSA "unambiguously" trumps any conflicting provision of state law.<sup>24</sup> The Court found that state laws governing marijuana could not in any way diminish the federal power to regulate drugs as exercised in the CSA.<sup>25</sup> As a result, the provisions of the CSA apply over any contrary provision of state law, even for marijuana that is grown and used entirely within the state. Indeed, these provisions apply even if the marijuana at issue were to be grown and consumed by the same person.<sup>26</sup>

# Statements from the U.S. Department of Justice Concerning its Enforcement Priorities Do Not Change Marijuana's Status as a Schedule I Substance

20. In 2009, <sup>27</sup> 2011, <sup>28</sup> and 2013 <sup>29</sup> the U.S. Department of Justice ("DOJ") sent memoranda to U.S. Attorneys outlining its CSA enforcement priorities regarding marijuana in light of changes in state

<sup>&</sup>lt;sup>20</sup> Id. at 7.

See, e.g., Craker v. Drug Enforcement Administration, 714 F.3d 17, 29 (1st Cir. 2013).

<sup>&</sup>lt;sup>22</sup> Gonzales v. Raich, 545 U.S. 1 (2005).

<sup>&</sup>lt;sup>23</sup> *Id.* at 15-33.

<sup>&</sup>lt;sup>24</sup> *Id.* at 29.

<sup>&</sup>lt;sup>25</sup> Id.

See id. at 7 ("Respondent Monson cultivates her own marijuana, and ingests the drug in a variety of ways").

Memorandum from James M. Cole, Deputy Attorney General, to Selected United States Attorneys (Oct. 19, 2009), available at http://www.justice.gov/opa/documents/medical-marijuana.pdf.

laws related to marijuana. The 2009 and 2011 memoranda draw a distinction between, on the one hand, patients and their caregivers using marijuana in a manner consistent with state law as part of treatment regime for a serious disease and, on the other hand, commercial entities engaged in the cultivation, sale, and distribution of marijuana. The 2013 memorandum outlines the current enforcement priorities that are particularly important to the federal government and notes that they are listed in general terms and "each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA:

- a. Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- c. Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- d. Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking or other illegal drugs or other illegal activity;
- e. Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- f. Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- g. Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands;
- h. Preventing marijuana possession or use on federal property."30
- 21. The 2013 DOJ memorandum also notes that it rests on DOJ's expectation that states that have enacted marijuana legislation "will implement strong and effective regulatory and enforcement systems that

<sup>30</sup> *Id.* at 1-2.

Memorandum from James M. Cole, Deputy Attorney General, to United States Attorneys (June 29, 2011), available at http://www.justice.gov/oip/docs/dag-guidance-2011-for-medical-marijuana-use.pdf.

Memorandum from James M. Cole, Deputy Attorney General, to All United States Attorneys (Aug. 29, 2013), available at http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf.

- will address the threat those state laws could pose to public safety, public health, and other law enforcement interests."<sup>31</sup>
- 22. The exercise of investigative and prosecutorial discretion is subject to change. Notably, the 2013 Memorandum states: "This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA."
- 23. For the foregoing reasons, federal law prohibits the cultivation, manufacture and distribution of marijuana in the United States, even if authorized or required by state law and even if such activity is for research purposes only. The only marijuana that can be possessed and used for research-related purposes is marijuana that the federal government supplies through NIDA. Thus, any other institution or person would be in violation of the CSA if it participates in the cultivation, manufacture or distribution of marijuana for research, medical treatment, or any other purpose. Violations of the CSA can result in civil and criminal penalties that can range from suspension or revocation of controlled substance registrations, to civil money penalties, property forfeiture and imprisonment.

#### State Regulation of Marijuana

24. Despite the CSA's clear proscription against the use and manufacture of marijuana absent a valid DEA registration, many U.S. states (35) have enacted laws which permit the medical use of marijuana. Of those 33 states, less than half (15) permit patients or their primary caregivers to personally produce marijuana, and many impose limits on the amount of marijuana a patient may grow. Every state that permits personal production 33 also permits the manufacture or cultivation of marijuana by other sources, such as through a state registered marijuana dispensary. Of the states that do not permit

<sup>31</sup> *Id.* at 2.

<sup>32</sup> *Id.* at 4.

For purposes of this report, the term "personal production" means the cultivation of marijuana plants by patients for medicinal use.

- personal production of marijuana, most (18) provide for alternative sources of obtaining marijuana. A few states do not provide an alternative cultivation source and prohibit personal production.<sup>34</sup>
- 25. Some states also limit the form of marijuana that may be consumed by patients. These states can generally be divided into two groups: those that limit the availability of certain high-potent forms of marijuana, such as hashish and oil; and those that make a single form of low-THC marijuana, such as cannabidiol, available for use by a narrow subset of patients, typically those who suffer from intractable epilepsy or other seizure related illnesses.

#### State Medical Marijuana Laws, Generally

26. As discussed above, there are currently 35 jurisdictions in the United States that permit the medical use of marijuana outside of a federal government sanctioned clinical trial. These jurisdictions, and the respective date of enactment of their medical marijuana laws, include: Alabama (2014), <sup>35</sup> Alaska (1998), <sup>36</sup> Arizona (2010), <sup>37</sup> California (1996), <sup>38</sup> Colorado (2000), <sup>39</sup> Connecticut (2012), <sup>40</sup> Delaware (2011), <sup>41</sup> District of Columbia (1998), <sup>42</sup> Florida (2014), <sup>43</sup> Hawaii (2000), <sup>44</sup> Illinois (2013), <sup>45</sup> Iowa (2014), <sup>46</sup> Kentucky (2014), <sup>47</sup> Maine (1999), <sup>48</sup> Maryland (2013), <sup>49</sup> Massachusetts (2012), <sup>50</sup> Michigan (2008), <sup>51</sup> Minnesota (2014), <sup>52</sup> Mississippi (2014), <sup>53</sup> Missouri (2014), <sup>54</sup> Montana (2004), <sup>55</sup> Nevada

<sup>&</sup>lt;sup>34</sup> See e.g., Iowa Code Ann. § 124D.6(1)(b) (stating medicinal marijuana must be obtained from an out-of-state source).

<sup>35</sup> Ala. Code § 13A-12-214.2.

Alaska Stat. Ann. §§ 17.37.030(a), 11.71.090(a); 1998 Ballot Measure No. 8 (approved by vote Dec. 1, 1998) repealed and reenacted as amended Jan. 1, 1999, (1999 Alaska Laws Ch. 37 (S.B. 94)).

