

Medical Marijuana Health Impact Assessment Update

April 2019

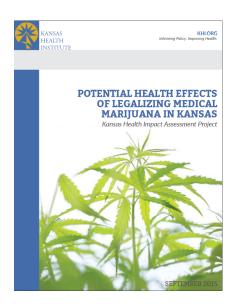
WHO WE ARE

- Nonprofit, nonpartisan educational organization based in Topeka.
- Established in 1995 with a multi-year grant by the Kansas Health Foundation and located directly across from Kansas Statehouse in downtown Topeka.
- Committed to convening meaningful conversations around tough topics related to health.

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PROJECT

- Update key issues from 2015 HIA:
 - Medical marijuana policies in the U.S.
 - Research about medical marijuana
 - Findings on potential health impacts of medical marijuana legalization



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3

In 2015, Kansas Health Institute conducted a health impact assessment (HIA) on legalizing medical marijuana in Kansas (available at https://www.khi.org/assets/uploads/news/13904/marijuanahia_web.pdf). This presentation and an accompanying issue brief (http://bit.ly/2uCb4sS) updates key information about medical marijuana policies in the U.S., research about medical marijuana and potential health impacts of medical marijuana legalization.

TODAY'S AGENDA

- 1. Background on marijuana
- 2. Policy issues
- 3. Potential health effects of medical marijuana
- 4. Recommendations

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WHAT IS MARIJUANA?

- "Marijuana" refers to dried leaves, flowers, stems and seeds from Cannabis sativa plant
- "Cannabis" refers to marijuana and other organic products derived from Cannabis plants
- For simplicity, "marijuana" is primarily used in this presentation



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THC AND CBD

Delta-9-tetrahydrocannabinol (THC)

Cannabidiol

- Delta-9-tetrahydrocannabinol (THC) is main psychoactive compound
- · Cannabidiol (CBD) is nonintoxicating

Source: Atakan, Z. (2012)

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7

Cannabis is a complex plant with more than 400 chemical compounds. The major compounds of interest are THC and the approximately 100 related compounds called cannabinoids, including cannabidiol (CBD). CBD was first isolated in 1963 and THC was first isolated in 1964.

Source: Atakan Z. (2012). Cannabis, a complex plant: different compounds and different effects on individuals. *Therapeutic Advances in Psychopharmacology*, 2(6), 241-54.

HISTORY OF MARIJUANA

 Evidence of use dates back at least 5,000 years

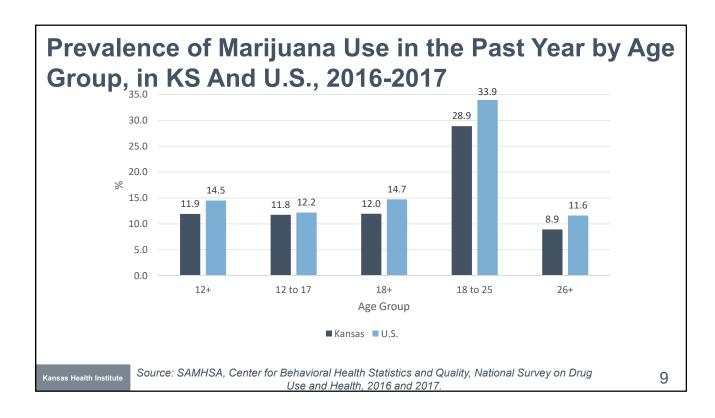


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8

Based on archaeological evidence, marijuana has been used extensively for millennia. This picture shows a tomb found in China with remains thought to belong to a shaman along with plant material identified to be *C. sativa*. The tomb was dated to 2700 BP (i.e., 2,700 years before 1950).

Source: Russo, E. B., Jiang, H. E., Li, X., Sutton, A., Carboni, A., del Bianco, F., Mandolino, G., Potter, D. J., Zhao, Y. X., Bera, S., Zhang, Y. B., Lü, E. G., Ferguson, D. K., Hueber, F., Zhao, L. C., Liu, C. J., Wang, Y. F., ... Li, C. S. (2008). Phytochemical and genetic analyses of ancient cannabis from Central Asia. *Journal of Experimental Botany*, *59*(15), 4171-82.

