

**Special Commentary**

**Advocating the rescheduling of  
marijuana in US federal and state drug  
law to permit the use of medical  
marijuana in the pediatric patient  
population**

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**ABSTRACT**

Congress must pass the Compassionate Access, Research Expansion, and Respect States Act of 2015 in order to reschedule marijuana at the federal level to allow the progression of clinical research, general production, and prescription of medical marijuana to alleviate the suffering of pediatric patients with medical conditions that would benefit from use of the drug.

## Introduction

*Very few drugs, if any, have such a tangled history as a medicine. In fact, prejudice, superstition, emotionalism, and even ideology have managed to lead cannabis to ups and downs concerning both its therapeutic properties and its toxicological and dependence-inducing effects.*

*E. A. Carlini<sup>1</sup>*

Federal and state laws must be amended to legalize medical marijuana to permit the general production, prescription and increase accessibility in order to alleviate the suffering of pediatric patients with medical conditions that would benefit from the use of medical marijuana.

In spite of the potential benefits of medical marijuana for pediatric patients, at the federal level medical marijuana is illegal<sup>2</sup>, which has led to significant barriers clinical research.<sup>3</sup> From the viewpoint of many medical researchers, there is an explicit and immediate interest in freely pursuing research involving the use of medical marijuana as a therapeutic agent. In March 2015, arguably the preeminent voice in pediatric patient care - the American Academy of Pediatrics (AAP) – issued a policy statement and accompanying technical report stating “Research and development should be conducted of pharmaceutical cannabinoids. The AAP recommends changing marijuana from a DEA Schedule 1 to a DEA Schedule 2 substance to facilitate this research.”<sup>4</sup> A 2012 Mayo Clinic critique of the status of federal and state laws illustrate the frustration with the inability for the medical community to evaluate the efficacy of medical marijuana “...raises the possibility of many promising pharmaceutical applications, even as draconian federal restrictions that hamstring research show no signs of softening.”<sup>5</sup> The barriers to research are succinctly articulated in another 2012 Mayo Clinic journal article which noted, “Recent research has shown that many of the therapeutic effects of cannabinoids...which causes no psychoactivity but attenuates

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<sup>1</sup> Carlini E.A. The good and the bad effects of (-) trans-delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) on humans. *Toxicol.* 2004;44(4):461–467.

<sup>2</sup> Schedule of Controlled Substances 21 USCS § 801 1970

<sup>3</sup> Bostwick JM. The use of cannabis for management of chronic pain. *Gen Hosp Psychiatry.* 2014 Jan-Feb;36(1):2-3. doi: 10.1016/j.genhosppsy.2013.08.004. Epub 2013 Oct 1.

<sup>4</sup> Ammerman S, Ryan S, Adelman WP; COMMITTEE ON SUBSTANCE ABUSE, THE COMMITTEE ON ADOLESCENCE; COMMITTEE ON SUBSTANCE ABUSE THE COMMITTEE ON ADOLESCENCE. The impact of marijuana policies on youth: clinical, research, and legal update. *Pediatrics.* 2015 Mar;135(3):e769-85.

<sup>5</sup> Bostwick, J. Michael, *supra* note 3

inflammation, decreases injury, and accelerates regeneration in many disease states.<sup>6</sup> However, essentially all the published research on [this] specific stimulation has been done in animals.”<sup>7</sup>

In contrast to federal law, a number of states have legalized marijuana for medicinal use in the last few decades.<sup>8</sup> At the time of this publication medical marijuana is legal under state law for adults 21 years and older in 23 states and the District of Columbia.<sup>9</sup> However, only a subset of those states (roughly 1/3<sup>rd</sup>) has clearly articulated the legal status of medical marijuana for pediatric patients.<sup>10</sup> The degree of rigor around the legality and accessibility of medical marijuana for pediatric patients does vary from state to state, but predominately revolves around parental consent and control of the drug.<sup>11</sup> In the majority of those states minors are required to meet additional criteria compared to their adult counterparts who qualify for medicinal marijuana.<sup>12</sup> As an example, according to the Michigan Medical Marijuana Act pediatric patients are able to obtain medical marijuana cards, but require parental approval on their application and certification from two clinicians whereas adults only require one physician signature.<sup>13</sup>

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<sup>6</sup> Pacher P., Mechoulam R. Is lipid signaling through cannabinoid 2 receptors part of a protective system? *Prog. Lipid Res.* 2011;50(2):193–211.

<sup>7</sup> Mechoulam, Raphael. “Cannabis—A Valuable Drug That Deserves Better Treatment.” *Mayo Clinic Proceedings* 87.2 (2012): 107–109. *PMC*. Web. 25 Mar. 2015.

<sup>8</sup> “Marijuana Resource Center: State Laws Related to Marijuana.” *Office of National Drug Control Policy*. Office of National Drug Control Policy. Web. 26 Mar. 2015. <<https://www.whitehouse.gov/ondcp/state-laws-related-to-marijuana>>.

<sup>9</sup> “Medical Marijuana Laws by State - FindLaw.” *Findlaw*. Web. 25 Mar. 2015. <<http://healthcare.findlaw.com/patient-rights/medical-marijuana-laws-by-state.html>>.