Ariz. Rev. Stat. Ann. § 36-2811(A); Ariz. Legis. Serv., Initiative Measure, Prop. 203.

Cal. Health & Saf. Code, §§ 11362.5, 11362.71(a)(1), 11362.765, 11362.775; 1996 Cal. Legis. Serv. Prop. 215.
 Colo. Const. art. XVIII, sec. 14 (4)(a); see also Colo. Const. art. XVIII, sec. 14 (4)(a) (2012) (West) (credits)

stating the law was added by initiative on Nov. 7, 2000).

Conn. Gen. Stat. Ann. § 21a-408a(a); 2012 Conn. Legis. Serv. P.A. 12-55 (H.B. 5389).

Del. Code Ann. tit. 16, §§ 4903A(a), 4913A; 2011 Delaware Laws Ch. 23 (S.B. 17).

<sup>&</sup>lt;sup>42</sup> D.C. Code §§ 7-1671.02, 7-1671.05; 2000 District of Columbia Laws 13-315 (13-138 Act) (I.M. 59).

<sup>&</sup>lt;sup>43</sup> Fla. Stat. Ann. § 381.986(7)(a); 2014 Fla. Sess. Law Serv. Ch. 2014-157 (C.S.C.S.S.B. 1030).

<sup>44</sup> Haw. Rev. Stat. §§ 329-122(a), 329-125(a); 2000 Hawaii Laws Act 228 (S.B. 862).

<sup>45 410</sup> Ill. Code. § 130/25(a); 2013 Ill. Legis. Serv. P.A. 98-122 (H.B. 1).

<sup>46</sup> Iowa Code Ann. § 124D.6(3)(a); 2013 Iowa Laws (S.F. 2360).

<sup>&</sup>lt;sup>47</sup> Ky. Rev. Stat. Ann. § 218A.010 (21)(b); 2014 Kentucky Laws Ch. 112 (S.B. 124).

<sup>&</sup>lt;sup>48</sup> Me. Rev. Stat. tit. 22, §§ 2423-A, 2423-E; see also Me. Rev. Stat. tit. 22, § 2383-B(5), (6) (1999).

<sup>49</sup> Md, Code Ann § 13-3313(a)(1); 2013 Maryland Laws Ch. 403 (H.B. 1101).

Mass. Gen. Laws Ann. ch. 94C, § 1-4; see Commonwealth of Massachusetts, Dept. of Public Health, FAQ Regarding the Medical Use of Marijuana in Massachusetts.

Mich. Comp. Law §§ 333.26424(4)(a), 333.26428(8)(a); Michigan, Initiated Law 1 of 2008 (eff. Dec. 4, 2008).

<sup>&</sup>lt;sup>2</sup> Minn. Stat. Ann. § 152.32(1)(a); 2014 Minn. Sess. Law Serv. Ch. 311 (S.F. 2470).

(2001),<sup>56</sup> New Hampshire (2013),<sup>57</sup> New Jersey (2010),<sup>58</sup> New Mexico (2007),<sup>59</sup> New York (2014),<sup>60</sup> North Carolina (2014),<sup>61</sup> Oregon (1998),<sup>62</sup> Rhode Island (2006),<sup>63</sup> South Carolina (2014),<sup>64</sup> Tennessee (2014),<sup>65</sup> Utah (2014),<sup>66</sup> Vermont (2004),<sup>67</sup> Washington (1998),<sup>68</sup> and Wisconsin (2014).<sup>69</sup>

### Nearly All States That Permit Personal Cultivation Impose Growth/Possession Limits

- 27. Less than half of the states with medical marijuana laws (15) permit patients or their caregivers to personally produce marijuana. These states include Alaska, <sup>70</sup> Arizona, <sup>71</sup> California, <sup>72</sup> Colorado, <sup>73</sup> Hawaii, <sup>74</sup> Maine, <sup>75</sup> Massachusetts, <sup>76</sup> Michigan, <sup>77</sup> Montana, <sup>78</sup> Nevada, <sup>79</sup> New Mexico, <sup>80</sup> Oregon, <sup>81</sup> Rhode Island, <sup>82</sup> Vermont, <sup>83</sup> and Washington. <sup>84</sup>
- 28. Nearly all of these states, however, limit the amount of marijuana the patient and/or his caregiver can possess and/or grow. Specifically:

<sup>&</sup>lt;sup>53</sup> 2014 Miss. Legis. Serv. (H.B. no. 1231) at 20; see Miss. Code. Ann. § 41-29-113(31) (2014) (West) (credits).

Mo. Ann. Stat. § 195.207, 2014 Mo. Legis. Serv. H.B. 2238.

<sup>55</sup> Mont. Code Ann. §§ 50-46-319(2), 50-46-303(1); see Mont. Code. Ann. § 50-46-101 (2007).

<sup>&</sup>lt;sup>56</sup> Nev. Rev. Stat. § 453A.200(1); 2001 Nevada Laws Ch. 592 (A.B. 453).

<sup>&</sup>lt;sup>57</sup> N.H. Rev. Stat. Ann. § 126-X:2(I); 2013 N.H. Laws (H.B. 573).

<sup>58</sup> N.J. Stat. Ann. § 24:6I-6; 2009 NJ Sess. Law Serv. Ch. 307 (SENATE 119).

<sup>&</sup>lt;sup>59</sup> N.M. Stat. Ann. § 26-2B-4(a), New Mexico Laws Ch. 210 (S.B. 523).

<sup>60</sup> N.Y. Pub. Health Law §§ 3362(1), 3369(1); 2014 N.Y. Laws (Bill No. A06357E).

<sup>61</sup> N.C. Gen. Stat. §§ 90-94.1(b), 90-113.101(h); 2014 N.C. Sess. Laws (HB 1220).

<sup>62</sup> Or. Rev. Stat. Ann. § 475.319(1); 1998 Or. Laws (Initiative 67).

<sup>63</sup> R.I. Gen, Laws Ann. § 21-28.6-4(a); 2005 Rhode Island Laws Ch. 05-442 (05–S 710B).

<sup>64</sup> S.C. Code Ann. § 44-53-110(27)(b)(vi); 2013 S.C. Sess. Laws (S. 1035).

<sup>65 2014</sup> Tenn. Pub. Acts No. 936.

<sup>66</sup> Utah Code Ann. § 58-37-4.3(2); 2014 Utah Laws (H.B. 105).

<sup>67</sup> Vt. Stat. Ann. tit. 18, § 4474b(a); 2004 Vermont Laws P.A. 135 (S. 76).

Wash. Rev. Code Ann. § 69.51A.040; see Wash. Rev. Code § 69.51A.005 (West) (credits).