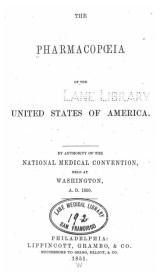




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POLICY HISTORY

- Widespread use in 19th and early 20th centuries before restricted in 1937
- California first state to legalize medical marijuana in 1996
- Three FDA-approved drugs made with synthetic THC
- Epidiolex ® (CBD) became first FDA-approved drug from natural marijuana plant (June 2018)



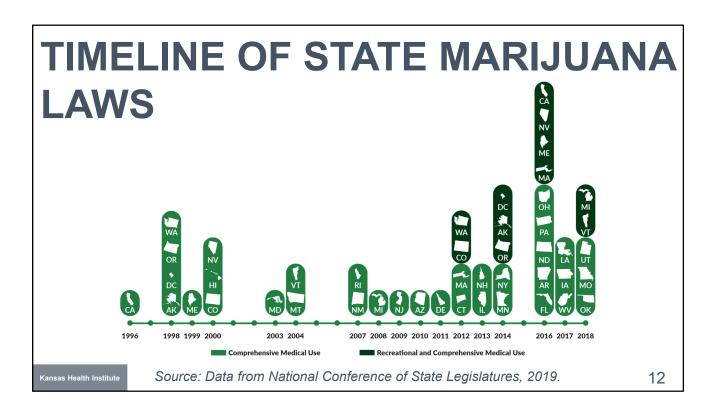
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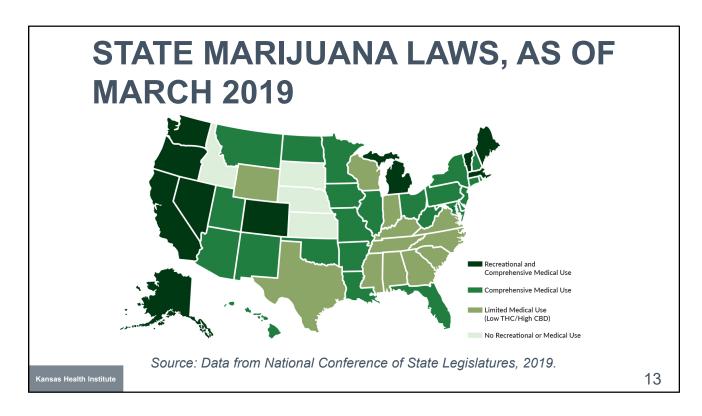
Marijuana was first described in *United States Pharmacopoeia* in 1850 and was used extensively for medical purposes through the 18th and early 19th centuries until its restriction with the "Marihuana Tax Act" (sic) of 1937. It was removed from *United States Pharmacopoeia* in 1942. In 1996, California became the first state to legalize medical marijuana. However, marijuana is still classified as a Schedule I substance by the U.S. Drug Enforcement Agency (DEA).

Primary source: Bridgeman, M. B., & Abazia, D. T. (2017). Medical cannabis: history, pharmacology, and implications for the acute care setting. *Pharmacy and Therapeutics*, *42*(3), 180-188.

Only three drugs made with synthetic forms of tetrahydrocannabinol (THC) — the main psychoactive compound found in the plant — have been licensed by the FDA: Marinol® and Syndros® are both oral forms of dronobinol and Cesamet® is an oral form of nabilone. All three drugs are used for treatment of chemotherapy induced nausea and for increasing appetite in AIDS patients (HIV stage 4). In June 2018, Epidiolex® (cannabidiol) [CBD] oral solution — used to treat rare, severe forms of epilepsy — became the first drug derived from the natural marijuana plant to be approved by the FDA. While CBD is a cannabinoid, it is not psychoactive.



After California became the first state to legalize medical marijuana in 1996, similar laws were passed in other states. Colorado and Washington state became the first states to legalize recreational use of marijuana.



Thirty-four states, the District of Columbia, Guam and Puerto Rico have legalized comprehensive medical use of marijuana. These laws provide protection from criminal penalties for medical use, allow broad access through home cultivation or dispensaries, or both, to a variety of strains (including those with high concentrations of THC), and allow smoking or vaping. Ten of these states and the District of Columbia, representing 24 percent of the U.S. population, also have legalized adult recreational use of marijuana, as has the Commonwealth of the Northern Mariana Islands. Twelve additional states have legalized limited medical use of marijuana, with more restrictions on qualifying medical conditions and types of products, including thresholds for THC and CBD concentrations. Idaho, Kansas, Nebraska and South Dakota, representing only 2 percent of the U.S. population, are the only states that have not established medical marijuana programs, although CBD is legal in some forms in each.