<sup>10</sup> “Marijuana Policy Project.” *Medical Marijuana Laws by State*. Marijuana Policy Project, 25 July 2014. Web. 26 Mar. 2015. <<http://www.mpp.org/assets/pdfs/library/MMJLawsSummary.pdf>>.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 12

<sup>13</sup> MCL § 333.26421

## History of Medical Cannabis Use

The use of cannabis<sup>14</sup> (and its' derivatives) for medicinal purposes is not a new societal construct.<sup>15</sup> For thousands of years the psychotropic and medicinal benefits of marijuana have been leveraged for both recreational and clinical use.<sup>16,17</sup> A 2009 TIME magazine article noted “As early as 2737 B.C., the mystical Emperor Shen Neng of China was prescribing marijuana tea for the treatment of gout, rheumatism, malaria and, oddly enough, poor memory.”<sup>18</sup> From the 8<sup>th</sup> to the 18<sup>th</sup> century “Arabic physicians knew and used its diuretic, anti-emetic, anti-epileptic, anti-inflammatory, painkilling and antipyretic properties, among others.”<sup>19</sup> In more modern history, “At the turn of the 20<sup>th</sup> century the Scandinavian...cannabis-based drink *Maltos*-cannabis was widely available in Denmark and Norway...Promoted as "an excellent lunch drink, especially for children and young people".<sup>20</sup> As stated in a 2014 article featured in *Hawai'i Journal of Medicine & Public Health* “Until the early 1940s in the United States, marijuana was found in more than 20 medications for a variety of ailments. It continued to be included in the US Pharmacopoeia, the predecessor of the Physician's Desk Reference, five years after the Marijuana Stamp Act<sup>21</sup> was passed.”<sup>22</sup>

## Medical Marijuana is Illegal under Federal Law

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<sup>14</sup> [Cannabis/Marihuana] “Marijuana refers to the dried leaves and flowers of the cannabis plant, which contains a large number of biologically active cannabinoids. There are numerous species and subspecies of cannabis. Leaves of the plant are smoked, vaporized, or cooked to extract cannabinoids, which can then be ingested for their pleasurable psychoactive effects. Cannabinoids from marijuana may also produce therapeutic benefits, which has led to the use of marijuana as a medication.”

<sup>15</sup> Gumbiner Ph.D., Jan. "History of Cannabis in Ancient China." *Psychology Today*. 10 May 2011. Web. 1 Mar. 2015. <<https://www.psychologytoday.com/blog/the-teenage-mind/201105/history-cannabis-in-ancient-china>>.

<sup>16</sup> *Id.*

<sup>17</sup> Li, Hui-Lin (1974). "An Archaeological and Historical Account of Cannabis in China", *Economic Botany* 28.4:437–448, p. 444.

<sup>18</sup> Suddath, Patrick. "Medical Marijuana." *Time*. Time Inc., 21 Oct. 2009. Web. 21 Mar. 2015. <<http://content.time.com/time/health/article/0,8599,1931247,00.html>>.

<sup>19</sup> Lozano, Indalecio (2001). "The Therapeutic Use of Cannabis sativa (L.) in Arabic Medicine". *Journal of Cannabis Therapeutics* 1: 63. doi:10.1300/J175v01n01\_05.

<sup>20</sup> Decorte, Tom. *World Wide Weed Global Trends in Cannabis Cultivation and Its Control*. Farnham, England: Ashgate, 2011. 59. Print.

<sup>21</sup> Interchangeable with Marijuana Tax Act (see Marihuana Tax Act of 1937)

<sup>22</sup> McKenna, Gerald J. “The Current Status of Medical Marijuana in the United States.” *Hawai'i Journal of Medicine & Public Health* 73.4 (2014): 105–108. Print.

The status of medical marijuana has been legislated numerous times at the federal level, e.g. *Pure Food and Drugs Act* (1906)<sup>23</sup>, *Harrison Narcotics Tax Act* (1914)<sup>24</sup> and the *Marijuana Tax Act* (1937)<sup>25</sup>. In the context of United States federal law, the *Comprehensive Drug Abuse Prevention and Control Act* (CSA)<sup>26</sup> is the single most important piece of federal legislation requiring amendment to facilitate the prescription of medical marijuana to the pediatric patient population. Medical marijuana has been illegal in the United States since the CSA passed in 1970.<sup>2728</sup> The CSA intends to curtail “The illegal importation, manufacture, distribution, and possession and improper use of controlled substances [that] have a substantial and detrimental effect on the health and general welfare of the American people.<sup>29</sup> The CSA established the current legal framework of governing the illegality of marijuana by assigning a schedule to the drug.<sup>30</sup> The CSA grouped illicit substances into five schedules based on the substance’s potential for abuse and regulated the ability for the drug to be used in a clinical setting.<sup>31</sup> Marijuana was assigned a Schedule 1 – the highest severity as Schedule 1 substances have a high potential for abuse, no accredited medical use, and a lack of accepted safety.<sup>32</sup> The rescheduling of medical marijuana to a Schedule II or III drug would permit the progression of clinical research. President Richard Nixon’s administration designation of marijuana as a Schedule 1 drug<sup>33</sup> contradicted that of the findings of the National Commission on Marihuana and Drug Abuse, which ascertained that there was “little proven danger of physical or psychological harm from the

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<sup>23</sup> Food and Drugs Act, 34 Stat. 768; required that active ingredients be placed on the label of a drug’s packaging and established purity standards – including marijuana

<sup>24</sup> Harrison Narcotics Tax Act, 785 § 1-38 (1914); tax on all opiates – legal definition included marijuana

<sup>25</sup> Marihuana Tax Act of 1937, Pub. 238, 75th Congress, 50 Stat. 551 (Aug. 2, 1937) placed a tax on the sale of cannabis (since repealed in 1970) - possession or transfer of cannabis illegal throughout the United States under federal law, excluding medical and industrial uses, through imposition of an excise tax on all sales of hemp.

<sup>26</sup> Comprehensive Drug Abuse Prevention and Control Act 21 USCS § 801

<sup>27</sup> *Id.*

<sup>28</sup> Emphasis on the fact that the *medical* use of marijuana has been illegal since 1970; recreational use of the drug was made illegal at the federal level in 1937 under the Marihuana Tax Act.