<sup>&</sup>lt;sup>69</sup> Wis. Stat. Ann. §§ 961.14(4)(t), 961.38(1n), 961.34; 2013 Wis. Sess. Laws (267).

<sup>&</sup>lt;sup>70</sup> Ala Stat §§ 17.37.030(a), 11.71.090(a).

<sup>&</sup>lt;sup>71</sup> Az. Rev. Stat. Ann §§ 36-2801(1)(a)(ii), 36-2804.02(A)(f).

<sup>&</sup>lt;sup>72</sup> Cal. Health & Saf. Code, §§ 11362.5; 11362.775.

Colo. Const. art. XVIII, sec. 14(1)(b).

<sup>&</sup>lt;sup>74</sup> Haw. Rev. Stat. § 329-121.

<sup>&</sup>lt;sup>75</sup> Me. Rev. Stat. tit. 22, §§ 2423-A(1)(B), § 2423-E(1).

<sup>&</sup>lt;sup>76</sup> Mass. Gen. Laws Ann. ch. 94C, §§ 1-4, 1-2.

<sup>&</sup>lt;sup>77</sup> Mich. Comp. Law §§ 333.26424(4)(a), 333.26423(f).

<sup>&</sup>lt;sup>78</sup> Mont. Code Ann. § 50-46-301(1)(b).

<sup>&</sup>lt;sup>79</sup> Nev. Rev. Stat. § 453A.120, 453A.200.

<sup>80</sup> N.M. Stat. Ann. §§ 26-2B-3(A), (D), and (F), N.M. Admin. Code § 7.34.2(D).

<sup>81</sup> Or. Rev. Stat. Ann. §§ 475.316(1)(e), 475.304(1).

<sup>82</sup> R.I. Gen. Laws Ann. § 21-28.6-3(7).

<sup>&</sup>lt;sup>83</sup> Vt. Stat. Ann. tit. 18, §§ 4474b; 4230.

<sup>&</sup>lt;sup>84</sup> Wash. Rev. Code Ann. § 69.51A.040.

- Alaska provides that a patient can only possess one ounce of marijuana in usable form and six marijuana plants, with no more than three mature and flowering plants producing usable marijuana at any one time;<sup>85</sup>
- b. Arizona permits a patient to possess up to two-and-one-half ounces of usable marijuana. <sup>86</sup> If the patient is also authorized by the state to cultivate his own marijuana, he may cultivate twelve marijuana plants at one time; <sup>87</sup>
- c. While California's medical marijuana law does not limit the amount of marijuana a patient may possess or produce, it specifically authorizes local jurisdictions to do so. Most localities have availed themselves of this rule. Currently, there are over 50 California municipal regulations and ordinances that limit either the grow area or the number of marijuana plants that an individual may cultivate. Some localities have imposed complete bans on cultivation of marijuana in their jurisdictions; <sup>89</sup>
- d. Colorado's marijuana laws state that possession of two ounces of useable marijuana and no more than six marijuana plants, with three or fewer being mature, is lawful;<sup>90</sup>
- e. Hawaii permits a patient and caregiver, collectively, to possess not more than an "adequate supply" to ensure the uninterrupted availability of marijuana to alleviate the patient's symptoms which, until January 2, 2015, shall not exceed three mature plants, four immature plants, and one ounce of useable marijuana; and after January 2, 2015, is not more than seven mature and/or immature plants and four ounces of useable marijuana; <sup>91</sup>

86 Ariz. Rev. Stat. Ann § 36-2801(1)(a)(i).

<sup>85</sup> Ala. Stat. § 17.37.040(a)(4).

Ariz. Rev. Stat. Ann §§ 36-2801(1)(a)(ii); The state will grant the patient authorization to grow if the patient can demonstrate that the patient resides outside of a 25 mile radius of a registered dispensary; See Ariz. Rev. Stat. Ann § 36-2804.02(A)(f).

See Cal. Health & Saf. Code § 11362.83. While the text of Cal. Health & Saf. Code § 11362.77 imposes possession limits of eight ounces of dried marijuana and six mature or 12 immature plants, the Supreme Court of California has held that provision unconstitutional to the extent that it limits a defense that the amount possessed by a patient is for personal medical use under the California Compassionate Use Act. People v. Kelly, 222 P.3d 186, 213 (Cal. 2010).

See, e.g., Fresno Co., Ca., Code § Ordinance No. 2014-20. (April 8, 2014).

See Colo. Const. art. XVIII, sec. 14(4)(a).

<sup>&</sup>lt;sup>91</sup> See Haw. Rev. Stat. § 329-121.

- f. Maine permits a patient to possess two-and-one-half ounces of prepared marijuana, an incidental amount of marijuana, and six mature plants; 92
- g. Massachusetts permits a patient to possess marijuana in sufficient amounts to maintain a 60-day supply, which Massachusetts has found to be 10 ounces, unless more is specified by patient's certifying physician;<sup>93</sup>
- Michigan permits individuals to possess two-and-one-half ounces of usable marijuana, any incidental amount of seeds, stalks, and unusable roots, and if authorized to cultivate, 12 marijuana plants;<sup>94</sup>
- Montana permits an individual to produce up to four mature plants, 12 seedlings, and one ounce of usable marijuana;<sup>95</sup>
- j. Nevada permits the possession and/or cultivation of two-and-one-half ounces of usable marijuana in any one 14-day period; 12 marijuana plants, irrespective of whether the marijuana plants are mature or immature; and a maximum allowable quantity of edible marijuana products and marijuana-infused products as established by the State. In defense of prosecution for possessing or cultivating more than the allowable amount, a patient may prove that the amount he possessed and/or cultivated is medically necessary, as determined by the patient's attending physician, to mitigate the symptoms or effects of the person's chronic or debilitating medical condition; <sup>96</sup>
- k. New Mexico limits possession and cultivation to six ounces of useable cannabis (or more if authorized by the patient's physician), and 16 plants (four mature, 12 immature), or the patient may possess a three month supply of topical cannabis treatment;<sup>97</sup>
- Oregon permits the personal production and possession of 24 ounces of usable marijuana, six mature plants, and 18 immature seedlings;<sup>98</sup>

Me. Rev. Stat. tit. 22, §§ 2423-A(1)(A), 2422(4)(A) (Incidental amount means an amount of nonflowering marijuana plants and marijuana seeds, stalks and roots defined by rules adopted by the department.).

<sup>93</sup> Mass. Gen. Laws Ann. ch. 94C, §§ 1-4, 1-8; 105 CMR 725.010 (I).