COMPREHENSIVE MEDICAL MARIJUANA PROGRAMS

- Protection from criminal penalties
- Home cultivation or dispensaries
- Variety of strains, including those more than "low THC"
- · Smoking or vaporization allowed

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14

According to the National Conference of State Legislatures, comprehensive medical marijuana programs provide protection from criminal penalties for medical use, allow broad access through home cultivation and/or dispensaries to a variety of strains (including those with high concentrations of THC), and allow smoking or vaping.

COMPREHENSIVE MEDICAL MARIJUANA PROGRAMS (CONT.)

Among 34 states and Washington, DC:

- 31 states and the District of Columbia allow dispensaries
- 32 states specify medical conditions
- Details pending in remaining states

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LIMITED MEDICAL MARIJUANA PROGRAMS

- Allows use of "low THC, high CBD" products
 - For medical reasons
 - Limited circumstances

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16

According to the National Conference of State Legislatures, states with limited medical marijuana access programs restrict qualifying medical conditions, types of products, maximum concentrations of THC and minimum concentrations of CBD.

PROGRAMS (CONT.)

Out of 12 states:

- 10 states define maximum levels of THC or minimum levels of CBD, or both
- All 12 states specify medical conditions

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CHARACTERISTICS OF MEDICAL MARIJUANA PROGRAMS

- Variability in medical conditions
- Mental health conditions covered less commonly than chronic medical conditions
- Variability in allowable supply

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State medical marijuana programs vary considerably in the number and types of conditions for which medical marijuana may be used. For example, Illinois permits medical marijuana use for 40 conditions, while Washington specifies just seven conditions. State programs also vary considerably with respect to the amount of medical marijuana that may be purchased or the number of plants that may be cultivated.

Mental health conditions, such as post-traumatic stress disorder (PTSD) are less commonly included than are chronic conditions such as muscle spasms or terminal conditions such as amyotrophic lateral sclerosis (ALS). The majority of states approve the use of medical marijuana for either epilepsy as a diagnosis or for treatment of seizures or muscle spasms.

CHARACTERISTICS OF MEDICAL MARIJUANA PROGRAMS (CONT.)

- Dispensary fees
 - Application
 - License
 - Renewal
- Packaging and label standards
- Safety and security standards

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19

State medical marijuana programs typically include three different types of fees that dispensaries may be required to pay. These include an application fee, license fee and renewal fee. However, not all states require all three types of fees.

Many states require marijuana products to adhere to packaging and labeling standards. In addition, most states require dispensaries to have one or more safety features, such as enclosed growing areas, locked doors and surveillance cameras.



In 2009, United States Deputy Attorney General Ogden released a memorandum stating that federal prosecutors should deprioritize cases in which an individual was in compliance with state law.

In 2012, Colorado and Washington passed the first laws that permitted recreational use of marijuana. Prior to 2013, 22 states had passed laws permitting use of some form of marijuana for medical purposes.

In August 2013, the U.S. Justice Department issued the "Cole Memo" from Deputy Attorney General James Cole. This memorandum reiterated the fact that marijuana was still illegal under federal law. However, it also stated that federal enforcement would be prioritized around prevention in eight (8) areas:

- · Distribution to minors:
- Revenue to criminal enterprises and gangs;
- Diversion from states where marijuana is legal to those where it is not;
- Using state-authorized activity as a cover for other illegal activity:
- · Violence;
- Drugged driving;
- · Growing on public lands; and
- · Possession / use on federal property.

Enforcement outside these priority areas would be deferred to states. In January 2018, U.S. Attorney General Jeff Sessions issued a memorandum that rescinded the Cole Memo and directed federal prosecutors to determine enforcement priorities.



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HISTORY OF MEDICAL MARIJUANA EFFORTS IN KS

- 18 bills introduced in last 13 years
- Lack of specificity re: THC and CBD
- Most specified medical conditions

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22

There have been many unsuccessful efforts to legalize medical marijuana use in Kansas. Eighteen bills have been introduced since 2006, most of which specified medical conditions, set taxes and fees, and permitted the establishment of dispensaries. While some of these bills established maximum THC concentration, none established limits on CBD concentration.