<sup>29</sup> Schedule of Controlled Substances *supra* note 1, at (B)

<sup>30</sup> Comprehensive Drug Abuse Prevention and Control Act 21 USCS § 801

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

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

<sup>33</sup> *Gonzales v. Raich*, 545 U.S. 1, 125 S.Ct. 2195 (2005)

experimental or intermittent use of the natural preparations of cannabis.”<sup>34</sup> Additionally the commission noted that “In summary, marihuana containing Delta-9-THC is a pharmacologically active drug with minimal acute physiological effects at the low to moderate doses used by man.”<sup>35</sup> Despite the evidence and recommendations presented in the formal report constructed by the leading scientific minds tasked with formalizing the nation’s drug policy, marijuana was determined to be without any medical value according to federal law.<sup>36</sup>

It must be noted that at the federal level there have been recent amendments to the longstanding ruling on medical marijuana. In 2014, the \$1.1 trillion federal spending bill signed into law by President Barack Obama contained an amendment that prohibits the Department of Justice from spending money to prosecute medical marijuana dispensaries or patients that abide by state laws.<sup>37</sup> A major component of the federal budget included the *Respect State Marijuana Laws Act of 2013*, colloquially referred to as the Rohrabacher Act<sup>38</sup> which “Amends the Controlled Substances Act to provide that provisions of such Act related to marihuana shall not apply to any person acting in compliance with state laws relating to the production, possession, distribution, dispensation, administration, or delivery of marihuana.”<sup>39</sup> By effectively prohibiting the use of federal funds, the Act should reduce instances of prosecution related to restricted operating conditions faced by state medical marijuana dispensaries<sup>40,41,42</sup> It has yet to be seen to what degree the Act will have an effect on medical marijuana patients as the wording of the Act does not make marijuana legal – it precludes prosecution primarily for business entities.<sup>43</sup>

A further blow to accessibility for pediatric medical marijuana patients is supply of empirical evidence related to the potential benefits of marijuana

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<sup>34</sup> Nahas, G G, and A Greenwood. “The First Report of the National Commission on Marihuana (1972): Signal of Misunderstanding or Exercise in Ambiguity.” *Bulletin of the New York Academy of Medicine* 50.1 (1974): 55–75. Print.

<sup>35</sup> *Id.*

<sup>36</sup> Bostwick, J. Michael. *Supra* note 3

<sup>37</sup> H.R.83 - Consolidated and Further Continuing Appropriations Act, 2015

<sup>38</sup> Amendment 25 to H.R. 4660, the Commerce, Justice, Science, and Related Agencies Appropriations Act, 2014

<sup>39</sup> *Id.*

<sup>40</sup> *City of Lake Forest v. Evergreen Holistic Collective*, 203 Cal. App. 4th 1413, 138 Cal. Rptr. 3d 332 (2012)

<sup>41</sup> *Marin Alliance for Med. Marijuana v. Holder*, 866 F. Supp. 2d 1142 (N.D. Cal. 2011)

<sup>42</sup> *River North Props., LLC v. City & County of Denver*, 2014 U.S. Dist. LEXIS 178206 (D. Colo. Dec. 30, 2014)

<sup>43</sup> *Id.*

due to its' legal status.<sup>44</sup> At present there is only one federally sanctioned facility permitted to grow and study marijuana operating out of the University of Mississippi.<sup>45</sup> In order for researchers to access the marijuana for clinical evaluation purposes they must be obtain a Schedule 1 drug license from the DEA and in some instances obtain sign off from the National Institute on Drug Abuse (NIDA) – a time consuming process.<sup>46</sup> As tangible evidence of the arduousness of the process to obtain federal authorization and lack of overall clinical research into therapeutic benefits, a search of the US Department of Health and Human Services *rePORTER* database returned only nine research project results with the parameters of “medical marijuana” and “pediatrics”; all in the context of substance abuse and not clinical efficacy.<sup>47,48</sup>

## Fewer states have legalized medical marijuana for pediatric patients

More than half of all United States' have laws that make medical marijuana illegal. At the time of this publication medical marijuana is legal under state law for adults 21 years and older in 23 states and the District of Columbia.<sup>49</sup> In those states where medical marijuana is legal, most require the patient to be over the age of 18.<sup>50</sup> Seventeen states have legalized medical marijuana for minors as they are able to obtain medical marijuana with

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<sup>44</sup> “5 Questions: Ammerman on Pediatrics Academy's Opposition to Legalizing Pot.” News Center. Web. 27 Mar. 2015. <http://med.stanford.edu/news/all-news/2015/01/ammerman-on-pediatrics-academys-opposition-to-marijuana.html>

“I also think the AAP’s stance in favor of having marijuana reclassified by the federal Drug Enforcement Administration as a schedule-2 drug is important because this would make it somewhat easier for researchers to study cannabinoids’ possible medical benefits. We know from limited research that certain cannabinoids, which are the compounds from the cannabis plant, have some medical benefits. But this area of research is in its infancy. Reclassification and more research could lead to Food and Drug Administration regulation and standardization of cannabinoid-containing products.”

<sup>45</sup> “NIDA's Role in Providing Marijuana for Research.” *NIDA's Role in Providing Marijuana for Research*. Web. 15 Feb. 2015. <<http://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research>>.

<sup>46</sup> *Id.*

<sup>47</sup> RePORTER includes information on research projects funded by the NIH as well as the Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and U.S. Department of Veterans Affairs (VA). RePORTER also includes links to publications and patents citing support from these projects.

<sup>48</sup> “NIH RePORTER.” *Search*. US Department of Health and Human Services. Web. 26 Mar. 2015. <<http://projectreporter.nih.gov/reporter.cfm>>.

<sup>49</sup> “Medical Marijuana Laws by State - FindLaw.” *Findlaw*. Web. 25 Mar. 2015. <<http://healthcare.findlaw.com/patient-rights/medical-marijuana-laws-by-state.html>>.