<sup>94</sup> Mich, Comp. Law § 333,26424(4)(a).

<sup>95</sup> Mont. Code Ann. §50-46-319(1)(a).

Nev. Rev. Stat. §§ 453A.200(3)(b), 453A.310(1)(a)(3).

N.M. Stat. Ann. § 26-2B-3(A); N.M. Admin. Code § 7.34.2.7(D).

- m. Rhode Island limits personal possession and cultivation to two-and-one-half ounces of useable marijuana and 12 mature plants;<sup>99</sup>
- n. Vermont limits the amount of marijuana between a caregiver and a patient to no more than two ounces of useable marijuana, and no more than seven marijuana plants, of which no more than two may be mature; and <sup>100</sup>
- o. Washington permits possession of 24 ounces of usable marijuana and up to 15 marijuana plants, no more cannabis product than what could reasonably be produced with no more than 24 ounces of useable cannabis, or a combination of useable cannabis and cannabis product that does not exceed a combined total representing possession and processing of no more than 24 ounces of useable cannabis.<sup>101</sup>

# Nearly All Jurisdictions That Prohibit Personal Cultivation Create Alternative Means of Accessing Medical Marijuana

29. As indicated above, most U.S. jurisdictions that have medical marijuana programs, and that do not permit the personal production of marijuana, have identified alternative means of accessing medical marijuana. These jurisdictions include: Alabama, <sup>102</sup> Connecticut, <sup>103</sup> Delaware, <sup>104</sup> District of Columbia, <sup>105</sup> Florida, <sup>106</sup> Illinois, <sup>107</sup> Kentucky, <sup>108</sup> Maryland, <sup>109</sup> Minnesota, <sup>110</sup> Mississippi, <sup>111</sup> Missouri, <sup>112</sup> New Hampshire, <sup>113</sup> New Jersey, <sup>114</sup> New York, <sup>115</sup> North Carolina, <sup>116</sup> Tennessee, <sup>117</sup> Utah <sup>118</sup> and Wisconsin. <sup>119</sup>

<sup>98</sup> Or. Rev. Stat. Ann. § 475.320(1)(a), (4)(a).

<sup>&</sup>lt;sup>99</sup> R.I. Gen. Laws Ann. § 21-28.6-4(a).

<sup>&</sup>lt;sup>100</sup> Vt. Stat. Ann. tit. 18, § 4472(10).

<sup>&</sup>lt;sup>101</sup> Wash. Rev. Code Ann. § 69.51A.040(1)(a).

<sup>&</sup>lt;sup>102</sup> See Ala. Code § 13A-12-214.2(f).

<sup>&</sup>lt;sup>103</sup> See Conn. Gen. Stat. Ann. §§ 21-408j, 21a-408b.

<sup>&</sup>lt;sup>104</sup> See Del. Code Ann. tit. 16, § 4903A(b), (i).

<sup>&</sup>lt;sup>105</sup> See D.C. Code §§ 7-1671.02(b), 7-1671.06(a).

<sup>&</sup>lt;sup>106</sup> See Fla. Stat. Ann. § 381.986(7).

See 410 Ill. Code. § 130/25(b), (f).

<sup>&</sup>lt;sup>108</sup> See Ky. Rev. Stat. Ann. § 218A.010 (21)(b).

<sup>&</sup>lt;sup>109</sup> See Md. Code Ann. § 13-3307(f)(5)(i).

<sup>&</sup>lt;sup>110</sup> See Minn. Stat. Ann. §§ 152.29(3), 152.30(c).

<sup>&</sup>lt;sup>111</sup> See 2014 Miss. Legis. Serv. (H.B. 1231) at 19.

<sup>&</sup>lt;sup>112</sup> See Mo. Ann. Stat. §§ 192.945(5)(2), 261.265(1)(1).

<sup>&</sup>lt;sup>113</sup> See N.H. Rev. Stat. Ann. § 126-X:2(II), (IX).

<sup>&</sup>lt;sup>114</sup> See N.J. Stat. Ann. § § 24:61-3, 24:61-6.

<sup>&</sup>lt;sup>115</sup> See N.Y. Pub. Health Law §§ 3362(1), 3364(2), 3365(9).

- 30. One of the most commonly prescribed forms of access to medical marijuana is a state registered dispensary.
- 31. Otherwise, some states that prohibit home cultivation permit a qualifying patient to obtain marijuana from his or her designated caregiver. However, those states do not authorize the caregiver to engage in home cultivation. Thus, the caregiver would likely obtain the patient's marijuana from an authorized source, such as a state registered dispensary.
- 32. Also, some states require that medical marijuana be obtained from or with the cooperation of state research institutions, such as state Universities. As discussed above, this may prove difficult for Universities who seek to remain compliant with federal law, as DEA has not authorized such programs outside of federal law compliant research studies.
- 33. The specific forms of access provided by each state that does not permit personal production are:
  - a. health care practitioners of the University of Alabama, in Alabama; 121
  - b. the patient's primary caregiver or a state licensed dispensary, in Connecticut; 122
  - c. a registered caregiver or a compassion center, in Delaware; 123
  - d. the patient's qualified caregiver or the patient's designated dispensary, in the District of Columbia; 124
  - e. the patient's caregiver or a dispensing organization, in Florida; 125
  - f. a registered designated caregiver or a registered dispensing organization, in Illinois; 126
  - g. pursuant to a written order of a physician practicing at a hospital or associate clinic affiliated with Kentucky public university having a college or school of medicine, in Kentucky; 127

<sup>&</sup>lt;sup>116</sup> See N.C. Gen. Stat. §§ 90-94.1(c), 90-113.105(a).

<sup>&</sup>lt;sup>117</sup> See 2014 Tenn. Pub. Acts No. 936.

<sup>&</sup>lt;sup>118</sup> See Utah Code Ann. § 4-41-103(2).

<sup>&</sup>lt;sup>119</sup> See Wis. Stat. Ann. §§ 961.38(1)(n), 961.34(2).

<sup>&</sup>lt;sup>120</sup> See, e.g., 2014 Miss. Legis. Serv. (H.B. no. 1231) at 19.

<sup>&</sup>lt;sup>121</sup> Ala. Code § 13A-12-214.2(f).

<sup>&</sup>lt;sup>122</sup> Conn. Gen. Stat. Ann. §§ 21-408j(b), 21a-408b(b).

Del. Code Ann. tit. 16, § 4903A(b), (i).

D.C. Code §§ 7-1671.02(b), 7-1671.06(a).

<sup>&</sup>lt;sup>125</sup> Fla. Stat. Ann. § 381.986(7).