OTHER KS MARIJUANA-RELATED BILLS ENACTED

- 2016: Reduced severity (SB HB 2462)
- 2017: Reduced severity (SB 112)
- 2017: Scheduling of CBD (House Sub. for SB 51)
- 2018: Industrial hemp

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23

In 2016, House Bill (HB) 2462 reduced the severity for marijuana possession:

- First offense for possession: Class B nonperson misdemeanor;
- · Second offense: Class A misdemeanor; and
- Third and subsequent offenses: Level 5 felony.

In 2017, Senate Bill (SB) 112 reduced the severity for possession to a class B misdemeanor when:

- Used to cultivate <5 marijuana plants; or
- Used to store, contain, conceal, inject, ingest, inhale or otherwise consume controlled substance.

Also in 2017, House Substitute for SB 51 placed CBD in schedule IV of the Kansas Controlled Substance Act when comprising the sole active ingredient of a drug approved by the U.S. FDA.

In 2018, SB 263 permitted the Kansas Department of Agriculture to grow, cultivate and promote research and development of industrial hemp.

ADDITIONAL POLICIES RELATED TO CBD

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KS ATTORNEY GENERAL OPINION RE: CBD - JANUARY 2018

- Question: Is CBD oil that does not contain THC legal to possess and/or sell in Kansas?
- Answer: No.

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25

In January 2018, Kansas Attorney General Derek Schmidt issued an opinion in response to a request by District Attorneys in Johnson and Sedgwick counties to answer the question, "Is CBD oil that does not contain THC legal to possess and/or sell in Kansas?"

In the synopsis of this opinion, Schmidt stated that under Kansas law, at that time, it was unlawful to possess or sell products or substances containing any amount of CBD or THC. The determination was based on two primary factors. First, CBD fit within the general definition of marijuana. Second, CBD oil did not fit under either of the two exclusions in the legal definition of marijuana. The first exclusion specifies certain parts of or derivatives of the plant. The second exclusion specifies any substance as the sole active ingredient listed in schedules II through V of the uniform controlled substances act. At that time the FDA had not yet approved such a drug with CBD.

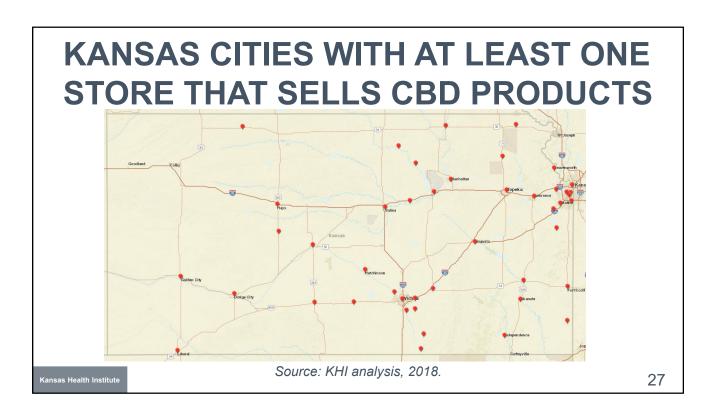
CBD EXCLUSION FROM MARIJUANA DEFINITION

- 2018: SB 282
 - Excluded CBD with no THC from definition of marijuana
 - CBD products may now be sold or possessed
 - No restrictions (medical or otherwise)
 - No registry

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26

In 2018, Kansas passed legislation excluding CBD from the state definition of marijuana. This change permitted the legal, retail sale of CBD products with no limits on qualifying medical conditions, age or other restrictions typical in other states.



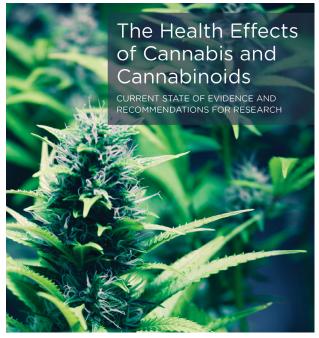
In November 2018, a web-based search identified 128 individual stores in 45 towns or cities in Kansas selling CBD products. Examples of products include tinctures, oral capsules, lotions and edible products such as gummies, chocolates and cookies. Many of these stores also offer online sales.

HEALTH EFFECTS OF MARIJUANA

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NATIONAL ACADEMIES, 2017

- Negative health effects
- Therapeutic benefits



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29

In 2017, prior to the FDA approval of Epidiolex®, the National Academies of Sciences, Engineering, and Medicine (the National Academies) published a comprehensive study of the medical and scientific literature regarding the health effects of marijuana.