<sup>50</sup> *Id.*

parents' written permission or other required authorization(s).<sup>51</sup><sup>52</sup> In 1996, California voters passed Proposition 215, making the Golden State the first in the union to allow for the medical use of marijuana. <sup>53</sup><sup>54</sup>

Specifics of the medical marijuana laws vary by state, but all allow adults to use marijuana for medical purposes, usually for certain specified conditions, if recommended by a physician, although general categories also often include "pain."<sup>55</sup>

Despite its' legal status in these, accessing marijuana is not as simple as walking into a dispensary. There exist a multitude of procedural steps in order for patients to access medical marijuana by navigating a complex and time consuming environment of processes and inconsistencies in enforcement from state to state. In most states a pediatric patient must establish a primary caregiver(s) whom is responsible for the procurement and caretaking of the medical marijuana. <sup>56</sup> There are strict laws governing the purchase, transportation of the medical marijuana and variances from these guidelines shift the patient and caretaker into the realm of illegality.<sup>57</sup> For instance in Michigan the medical marijuana "must be in a case in a trunk while it is transported, or — if the vehicle has no trunk — it must be in a case that isn't readily accessible from inside the vehicle."<sup>58</sup> ; Non-compliance with this stringent rule could result in the arrest of all parties. In some states pediatric patients must submit a plethora of documentation to county and/or state agencies that compile and approve the issuance of a medical marijuana ID <sup>59</sup>, <sup>60</sup>, <sup>61</sup> while others simply require a handwritten prescription from a

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<sup>51</sup> "Marijuana Policy Project." *Medical Marijuana Laws by State*. Marijuana Policy Project, 25 July 2014. Web. 26 Mar. 2015. <<http://www.mpp.org/assets/pdfs/library/MMJLawsSummary.pdf>>.

<sup>52</sup> 410 ILCS 130/30

The state of Illinois has recently enacted *Compassionate Use of Medical Cannabis Pilot Program Act* "concerning alternative treatment for serious diseases causing chronic pain and debilitating conditions

<sup>53</sup> Cal Health & Saf Code § 11362.5

<sup>54</sup> *Id.*

<sup>55</sup> Cal. Health and Safety Code §11362.5 and 11362.7 et seq

<sup>56</sup> "Primary caregiver" means the individual, designated by a qualified patient or by a person with an identification card, who has consistently assumed responsibility for the housing, health, or safety of that patient or person California Compassionate Use Act of 1996 (HEALTH AND SAFETY CODE SECTION 11362.7-11362.83)

<sup>57</sup> "Arrests, Fines Follow Mass. Medical Marijuana Law." *The Boston Globe* 20 May 2014. The Boston Globe. Web. 22 Mar. 2015. <<http://www.bostonglobe.com/lifestyle/health-wellness/2014/05/19/confusion-over-medical-marijuana-law-leads-patient-arrests/AIoMv8Suoh35n5C7R8PGAI/story.html>>.

<sup>58</sup> MCL § 333.26421

<sup>59</sup> N.M. Stat. Ann. § 26-2B-1



physician. The foremost example of the perplexing legal status of medical marijuana at the state level is Maryland's law which only provides affirmative defense protection once a patient is arrested.<sup>62,63</sup> This means that a patient can still be arrested, processed and proceed to trial – and only then may they offer a defense to have the charges expunged.<sup>64</sup> A Michigan mother charged with administering marijuana to her children faced “...up to 4 years in prison and the child-abuse charge carries up to 2 years in prison or 5 years of probation”<sup>65</sup> inasmuch as the conditions she was treating her children under did not meet the narrow definition of chronic medical conditions in outlined in the 2008 Michigan Medical Marijuana Act.<sup>66</sup>

Even states with mature and medical marijuana laws are not immune to faults. Oregon courts consider the Oregon Medical Marijuana Act (OMMA) as it only applies to Oregonians suffering from a defined set of acute and chronic medical conditions that have obtained an attending physicians' prescription for marijuana.<sup>67</sup> Under OMMA, in order to access medical marijuana the patient is required to:

1. Register their prescription and obtain a medical marijuana registered identification card from the Department of Human Services;
2. Declare and submit written documentation to DHS of the nominated adult primary caregiver;<sup>68</sup>

However, “Oregon's law, approved by voters 14 years ago, requires no monitoring of a child's medical marijuana use by a pediatrician. The law instead invests authority in parents to decide the dosage, frequency and manner of a child's marijuana consumption.”<sup>69</sup>

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<sup>60</sup> Vt. Stat. Ann. tit. 18 § 4472

<sup>61</sup> Cal. Health and Safety Code §11362.5

<sup>62</sup> A defense in which the defendant introduces evidence, which, if found to be credible, will negate criminal or civil liability, even if it is proven that the defendant committed the alleged acts ("Affirmative Defense." Affirmative Defense. Web. 23 Feb. 2015. <[http://www.law.cornell.edu/wex/affirmative\\_defense](http://www.law.cornell.edu/wex/affirmative_defense)>.)

<sup>63</sup> Maryland HB 881 and SB 923

<sup>64</sup> *Id.*

<sup>65</sup> "Mom Charged for Giving Sons Pot for Medical Reasons." *Yahoo! News*. Associated Press, 17 Dec. 2014. Web. 28 Feb. 2015. <<http://news.yahoo.com/mom-charged-giving-sons-pot-medical-reasons-172021556.html>>.

<sup>66</sup> Michigan Medical Marijuana Act MCLS § 333.26421

<sup>67</sup> ORS § 475.300 to § 475.346

<sup>68</sup> *Id.*

<sup>69</sup> Crombie, Noelle. "Medical Marijuana for a Child with Leukemia." <i>OregonLive</i>. The Oregonian, 24 Nov. 2012. Web. 28 Feb. 2015.