<sup>&</sup>lt;sup>126</sup> 410 III. Code, § 130/25(b).

<sup>&</sup>lt;sup>27</sup> Ky. Rev. Stat. Ann. § 218A.010 (21)(b).

- h. a qualifying caregiver, a licensed medical marijuana grower, or a licensed dispensary, in
   Maryland;<sup>128</sup>
- i. a pharmacist employed by a registered manufacturer, in Minnesota; 129
- j. the Department of Pharmacy Services at the University of Mississippi Medical Center, in Mississippi; 130
- k. a cannabidiol oil care center, in Missouri; 131
- 1. the patient's designated caregiver or an alternative treatment center, in New Hampshire; 132
- m, the patient's designated caregiver or an alternative treatment center, in New Jersey; 133
- n. the patient's designated caregiver or the dispensing site of a registered organization, in New York;<sup>134</sup>
- a registered caregiver or a neurologist affiliated with the University of North Carolina Chapel
   Hill, East Carolina University, Duke University, or Wake Forest University, who is also engaged in a registered "pilot" study, in North Carolina;<sup>135</sup>
- p. through a physician practicing at a hospital or associated clinic affiliated with a university having a college or school of medicine and as part of a clinical research study, in Tennessee.<sup>136</sup>
- q. a higher education program certified by the State of Utah to grow hemp extract, in Utah; 137
- r. an approved pharmacy or physician, in Wisconsin. 138
- 34. A few states that permit medicinal marijuana and prohibit personal production do not create means through which the patients may access the medication within the state. 139

<sup>&</sup>lt;sup>128</sup> Md. Code Ann. § 13-3307(f)(5)(i).

<sup>&</sup>lt;sup>129</sup> Minn, Stat. Ann. §§ 152.29(3), 152.30(c)..

<sup>&</sup>lt;sup>130</sup> 2014 Miss. Legis, Serv. (H.B. 1231) at 19.

<sup>&</sup>lt;sup>131</sup> Mo. Ann. Stat. §§ 192.945(5)(2), 261.265(1)(1).

<sup>&</sup>lt;sup>132</sup> N.H. Rev. Stat. Ann. § 126-X:2(II), (IX).

<sup>&</sup>lt;sup>133</sup> N.J. Stat. Ann. §§ 24:6I-3, 24:6I-6.

<sup>&</sup>lt;sup>134</sup> N.Y. Pub. Health Law §§ 3362(1), 3364(2), 3365(9).

<sup>&</sup>lt;sup>135</sup> N.C. Gen. Stat. §§ 90-94.1(c), 90-113.105(a).

<sup>&</sup>lt;sup>136</sup> 2014 Tenn. Pub. Acts No. 936.

<sup>&</sup>lt;sup>137</sup> Utah Code Ann. § 4-41-103(2).

Wis. Stat. Ann. §§ 961.38(1)(n). Wisconsin will approve physicians and pharmacies to dispense medical marijuana in Wisconsin, if the prescribing physician obtains an investigational drug permit from FDA or DEA removes the particular form of medicinal marijuana permitted in Wisconsin (cannabidiol) from Schedule I. *Id.* § 961.34(2).

# All States that Permit Personal Production Create Alternative Opportunities for Access to Medical Marijuana

35. Every state identified above that permits a patient's cultivation of marijuana, also provides for alternative mechanisms of access, similar to the categories identified above. Those states include Alaska, <sup>140</sup> Arizona, <sup>141</sup> California, <sup>142</sup> Colorado, <sup>143</sup> Hawaii, <sup>144</sup> Maine, <sup>145</sup> Massachusetts, <sup>146</sup> Michigan, <sup>147</sup> Montana, <sup>148</sup> Nevada, <sup>149</sup> New Mexico, <sup>150</sup> Oregon, <sup>151</sup> Rhode Island, <sup>152</sup> Vermont, <sup>153</sup> and Washington. <sup>154</sup> In some instance, those state permit access through the patient's primary caregiver, who is also authorized to cultivate marijuana. <sup>155</sup>

### Many Jurisdictions Limit the Form of Medical Marijuana Available To Patients

- 36. Marijuana can be ingested or administered in several different forms, including by smoking and inhalation, orally in combination with food products or as a tincture, or even topically. Oils that are extracted from the marijuana plant may have higher tetrahydrocannabinol ("THC") content, and, thus, may be more potent than traditional dry forms marijuana.<sup>156</sup>
- 37. Some U.S. jurisdictions have limited the form of marijuana available for medical use. For example, in response to apparent safety concerns, <sup>157</sup> the State of Colorado recently amended its marijuana laws to

See S.C. Code Ann. § 44-53-110(27)(b)(vi) (removing cannabidiol that is prescribed under the law from South Carolina's list of controlled substances but not creating mechanisms through which the patient may obtain cannabidiol in the state); Iowa Code Ann. § 124D.6(1)(b) (specifically requiring that cannabidiol be obtained from an out-of-state source).

Alaska Ala Stat. § 11.71.090(a).

<sup>&</sup>lt;sup>141</sup> Ariz. Rev. Stat. Ann. § 36-2811, Ariz. Rev. Stat. Ann § 36-2804.02(A)(f), Ariz. Rev. Stat. Ann § 36-2804.

Cal. Health & Saf. Code § 11362.775; Cal. Health & Saf. Code § 11362.83; See also City of Riverside v. Inland Empire Patients Health and Wellness Center, 56 Cal. 4th 729, 300 P.3d 494 (2013).

<sup>&</sup>lt;sup>143</sup> Colo. Rev. Stat. Ann. § 25-1.5-106(13).

<sup>&</sup>lt;sup>144</sup> Haw. Rev. Stat. §§ 329-121, 329-125.

<sup>&</sup>lt;sup>145</sup> Me. Rev. Stat. tit. 22, § 2423-A(1)(B), Me. Rev. Stat. tit. 22, § 2428(1-A).

<sup>146</sup> Mass. Gen. Laws Ann. ch. 94C, § 1-9.

<sup>&</sup>lt;sup>147</sup> Mich. Comp. Law §§ 333.26424(b), 333.26428(8)(a).

<sup>&</sup>lt;sup>148</sup> Mont. Code Ann. §§ 50-46-319, 50-46-302.

<sup>&</sup>lt;sup>149</sup> Nev. Rev. Stat. § 453A.115.

<sup>&</sup>lt;sup>150</sup> N.M. Stat. Ann. § 26-2B-3; N.M. Regs. 7.34.4.8.