LEVEL OF EVIDENCE FOR EFFICACY

Condition	Conclusive/ Substantial	Moderate	Limited
Chronic pain in adults	✓		
Chemotherapy-induced nausea/vomiting	\checkmark		
Patient-reported multiple sclerosis spasticity	✓		
 Short-term sleep outcomes Obstructive sleep apnea Fibromyalgia Chronic pain Multiple sclerosis 		✓	

Note: Refers to effectiveness of cannabis or cannabinoids.

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Source: National Academies of Sciences, Engineering, and Medicine, 2017.

30

The National Academies study concluded that there was conclusive or substantial evidence of modest therapeutic benefit for the following:

- In adults with chemotherapy-induced nausea and vomiting, oral cannabinoids are effective antiemetics;
- In adults with chronic pain, patients treated with cannabis or cannabinoids are more likely to experience a clinically significant reduction in pain symptoms; and
- In adults with multiple sclerosis (MS)-related spasticity, short-term use of oral cannabinoids improves patient-reported spasticity symptoms.

While the National Academies study found moderate or limited evidence of therapeutic benefit for some other conditions evaluated, firm conclusions could not be made.

The National Academies study also concluded that marijuana use is associated with increased health risks, such as respiratory problems, lower birth weight in the offspring of women who smoke marijuana during pregnancy, problem marijuana use or other substance dependence, psychosocial impairment and mental health problems.

LEVEL OF EVIDENCE FOR EFFICACY (CONT.)

Condition	Conclusive/ Substantial	Moderate	Limited
Increasing appetite and decreasing weight loss associated with HIV/AIDS			✓
Clinician-measured multiple sclerosis spasticity			✓
Tourette syndrome			✓
Social anxiety disorders			✓
Post traumatic stress disorder			✓

Note: Refers to effectiveness of cannabis or cannabinoids

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Source: National Academies of Sciences, Engineering, and Medicine, 2017

While the National Academies study found moderate or limited evidence of therapeutic benefit for some other conditions evaluated, firm conclusions could not be made.

The National Academies study also concluded that marijuana use is associated with increased health risks, such as respiratory problems, lower birth weight in the offspring of women who smoke marijuana during pregnancy, problem marijuana use or other substance dependence, psychosocial impairment and mental health problems.

NATIONAL ACADEMIES RECOMMENDATIONS, 2017

- Address research gaps
- Improve research quality
- · Improve surveillance capacity
- Address research barriers

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32

In its 2017 report on the health effect of cannabis and cannabinoids, the National Academies of Sciences, Engineering and Medicine outlined four recommendations:

- 1. Address research gaps;
- 2. Improve research quality;
- 3. Improve surveillance capacity; and
- 4. Address research barriers.

QUALIFYING CONDITIONS

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If Kansas were to enact a medical marijuana bill with the same provisions regarding qualifying conditions as some bills introduced prior to 2019, how many patients would be eligible?

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Condition/Sym	ptom	Population Group	Year of Estimate	Estimated Number of Patients
TOTAL		-	-	356,543
	Cancer	All ages	2017	42,579
	Glaucoma	Age 40 and over	2010	23,761
	HIV / Stage 3 (formerly AIDS)	All ages	2017	3,062
	Past or Present Hepatitis C	Age 18 and over	2010	29,900
	Amyotrophic Lateral Sclerosis	Age 18 and over	2017	150
	Crohn's Disease	All ages	2017	6,088
	Alzheimer's Disease	Age 65 and over	2018	53,000
	Nail Patella Syndrome	All ages	2017	58
	Cachexia	All ages	2017	29,131
	Severe Pain	Age 18 and over	2017	138,914
	Epilepsy	All ages	2015	29,900
Note: The total is the sum of all conditions, and does not consider that some people could have co-occurring conditions. Source: KHI analysis of state and national reports, data sources and literature review, 2018.				

This table shows the results of an analysis that KHI conducted of state and national reports, data sources and literature review to determine the number of patients who could potentially qualify for medical marijuana if Kansas were to pass legislation with similar provisions found in bills that have been introduced prior to 2019. These are the conditions previously included in bills rather than the conditions for which there is evidence of therapeutic benefit. In some cases, these estimates vary substantially from the 2015 HIA due to updated information that became available and changes to methodology.