## Investigation into the clinical efficacy and potential uses medical marijuana

The applicability of medical marijuana in the treatment of acute and chronic medical conditions with both physical (e.g. heart attack recovery<sup>70</sup>) and mental (e.g. post-traumatic stress disorder<sup>71</sup>) presentations is of pronounced clinical significance.<sup>72</sup> Unfortunately as a direct result of marijuana's CSA schedule status most clinical research has been conducted under the mantra of 'investigational therapies' – meaning that most researchers are relegated to ascertaining clinical benefits based on the hypothetical applications of the drug's pharmacologic properties.<sup>73</sup>

The scarcity of clinical trials including medical marijuana as a therapeutic alternative is astounding. As an example, in reviewing all randomized trials involving cannabinoids and people with schizophrenia or schizophrenia-like illnesses, researchers for the Cochrane Schizophrenia Group found that only two of the 51 trials involving medical marijuana produced enough evidence to be statistically relevant.<sup>74</sup> The authors commented “At present, there is insufficient evidence to support or refute the use of cannabis/cannabinoid compounds for people suffering with schizophrenia. This review highlights the need for well designed, conducted and reported clinical trials to address the potential effects of cannabis based compounds for people with schizophrenia.”<sup>75</sup> It should be noted that the Group maintains the most comprehensive register of schizophrenia related trials. Unfortunately, even fewer studies exist<sup>76</sup> that concentrate on pediatric use of medical marijuana outside of scathing examinations of recreational abuse<sup>77 78 79 80</sup> or accidental marijuana ingestion<sup>81</sup>. The National Cancer

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&lt;[http://www.oregonlive.com/health/index.ssf/2012/11/medical\\_marijuana\\_for\\_a\\_child.html](http://www.oregonlive.com/health/index.ssf/2012/11/medical_marijuana_for_a_child.html)&gt;.

<sup>70</sup> Mukamal, Kenneth J. et al. “An Exploratory Prospective Study of Marijuana Use and Mortality Following Acute Myocardial Infarction.” *American heart journal* 155:3 (2008): 465–470. *PMC*. Web. 24 Mar. 2015.

<sup>71</sup> Akirav, Irit. “Targeting the Endocannabinoid System to Treat Haunting Traumatic Memories.” *Frontiers in Behavioral Neuroscience* 7 (2013): 124. *PMC*. Web. 24 Mar. 2015.

<sup>72</sup> Grant, Igor et al. “Medical Marijuana: Clearing Away the Smoke.” *The Open Neurology Journal* 6 (2012): 18–25. *PMC*. Web. 24 Mar. 2015.

<sup>73</sup> *Id.*

<sup>74</sup> Rathbone, John, Hannele Variend, and Hetal Mehta. “Cannabis and Schizophrenia.” *The Cochrane database of systematic reviews* 3 (2008): CD004837. *PMC*. Web. 24 Mar. 2015.

<sup>75</sup> Rathbone, John, Hannele Variend, and Hetal Mehta. “Cannabis and Schizophrenia.” *The Cochrane database of systematic reviews* 3 (2008): CD004837. *PMC*. Web. 24 Mar. 2015.

<sup>76</sup> Stubblefield S. *Medical marijuana and children*. *Del Med J.* 2014 Nov;86(11):345-9.

institute stated in a 2014 publication for healthcare professionals “A growing number of pediatric patients are seeking symptom relief with Cannabis or cannabinoid treatment, although studies are limited.”<sup>82</sup>

What limited empirical evidence has emanated from medical marijuana inclusive studies has been promising - A 2005 study in *Harm Reduction Journal* 2 noted “...compounds found in cannabis have been shown to kill numerous cancer types including: lung cancer<sup>83</sup>, breast and prostate<sup>84</sup>, leukemia and lymphoma<sup>85</sup>, glioma<sup>86</sup>, skin cancer<sup>87</sup>, and pheochromocytoma<sup>88</sup>”.<sup>89</sup> A 2008 clinical journal article titled

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<sup>77</sup> Vidot, Denise C. et al. “Emerging Issues for Our Nation’s Health: The Intersection of Marijuana Use and Cardiometabolic Disease Risk.” *Journal of addictive diseases* 33.1 (2014): 1–8. *PMC*. Web. 24 Mar. 2015.

<sup>78</sup> Salomonsen-Sautel, Stacy et al. “Medical Marijuana Use among Adolescents in Substance Abuse Treatment.” *Journal of the American Academy of Child and Adolescent Psychiatry* 51.7 (2012): 694–702. *PMC*. Web. 24 Mar. 2015.

<sup>79</sup> Lord, Sarah, and Lisa Marsch. “Emerging Trends and Innovations in the Identification and Management of Drug Use among Adolescents and Young Adults.” *Adolescent medicine: state of the art reviews* 22.3 (2011): 649–xiv. Print.

<sup>80</sup> Salomonsen-Sautel, Stacy et al. “Medical Marijuana Use among Adolescents in Substance Abuse Treatment.” *Journal of the American Academy of Child and Adolescent Psychiatry* 51.7 (2012): 694–702. *PMC*. Web. 25 Mar. 2015.

<sup>81</sup> Wang GS, Roosevelt G, Le Lait MC, Martinez EM, Bucher-Bartelson B, Bronstein AC, Heard K. *Association of unintentional pediatric exposures with decriminalization of marijuana in the United States*. *Ann Emerg Med*. 2014 Jun;63(6):684-9. doi: 10.1016/j.annemergmed.2014.01.017. Epub 2014 Feb 5.

<sup>82</sup> "Cannabis and Cannabinoids (PDQ®)." *National Cancer Institute*. 17 Dec. 2014. Web. 26 Mar. 2015. <<http://www.cancer.gov/cancertopics/pdq/cam/cannabis/healthprofessional>>.

<sup>83</sup> Antineoplastic activity of cannabinoids. *Munson AE, Harris LS, Friedman MA, Dewey WL, Carchman RA J Natl Cancer Inst*. 1975 Sep; 55(3):597-602.

<sup>84</sup> Inhibition of glioma growth in vivo by selective activation of the CB(2) cannabinoid receptor. *Sánchez C, de Ceballos ML, Gomez del Pulgar T, Rueda D, Corbacho C, Velasco G, Galve Roperh I, Huffman JW, Ramón y Cajal S, Guzmán M Cancer Res*. 2001 Aug 1; 61(15):5784-9

<sup>85</sup> Targeting CB2 cannabinoid receptors as a novel therapy to treat malignant lymphoblastic disease. *McKallip RJ, Lombard C, Fisher M, Martin BR, Ryu S, Grant S, Nagarkatti PS, Nagarkatti M Blood*. 2002 Jul 15; 100(2):627-34.