<sup>&</sup>lt;sup>151</sup> Or. Rev. Stat. Ann. § 475.314.

R.I. Gen. Laws Ann. § 21-28.6-12(4)(a), (d); See also 2014 Rhode Island Laws Ch. 14-515 (14-H 7610A) (effective Sept. 1, 2014).

<sup>&</sup>lt;sup>153</sup> Vt. Stat. Ann. tit. 18, § 4472.

<sup>&</sup>lt;sup>154</sup> Wash. Rev. Code Ann. §§ 69.51A.085(1), 69.51A.040(5)(11).

<sup>&</sup>lt;sup>155</sup> See e.g., Haw. Rev. Stat. §§ 329-121, 329-125.

United States Drug Enforcement Administration ("DEA"), Drug Fact Sheet, Marijuana (July 9, 2014).

See New York Post, Colorado's Pot Boom Leads to Rash of Cannabis Oil Explosions (May 6, 2014).

exclude lawful access to "marijuana concentrate." <sup>158</sup> Colorado defines "marijuana concentrate" as "hashish, tetrahydrocannabinols, or any alkaloid, salt, derivative, preparation, compound, or mixture, whether natural or synthesized, of tetrahydrocannabinols." <sup>159</sup>

- 38. Other states have similar exclusions in their medical marijuana laws. Namely,
  - a. Alaska does not permit access to hash, hashish, and oil, separately from marijuana, through its medical marijuana program. 160
  - b. Arizona excludes cannabis from its medical marijuana program. Arizona defines cannabis as "[t]he resin extracted from any part of a plant of the genus cannabis, and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or its resin ... and every compound, manufacture, salt, derivative, mixture or preparation of such resin or tetrahydrocannabinol;" 162
  - c. Maine excludes "the resin extracted from any part of such plant and every compound, manufacture, salt, derivative, mixture or preparation from such resin including hashish" from its definition of marijuana, 163 and, thus, from its medical marijuana program.
  - d. Montana excludes "hashish" from its medical marijuana program. "'Hashish', as distinguished from marijuana, means the mechanically processed or extracted plant material that contains tetrahydrocannabinol (THC) and is composed of resin from the cannabis plant." 164
  - e. New Jersey excludes "any compound, manufacture, salt, derivative, mixture, or preparation resin of the plant", which is separately defined as "Hashish," from its program." 165
- 39. Other states have delegated authority to government agencies or officials to determine whether certain forms of marijuana should be excluded from medical use. Specifically, the District of Columbia

<sup>&</sup>lt;sup>158</sup> See Colo. Rev. Stat. Ann. § 18-18-102(18).

<sup>1</sup>d. at 19.

<sup>&</sup>lt;sup>160</sup> Alaska Stat. Ann. §§ 11.71.900(14), 11.71.160(f)(1), 11.71.60.

<sup>&</sup>lt;sup>161</sup> See Ariz. Rev. Stat. Ann §§ 36-2801, 13-3401(4).

<sup>&</sup>lt;sup>162</sup> Ariz. Rev. Stat. Ann § 13-3401(4).

<sup>&</sup>lt;sup>163</sup> Me. Rev. Stat. tit. 17A, § 1101(1), (5).

Mont. Code Ann. § 50-32-101(15); State v. Pirello, 282 P.3d 662 (Mont. 2012)

<sup>&</sup>lt;sup>165</sup> N.J. Stat. Ann. §§ 24:6I-3, 24:21-2.

delegated this authority to the D.C. Mayor.<sup>166</sup> The Mayor did not, in turn, limit the form of marijuana available under the law.<sup>167</sup> Similarly, the State of New York recently delegated authority to the Commissioner of Health of the State of New York to limit the form of marijuana available, who has yet to do so.<sup>168</sup>

- 40. Some states have specifically excluded smoking from the definition of permissible medical use in their marijuana laws. These states are Florida, <sup>169</sup> New York, <sup>170</sup> and Minnesota. <sup>171</sup> Both Florida and Minnesota clarified that smoking does not include the use of a vaporizer. <sup>172</sup>
- 41. Florida also falls within a narrow category of states that recently enacted legislation to make a limited form of medical marijuana available to patients who suffer from certain rare diseases, such as intractable epilepsy or other seizure related illnesses. This category of states includes, in addition to Florida: Iowa, Kentucky, Mississippi, Mississippi, Missouri, North Carolina, South Carolina, Utah, and Wisconsin. The following list contains the substances permitted for use in these programs:
  - a. Cannabidiol, which is defined as "a nonpsychoactive cannabinoid found in the plant Cannabis sativa L. or Cannabis indica or any other preparation thereof that is essentially free from plant material, and has a tetrahydrocannabinol level of no more than three percent," for oral or transdermal administration, in Iowa;<sup>182</sup>

D.C. Code § 7-1671.13(a)(7).

<sup>&</sup>lt;sup>167</sup> See D.C. Mun. Regs. Tit. 22-C, § 5609 (2014).

<sup>&</sup>lt;sup>168</sup> N.Y. Pub. Health Law § 3302.

<sup>&</sup>lt;sup>169</sup> Fla. Stat. Ann. § 381.986(b), (c).

<sup>170</sup> N.Y. Pub. Health Law §§ 3360(1)

<sup>&</sup>lt;sup>171</sup> Minn. Stat. Ann. § 152,22(6).

<sup>&</sup>lt;sup>172</sup> Fla. Stat. Ann. § 381.986. Minn. Stat. Ann. § 152.22(6).

<sup>&</sup>lt;sup>173</sup> Fla. Stat. Ann. § 381.986; N.Y. Pub. Health Law § 3365.

<sup>174</sup> Iowa Code Ann. §§ 124D.6(3)(a).

<sup>175</sup> Ky. Rev. Stat. Ann. § 218A.010 (21)(b).

<sup>&</sup>lt;sup>176</sup> 2014 Miss. Legis. Serv. (H.B. no. 1231).

<sup>&</sup>lt;sup>177</sup> Mo. Ann. Stat. §195.207.

<sup>&</sup>lt;sup>178</sup> N.C. Gen, Stat. §§ 90-94.1(b).

<sup>&</sup>lt;sup>179</sup> S.C. Code Ann. § 44-53-110(27)(b)(vi).

<sup>&</sup>lt;sup>180</sup> Utah Code Ann. § 58-37-4.3(2)

<sup>&</sup>lt;sup>181</sup> Wis. Stat. Ann. § 961.14(4)(t).

<sup>&</sup>lt;sup>182</sup> Iowa Code Ann. § 124D.2(1).