IMPACT ON DRIVING UNDER THE INFLUENCE, TRAFFIC CRASHES AND FATALITIES

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KEY FINDINGS

- Marijuana use impairs driving skills and increases crash risk
- Overall impact on population uncertain
- Research findings on impact of legalization on crash risks have been mixed
- Research challenging due to lack of standard for marijuana impairment

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37

The National Academies study and other research have demonstrated that marijuana use impairs driving-related skills and increases the risk of motor vehicle crashes. However, the overall impact on the population is less clear. For example, although the U.S. Department of Transportation, in a 2017 report to Congress, stated that several indicators suggest that a problem exists, the scope and magnitude of marijuana-impaired driving could not be clearly specified.

Furthermore, research examining the impact of marijuana legalization on motor vehicle crashes is limited and findings have been mixed. Some studies have found that marijuana legalization is associated with increased risk of crashes, while others have found that the risk of crashes declines after legalization. Still others found that marijuana legalization has had no impact on crash risks.

It is important to note that this research is challenging because there is no standard to measure marijuana impairment through laboratory testing and no uniformity in defining impairment among law enforcement.

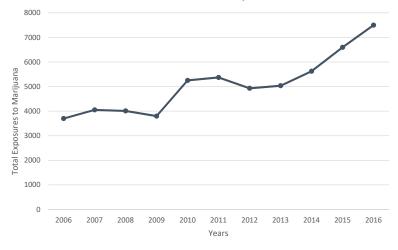
MARIJUANA-RELATED EXPOSURES REPORTED TO POISON CONTROL CENTERS

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38

As additional states have legalized marijuana, concerns about unintentional exposures have increased. Although marijuana and other cannabis products account for a small proportion of all exposures reported to U.S. poison control centers (less than 1 percent in 2016), exposures among all age groups have increased substantially, from 3,699 in 2006 to 7,497 in 2016. Especially concerning are exposures among children. Many edible marijuana products — such as chocolates, candy or baked goods palatable to young children — might contain high amounts of THC, thereby increasing the risk of acute toxicity. Clinical effects vary substantially, but can be severe, including central nervous system and respiratory problems.

TOTAL MARIJUANA EXPOSURES REPORTED TO POISON CONTROL CENTERS IN THE U.S., 2006-2016



Source: KHI analysis of data from the American Association of Poison Control Centers, 2006–2016.

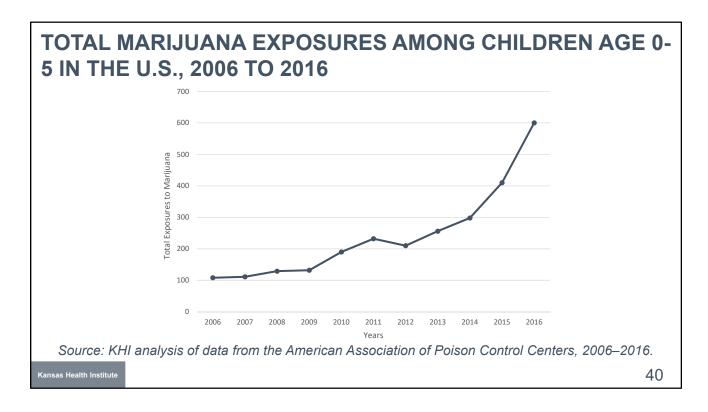
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39

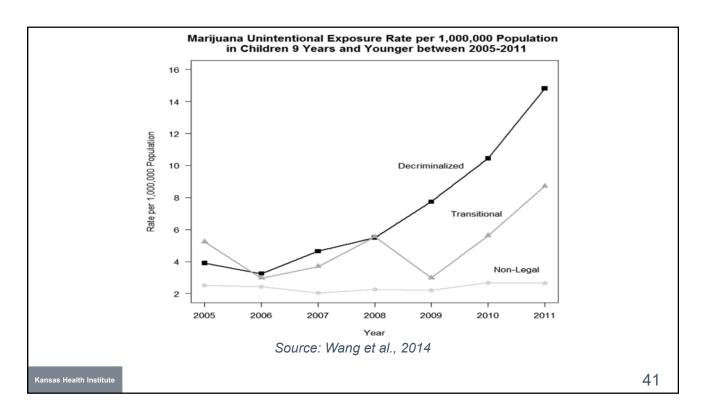
Although marijuana and other cannabis products account for a small proportion of all exposures reported to U.S. poison control centers (less than 1 percent in 2016), exposures among all age groups have increased substantially, from 3,699 in 2006 to 7,497 in 2016.