<sup>86</sup> Delta9-tetrahydrocannabinol induces apoptosis in C6 glioma cells. *Sánchez C, Galve-Roperh I, Canova C, Brachet P, Guzmán M FEBS Lett*. 1998 Sep 25; 436(1):6-10.

<sup>87</sup> Inhibition of skin tumor growth and angiogenesis in vivo by activation of cannabinoid receptors. *Casanova ML, Blázquez C, Martínez-Palacio J, Villanueva C, Fernández-Aceñero MJ, Huffman JW, Jorcano JL, Guzmán M J Clin Invest*. 2003 Jan; 111(1):43-50.

<sup>88</sup> Anandamide induces apoptosis of PC-12 cells: involvement of superoxide and caspase-3.

*Endocannabinoids in the Retina: From Marijuana to Neuroprotection* noted “There is great interest in endocannabinoids for their role in neuroplasticity as well as for therapeutic use in numerous conditions, including pain, stroke, cancer, obesity, osteoporosis, fertility, neurodegenerative diseases, multiple sclerosis, glaucoma and inflammatory diseases, among others...”<sup>90</sup> A 2013 article in *Journal of Neuroimmune Pharmacology* attests “...there is growing appreciation of the therapeutic potential of cannabinoids in multiple pathologic conditions involving chronic inflammation (inflammatory bowel disease, arthritis, autoimmune disorders, multiple sclerosis, HIV-1 infection, stroke, Alzheimer’s disease to name a few)...”<sup>91</sup> In a 2015 publication of *Movement Disorders*, “There is growing interest in the therapeutic potential of marijuana (cannabis) and cannabinoid-based chemicals within the medical community and, particularly, for neurological conditions...”<sup>92</sup>

However, the exclusion of clinical use based on the CSA Scheduling has precluded advancement in this area. As stated in *Current Neuropharmacology* in 2006 “The frequently held view of cannabis and its related products as drugs of abuse have slowed progress in the development of studies designed to take advantage of the properties of cannabinoid derivatives for therapeutic purposes.”<sup>93</sup>

The authors of a 2012 study of the potential pharmacological benefits of medical marijuana use on prostate cancer stated “...that cannabinoids should be considered as agents for the management of prostate cancer. If the hypothesis is supported by *in vivo* experiments, it is our conclusion that it would be of interest to conduct clinical trials involving medicinal cannabis or other cannabinoid agonists ... [patients] would not only benefit from the possible anti-androgenic effects of cannabinoids but also from analgesia of

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Sarker KP, Obara S, Nakata M, Kitajima I, Maruyama I  
*FEBS Lett.* 2000 Apr 21; 472(1):39-44.

<sup>89</sup> Melamede, Robert. “Cannabis and Tobacco Smoke Are Not Equally Carcinogenic.” *Harm Reduction Journal* 2 (2005): 21. *PMC*. Web. 24 Mar. 2015.

<sup>90</sup> Yazulla, Stephen. “Endocannabinoids in the Retina: From Marijuana to Neuroprotection.” *Progress in retinal and eye research* 27.5 (2008): 501–526. *PMC*. Web. 24 Mar. 2015.

<sup>91</sup> Rom, Slava, and Yuri Persidsky. “Cannabinoid Receptor 2: Potential Role in Immunomodulation and Neuroinflammation Review.” *Journal of neuroimmune pharmacology : the official journal of the Society on NeuroImmune Pharmacology* 8.3 (2013): 608–620. *PMC*. Web. 24 Mar. 2015.

<sup>92</sup> Kluger, Benzi, Piera Triolo, Wallace Jones, and Joseph Jankovic. “The Therapeutic Potential of Cannabinoids for Movement Disorders.” *Movement Disorders* 30.3 (2015): N/a. Web. 24 Mar. 2015. <<http://dx.doi.org/10.1002/mds.26142>>.

<sup>93</sup> Role of the cannabinoid system in pain control and therapeutic implications for the management of acute and chronic pain episodes. *Manzanares J, Julian M, Carrascosa A Curr Neuropharmacol.* 2006 Jul; 4(3):239-57.

bone pain, improving quality of life, while reducing narcotic consumption and preventing opioid dependence.”<sup>94</sup>

In January 1997, the White House Office of National Drug Control Policy (ONDCP) commissioned the Institute of Medicine (IOM) to “conduct a review of the scientific evidence...[and] potential health benefits and risks of marijuana...”<sup>95</sup> The resulting recommendations from this consortium was that “Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body”<sup>96</sup>; “Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.”<sup>97</sup>

### Concerning the Safety of Medical Marijuana Use

One of the primary arguments against the use of marijuana in a clinical setting is the safety of the drug. The near unanimous recommendation is that “Primary care clinicians must provide their adolescent patients with adequate screening and counseling about substance abuse.”<sup>98</sup> Additionally it must be acknowledged that most clinicians agree that “Smoked cannabis is contraindicated in patients who are 25 years of age or younger” for a number of physical and developmental reasons.<sup>99</sup> When considering delivery methods for the drug, the National Cancer Institute commented, “cannabis may be taken by mouth or may be inhaled....When Cannabis is smoked and inhaled, cannabinoids quickly enter the bloodstream. The additional psychoactive chemical is produced in smaller amounts than when taken by mouth.”<sup>100</sup>

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<sup>94</sup> Ramos, Juan A., and Fernando J. Bianco. “The Role of Cannabinoids in Prostate Cancer: Basic Science Perspective and Potential Clinical Applications.” *Indian Journal of Urology : IJU : Journal of the Urological Society of India* 28.1 (2012): 9–14. *PMC*. Web. 24 Mar. 2015.