- b. Cannabidiol, which is undefined by the state, in Kentucky; 183
- c. Processed cannabis plant extract, oil or resin that contains more than fifteen percent (15%) cannabidiol (CBD) or a dilution of the resin that contains at least fifty (50) milligrams of cannabidiol per milliliter, but not more than one-half of one percent (.5%) of tetrahydrocannabinol, in Mississippi; 184
- d. "Hemp extract" which is defined as "cannabis plant or a mixture or preparation containing cannabis plant material that: (1) Is composed of no more than three tenths percent tetrahydrocannabinol by weight; (2) Is composed of at least five percent cannabidiol by weight; and (3) Contains no other psychoactive substance" in Missouri; 185
- e. "Hemp Extract" which is defined as an extract from a cannabis plant, or a mixture or preparation containing cannabis plant material, that has all of the following characteristics: composed of less than three-tenths of one percent (0.3%) tetrahydrocannabinol by weight; is composed of at least ten percent (10%) cannabidiol by weight; and contains no other psychoactive substances, in North Carolina; 186
- f. "Cannabidiol" which is defined as "a nonpsychoactive cannabinoid, or any compound, manufacture, salt, derivative, mixture, or preparation of any plant of the genus cannabis that contains nine-tenths of one percent or less of tetrahydrocannabinol and more than fifteen percent of cannabidiol" in South Carolina; 187
- g. an "extract from a cannabis plant, or a mixture or preparation containing cannabis plant material, that: is composed of less than 0.3% tetrahydrocannabinol by weight; is composed of at least 15% cannabidiol by weight; and contains no other psychoactive substance" in Utah; 188 and
- h. Cannabidiol "in a form without a psychoactive effect," in Wisconsin. 189

<sup>&</sup>lt;sup>183</sup> See Ky. Rev. Stat. Ann. § 218A.010 (21)(b).

<sup>&</sup>lt;sup>184</sup> Miss. Code, Ann. § 41-29-113(31), 2014 Miss. Legis. Serv. (H.B. 1231) at 19.

<sup>&</sup>lt;sup>185</sup> Mo. Ann. Stat. § 192.945(1), (3).

<sup>&</sup>lt;sup>186</sup> N.C. Gen. Stat. § 90-94.1(a).

<sup>&</sup>lt;sup>187</sup> S.C. Code Ann. § 44-53-110(27)(b)(vi).

<sup>&</sup>lt;sup>188</sup> Utah Code Ann. § 58-37-4.3(1).

<sup>&</sup>lt;sup>189</sup> Wis. Stat. Ann. § 961.14(4)(t).

42. Florida's program is limited to the delivery of "Low-THC cannabis" which Florida defines as a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.<sup>190</sup>

43. New York has a similar program but has not yet defined the specific substances that will be made available in that program.<sup>191</sup>

#### Conclusion

44. Despite clear federal restrictions on the manufacture, possession, distribution and use of marijuana, many U.S. jurisdictions have adopted laws that permit the medical use of marijuana. These programs vary in nature and scope, yet display some commonalities. Namely, most state medical marijuana programs impose limitations on the amount of marijuana that a patient or his caregiver can possess or manufacture (if authorized to do so) under state law. Also, an overwhelming majority of states that do not permit patients to manufacture marijuana, have developed programs, including the registration of licensed manufacturers and dispensaries, to facilitate access to medical marijuana by patients and their caregivers. States that limit the form of marijuana available under their programs typically fall into two categories: those that exclude from their programs the use of hashish or other potent THC products, and those that limit their programs to exclusively low-THC products.

Lynn Whipkey Mehler

<sup>&</sup>lt;sup>190</sup> Fla. Stat. Ann. § 381.986(b).

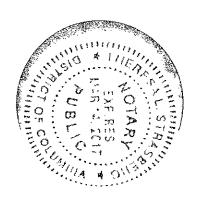
<sup>191</sup> See N.Y. Pub. Health Law § 3360(8).

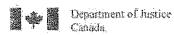
# Exhibit A Instruction Letter

This is Exhibit A referred to in the affidavit of Lynn Whipkey Mehler sworn before me this 20 day of OCTOBEL, 2014.

Notary Public of the District of Columbia

My commission expires: MARCH 14 2017





Ministère de la Justice Canada

900-840 Howe Street Vancouver, British Columbia V6Z 259 Telephone: 604-666-4304 Facsimile: 604-775-5942 Email: bj.wray@jastiee.gc.ca

June 3, 2014

By Email to: lynn.mehler@hoganlovells.com

Lynn Mehler Hogan Lovells US, LLP Columbia Square 555 Thirteenth St., NW Washington, D.C. 20004 Phone: 202-637-6419 Fax: 202-637-5910

Dear Ms. Mehler:

Allard et al. v. Her Majesty the Queen in Right of Canada Instruction Letter for Expert Report

Thank you for agreeing to provide the Attorney General of Canada ("AGC") with an expert report in the matter of Allard et al. v. Her Majesty the Queen in Right of Canada. As discussed, this Federal Court litigation involves a constitutional challenge to the Marihuana for Medical Purposes Regulations (the "MMPR").

### Background Information

The plaintiffs in this litigation, all of whom are medical marihuana users, are challenging the constitutionality of the MMPR on the basis that they cause several unjustified violations of their rights to liberty and security of the person under the Canadian Charter of Rights and Freedoms.

The plaintiffs' constitutional challenge in Allard focuses on four aspects of the MMPR that differ from the old medical marihuana regime: (1) the elimination of personal cultivation of marihuana in favour of requiring approved individuals to purchase from licensed producers; (2) the restriction that licensed producers may not cultivate marihuana in dwelling places or outdoor areas; (3) the limit on possession of marihuana to either 150g or 30 times the amount prescribed for daily consumption by the individual's medical practitioner, whichever is less; and (4) the failure of the MMPR to permit the production and possession of non-dried marihuana such as cannabis oils, salves, tinctures and edibles.

The plaintiffs have obtained an injunction from the Court that permits them to continue personal production of medical marihuana until the constitutionality of the MMPR is decided by the Court.

The AGC is the defendant and it is the AGC's position that the current medical marihuana regime is constitutionally sound, a position that will be defended by legal counsel on behalf of the AGC.

### Facts and Assumptions.

The facts alleged by the plaintiffs are outlined in the Amended Notice of Civil Claim which is enclosed.

### **Questions for Your Expert Report**

Please address the following matters in your expert report:

- 1. Briefly discuss United States federal law with respect to medical manhuana, including federal law with respect to research and clinical trials;
- 2. List all of the state medical marihuana laws in the United States that permit individual use of medical marihuana (other than through clinical trials alone) and the dates that those laws were initially enacted;
- Discuss which of the states in question number 2 permit the personal production of medical maribuana and set out the number of plants an individual is permitted to grow and/or the amount of medical maribuana an individual is permitted to possess or to consume;
- 4. Discuss which of the states in question number 2 do not permit the personal production of medical marihuana and describe how medical marihuana is obtained by individuals in those states;
- 5. Discuss which of the states in question number 2 permit both the personal production of medical marihuana and also provide for other sources of obtaining medical marihuana;
- 6. Discuss restrictions, if any, in state laws on the form of marihuana that may be consumed for medical purposes.

#### Format of Your Expert Report

Your report must be prepared in accordance with the Federal Courts Rules. As such, we ask that you do the following within the body of your report:

- 1. Set out the issues to be addressed in the report;
- 2. Describe your qualifications on the issues to be addressed;
- 3. Attach your current curriculum vitae as a schedule to the report;
- 4. Attach this letter of instruction as a schedule to the report;
- 5. Provide a summary of your opinions on the issues addressed in the report;
- 6. Set out the reasons for each opinion that is expressed in the report;

- 7. Attach any publications of other materials specifically relied on in support of the opinions:
- 8. If applicable, provide a summary of the methodology used in the report;
- Set out any caveats or qualifications necessary to render the report complete and accurate, including those relating to any insufficiency of data or research and an indication of any matters that fall outside of your field of expertise; and.
- 10. Particulars of any aspect of your relationship with a party to the proceeding or the subject matter of your report that might affect your duty to the Court.

Please number each paragraph of your report as this will aid us in referring to your report in Court.

Please sign and date your report.

## Duty to the Court

As an expert witness, you have a duty to the Court which is set out in the attached Code of Conduct for Expert Witnesses. Please carefully review this Code of Conduct and, after doing so, sign the attached Certificate and send it back to us.

## **Due Dates and Procedural Matters**

We are required to file our expert reports on or before November 1, 2014. The trial has been set for three weeks commencing February 23, 2015. You may be required to attend the trial for cross-examination and, if so, we will attempt to accommodate your schedule to the extent possible.

Please keep all correspondence pertaining to this assignment in a separate "Expert Witness Report" folder.

We look forward to receiving a draft of your report the first week of September, 2013,

Please do not hesitate to contact me by telephone at 604-666-4304 if you require further information or have questions regarding the foregoing.

Yours truly,

BJ Wray Counsel

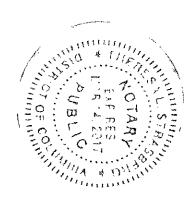
Enclosures: Certificate for Expert Witnesses; Code of Conduct for Expert Witnesses; Amended Notice of Civil Claim

# Exhibit B Certificate of Expert

This is Exhibit B referred to in the affidavit of Lynn Whipkey Mehler sworn before me this 20 day of OCIDBIER, 2014.

Notary Public of the District of Columbia

My commission expires: MARCH 14 , 20 /7



Court File No.: T-2030-13

#### FEDERAL COURT

BETWEEN:

NEIL ALLARD TANYA BEEMISH DAVID HEBERT SHAWN DAVEY

**PLAINTIFFS** 

and

### HER MAJESTY THE QUEEN IN RIGHT OF CANADA

**DEFENDANT** 

# **Certificate Concerning Code of Conduct for Expert Witnesses**

I, Lynn Mehler, having been named as an expert witness by the Defendant, Her Majesty the Queen in Right of Canada, certify that I have read the Code of Conduct for Expert Witnesses set out in the schedule to the *Federal Courts Rules* and agree to be bound by it.

Date: October 20, 2014

Lynn Mehler

Hogan Lovells US, LLP

Columbia Square

555 Thirteenth St., NW Washington, D.C. 20004

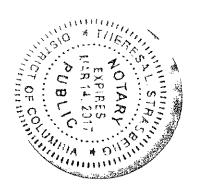
Phone: 202-637-6419 Fax: 202-637-5910

## Exhibit C Curriculum Vitae

This is Exhibit C referred to in the affidavit of Lynn Whipkey Mehler sworn before me this 20 day of Octuber, 2014.

Notary Public of the District of Columbia

My commission expires: MARCH 14 20 17



# Hogan Lovells

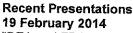
# Lynn Mehler

Partner, Washington, D.C.

Lynn Whipkey Mehler is a partner in our Washington, D.C. office, advising clients on regulatory matters related to controlled substances and pharmaceutical products regulated by the Food and Drug Administration (FDA).

Lynn served for 12 years with the FDA's Office of the Chief Counsel, most recently as a Senior Counsel for Drugs. Lynn was the primary attorney handling all FDA issues related to controlled substances and the Controlled Substances Act. In addition, as one of the primary attorneys advising the agency on drug safety matters, Lynn has extensive experience in the agency's use of Risk Evaluation and Minimization Strategies (REMS), required post-approval clinical studies and trials, and required safety label changes.

Lynn's clients include pharmaceutical and biotechnology companies, universities, associations and other entities. She counsels them on a range of controlled substances compliance and scheduling matters at both the state and federal level. In addition, she provides counsel on a wide array of FDA regulatory issues including the review, approval and oversight of drug products. Her FDA practice focuses primarily on approval and drug safety matters, with extensive experience in developing, modifying, and negotiating REMS before the agency and shared REMS with other sponsors.



"DEA and FDA Regulation of Controlled Substances: A Review of 2013, What to Expect in 2014," The Food and Drug Law Institute Conference

13 February 2012

"Controlled Substance Regulation: Understanding FDA and DEA Missions, Rules & Policies," The Food and Drug Law Institute Conference

#### **PUBLISHED WORKS**

"Controlled Substances: FDA and DEA Regulation of Pharmaceuticals." The Food and Drug Law Institute, (June 2012)



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lynn.mehler@hoganlovells.com

#### **Practices**

Government Regulatory
Food, Drug, Medical Device and Agriculture
Pharmaceutical and Biotechnology
Life Sciences Enforcement

#### **Industry Sectors**

Pharmaceutical and Biotechnology Life Sciences and Healthcare

#### Areas of Focus

Pharmaceutical Products Controlled Substances

#### Education

J.D., Order of the Coif, The College of William and Mary, 1997 B.A., Phi Beta Kappa, The College of Wooster, 1994

#### Awards/Rankings

FDA Commissioner's Award of Merit FDA Commissioner's Award of Excellence FDA Outstanding Service Award

#### **Bar Admission**

District of Columbia Virginia