<sup>95</sup> Joy, Janet E., and Stanley J. Watson, Jr. “Marijuana and Medicine Assessing the Science Base.” *INSTITUTE OF MEDICINE/Division of Neuroscience and Behavioral Health* (1999): 126–27. *Marijuana and Medicine Assessing the Science Base*. NATIONAL ACADEMY PRESS. Web. <[http://medicalmarijuana.procon.org/sourcefiles/IOM\\_Report.pdf](http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf)>.

<sup>96</sup> *Id.* at 4

<sup>97</sup> *Id.* at 5

<sup>98</sup> Greydanus, Donald E., and Dilip R Patel. “Substance Abuse in Adolescents: A Complex Conundrum for the Clinician.” *Pediatric Clinics of North America* 50.5 (2003): 1179–223. Print.

<sup>99</sup> Kahan, Meldon et al. “Prescribing Smoked Cannabis for Chronic Noncancer Pain: Preliminary Recommendations.” *Canadian Family Physician* 60.12 (2014): 1083–1090. Print.

<sup>100</sup> “Cannabis and Cannabinoids (PDQ®).” *National Cancer Institute*. National Institutes of Health. Web. 28 Feb. 2015. <[http://www.cancer.gov/cancertopics/pdq/cam/cannabis/patient/Page2#\\_76](http://www.cancer.gov/cancertopics/pdq/cam/cannabis/patient/Page2#_76)>.

While the potential for marijuana abuse does exist, the same risk is shared by abuse of prescription medications.<sup>101</sup> In fact, in 2013, of the 43,982 drug overdose deaths in the United States, 22,767 (51.8%) were related to pharmaceuticals.<sup>102</sup> The number of marijuana related deaths during the same timeframe was *zero*.<sup>103</sup> In one 2014 study the authors observed a correlation between states that have passed medical marijuana laws; noting a decrease in prescription opiate overdoses.<sup>104</sup> “Because chronic pain is a major indication for medical cannabis, laws that establish access to medical cannabis may change overdose mortality related to opioid analgesics in states that have enacted them.”<sup>105</sup>

Further to the misrepresentation regarding the safety of medical marijuana, In a 1988 Opinion and Recommended ruling, Administrative Law Judge Francis Young asserted that, “In practical terms, marijuana cannot induce a lethal response as a result of drug-related toxicity....In comparison, Valium, a commonly used prescriptive drug, may cause very serious biological damage if patients use ten times the recommended (therapeutic) dose.<sup>106</sup> The opinion was closed with the conclusion that “Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care.”<sup>107</sup>

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<sup>101</sup> Greydanus, Donald E. et al. “Marijuana: Current Concepts.” *Frontiers in Public Health* 1 (2013): 42. *PMC*. Web. 25 Mar. 2015.

<sup>102</sup> Centers for Disease Control and Prevention. National Vital Statistics System mortality data. (2015) Available from URL: <http://www.cdc.gov/nchs/deaths.htm>.

<sup>103</sup> "Author Insights: Legalizing Medical Marijuana May Reduce Opioid Deaths." *NewsJAMA*. Journal of the American Medical Association, 26 Aug. 2014. Web. 25 Mar. 2015. <<http://newsatjama.jama.com/2014/08/26/author-insights-legalizing-medical-marijuana-may-reduce-opioid-deaths/>>.

<sup>104</sup> Bachhuber MA, Saloner B, Cunningham CO, Barry CL. Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010. *JAMA Intern Med*. 2014;174(10):1668-1673. doi:10.1001/jamainternmed.2014.4005

<sup>105</sup> Bachhuber MA, Saloner B, Cunningham CO, Barry CL. Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010. *JAMA Intern Med*. 2014;174(10):1668-1673. doi:10.1001/jamainternmed.2014.4005

<sup>106</sup> Docket No. 86-22 Administrative Law Judge Francis I. Young, Opinion and Recommended Ruling, findings of fact, conclusions of law and decision of administrative law judge. MARIJUANA RESCHEDULING PETITION UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration. Available at <http://www.ccguid.org/young88.php>

“At present it is estimated that marijuana's LD-50 is around; 1:20,000 or 1:40,000. In layman terms this means that in order to induce death a marijuana smoker would have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette. NIDA-supplied marijuana cigarettes weigh approximately .9 grams. A smoker would theoretically have to consume nearly 1,500 pounds of marijuana within about fifteen minutes to induce a lethal response.”

<sup>107</sup> *Id.* at 16.

## Synthetic marijuana and pharmaceutical derivatives are not equivalent alternatives to medical cannabis in its' natural state

Another frequent rebuke to the use of medical marijuana in pediatric patients is that there exist synthetic versions of cannabis; the insinuation being that because they are synthetic they are lab created instead of organically grown. However there must be a differentiation between 'legal highs' and FDA approved medications

### 'Legal highs'

In the last decade there has been an increased prevalence of 'legal highs' such as *K2* and *Spice* in the marketplace.<sup>108</sup> These products are produced and contain substances that do not resemble the chemical structure of THC.<sup>109</sup> In articulating the difference between organic marijuana and the synthetic one journal article noted "Despite some similarities in smell, synthetic marijuana however can be up to 100 times stronger and has been described to lead to life-threatening complications such as respiratory failure requiring mechanical ventilation, myocardial infarction, status epilepticus, suicide, hypertensive crises, or in our case, respiratory compromise secondary to large eosinophilic pleural effusion<sup>110</sup>."<sup>111</sup> It is for these reasons that 'legal highs' are not to be considered for administration to pediatric patients in any clinical setting.

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<sup>108</sup> National Institute on Drug Abuse. K2/Spice ("Synthetic Marijuana") Retrieved from <http://www.drugabuse.gov/drugs-abuse/k2spice-synthetic-marijuana> on March 25, 2015

<sup>109</sup> Greydanus, Donald E. et al. "Marijuana: Current Concepts." *Frontiers in Public Health* 1 (2013): 42. *PMC*. Web. 25 Mar. 2015.

<sup>110</sup> Presence of blood or air in the lining of the lungs

<sup>111</sup> Synthetic Marijuana: A Different Breed of Weed Amitpal S. Nat; Shraddha Goyal; Amritpal S. Nat; Luke Yuhico; Arman Khorasani-zadeh; Bhargav Mudda; Amit Sharma; Amit Sharma; Michael C. Iannuzzi Available at <http://www.sгим.org/File%20Library/SGIM/Meetings/Annual%20Meeting/Onsite-final-for-web.pdf>

## Pharmaceutical Derivatives of Marijuana

Despite the federal prohibition regarding the use of medical marijuana, marijuana derivatives/alternatives have been developed to treat patients.<sup>112</sup> Pharmaceutical companies have developed Federal Drug Administration (FDA) approved marijuana synthetics including Marinol<sup>®</sup><sup>113</sup> and Cesamet<sup>®</sup><sup>114</sup>. Marinol is a Schedule III drug and Cesamet<sup>®</sup> a Schedule II drug in the CSA, and therefore are still considered controlled substances, yet may be prescribed by clinicians.<sup>115</sup> These synthetics are “structurally related to the active components in marijuana”<sup>116</sup>, but are manufactured to remove the “...unacceptable psychiatric effects...”<sup>117</sup> of the “... $\Delta^9$ -tetrahydrocannabinol ( $\Delta^9$ -THC, the principal psychoactive component of marijuana)”<sup>118</sup>

At present only Marinol<sup>®</sup> has been studied for use in pediatric patients; “Pediatrics: ...The pediatric dosage for the treatment of chemotherapy-induced emesis is the same as in adults. Caution is recommended in prescribing Marinol<sup>®</sup> Capsules for children because of the psychoactive effects.”<sup>119</sup> As discussed in a 2015 American Academy of Pediatrics Technical Report it should be noted “...the onset of symptom relief with Dronabinol is significantly longer than that of smoked or vaporized marijuana.”<sup>120</sup> On the other hand; “Cesamet<sup>®</sup> should be used with caution in pregnant patients, nursing mothers, or pediatric patients because it has not been studied in these patient populations.”<sup>121</sup>

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<sup>112</sup> "MARINOL (dronabinol Capsules)." *MARINOL (dronabinol Capsules)*. Web. 24 Mar. 2015. <<http://www.marinol.com/about-marinol.cfm>>.

<sup>113</sup> Marinol FDA approved medication insert; <http://www.fda.gov/ohrms/dockets/dockets/05n0479/05N-0479-emc0004-04.pdf>

<sup>114</sup> Cesamet FDA approved medication insert; [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2006/018677s011lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/018677s011lbl.pdf)

<sup>115</sup> (3) Schedule III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

<sup>116</sup> "In Focus - Marinol - Cessmet." *DEA.gov*. US Drug Enforcement Agency. Web. 28 Feb. 2015. <[http://www.dea.gov/divisions/sea/in\\_focus/marinol-cessmet.pdf](http://www.dea.gov/divisions/sea/in_focus/marinol-cessmet.pdf)>.

<sup>117</sup> Seely, Kathryn A. et al. “Marijuana-Based Drugs: Innovative Therapeutics or Designer Drugs of Abuse?” *Molecular Interventions* 11.1 (2011): 36–51. PMC. Web. 28 Feb. 2015.

<sup>118</sup> *Id.*

<sup>119</sup> Marinol FDA approved medication insert; <http://www.fda.gov/ohrms/dockets/dockets/05n0479/05N-0479-emc0004-04.pdf>

<sup>120</sup> Ammerman S, *supra* note 4

<sup>121</sup> Cesamet FDA approved medication insert; [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2006/018677s011lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/018677s011lbl.pdf)



## Conclusion

Prominent professor of sociology Marcello Truzzi has stated; “In science, the burden of proof falls upon the claimant; and the more extraordinary a claim, the heavier is the burden of proof demanded.”<sup>122</sup> It cannot be denied that advocating the medical use of marijuana for children is a near Sisyphean<sup>123</sup> task. However reactionary the emotional response may be, it must be noted that the claim of medical marijuana being of clinical benefit to pediatric patients has some validity. Anecdotal evidence has repeatedly demonstrated symptomatic relief in a number of clinical conditions where alternate methods of treatment have failed. Empirical scientific evidence using the natural state of marijuana, albeit limited, has demonstrated that there are unknown yet beneficial pharmacologic properties of marijuana ready for analysis.

The American Academy of Pediatrics found that the barrier to clinical research involving marijuana for pediatric was problematic noting, “...for pediatricians the recommendation of medical marijuana is problematic for the following reasons: It is not regulated by the FDA, its purity and THC content are not consistently verified, and because there are only small case studies available, the risk–benefit relationship cannot be determined.” Amending the aforementioned federal and state laws to allow for regimented exploration into potential clinical benefits would be the first step in rectifying the accessibility issues and potentially proving a new genus of therapeutic medications to pediatric patients. Without rectification at both the federal and state levels, medical marijuana use by American families will continue to face obstacles with respect to accessing what may prove to be a life changing treatment option for pediatric patients.

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<sup>122</sup> Truzzi, Marcello. "Commentaries: On Pseudo-Skepticism." *Commentaries: On Pseudo-Skepticism*. Zetetic Scholar, 1 Jan. 1987. Web. 28 Feb. 2015. <<http://www.anomalist.com/commentaries/pseudo.html>>.

<sup>123</sup> The gods had condemned Sisyphus to ceaselessly rolling a rock to the top of a mountain, whence the stone would fall back of its own weight. They had thought with some reason that there is no more dreadful punishment than futile and hopeless labour "The Myth of Sisyphus by Albert Camus." *The Myth of Sisyphus*. Web. 28 Feb. 2015. <<http://www.nyu.edu/classes/keefe/hell/camus.html>>..

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