Overall, cannabis exposures reported to poison control centers are relatively rare. Although cannabis exposures (excluding synthetic cannabinoids) account for 8.1 percent of single exposures in the "Stimulants and Street Drugs" category, they account for less than 1 percent of all exposures.

However, data from the American Association of Poison Control Centers (AAPCC) National Poison Data System (NPDS) demonstrates that among all age groups, marijuana exposures reported to poison control centers in the U.S. increased from 3,699 in 2006 to 7,497 in 2016. Most research in this area has focused on pediatric populations and consistently demonstrates significant increases among children in rates of marijuana exposures reported.



Especially concerning are exposures among children. Many edible marijuana products — such as chocolates, candy or baked goods palatable to young children — might contain high amounts of THC, thereby increasing the risk of acute toxicity. Clinical effects vary substantially, but can be severe, including central nervous system and respiratory problems.



Research suggests that rates of pediatric marijuana exposures have increased significantly more in states that have legalized medical marijuana than in states that have not. An often-cited national study (Wang et al. 2014) found that rates of marijuana exposures among children less than 9 years of age increased by an average of 30.3 percent per year between 2005 and 2011 in states that legalized medical marijuana before 2005. In contrast, rates increased by an average of 11.5 percent per year in states that legalized medical marijuana between 2005 and 2011 and an average of 1.5 percent per year in states that did not legalize medical marijuana.

Source: Wang, G. S., Roosevelt, G., Le Lait, M.-C., Martinez, E. M., Bucher-Bartelson, B., Bronstein, A. C., & Heard, K. (2014). Association of unintentional pediatric exposures with decriminalization of marijuana in the United States. *Ann. Emerg. Med.*, 63(6), 684–689. Retrieved from: https://doi.org/10.1016/j.annemergmed.2014.01.017

KEY FINDINGS

- Rates of pediatric exposures increased significantly in states that legalized marijuana, while there were no significant increases in states that did not
- Most pediatric exposures are due to ingestion
- Marijuana exposures account for less than 1% of total exposures reported to poison control centers, but have increased

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42

Although marijuana accounts for a small proportion of all drug exposures reported to poison control centers (8.1 percent of single substance exposures in the "stimulant and other street drugs" category in 2016), the risk of exposure, particularly among children, has increased significantly and appears to be associated with legalized access to marijuana.

IMPACT ON OPIOID PRESCRIBING AND OPIOID-RELATED MORTALITY

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IMPACT ON OPIOID PRESCRIBING

- Multiple studies suggested decreased opioid prescribing following medical cannabis legalization
- Extent of impact unclear

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While some studies suggest that decreased prescription opioid use and overdose deaths are associated with legalized medical marijuana use, there have been conflicting results. Studies based on self-report surveys among patients generally have shown a strong correlation between medical marijuana use and decreased opiate use, while studies examining the association between opioid prescribing rates and medical or recreational marijuana use laws have shown moderate impacts. The mechanism by which opioid prescriptions are reduced is unclear. Some studies suggest that medical marijuana augments the analgesic effects of opioids, thereby allowing for a lower dose of opioids. Other studies found that states with operational networks of medical marijuana dispensaries may experience a greater decrease in opioid prescribing than states without these networks.

IMPACT ON OPIOID MORTALITY

- Causal relationship not confirmed
- Declines in opioid-related mortality have been observed following medical marijuana laws
- Reduced mortality from semisynthetic opioids (e.g., oxycodone) but not synthetic opioids (e.g., fentanyl and heroin)

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45

While declines in opioid mortality rates have been observed following the passage of medical marijuana legislation, there has not been enough research to establish a causal relationship. Some studies suggest medical marijuana legalization reduced mortality from semisynthetic opioids (e.g., oxycodone) but not synthetic opioids (e.g., fentanyl and heroin).



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CBD OUTLETS

State agencies:

- Monitor research developments on safety and efficacy of CBD
- Monitor potential health impacts of increased access to CBD

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47

Given increased availability of CBD in Kansas:

- State agencies should monitor research developments on safety and efficacy of CBD and related products; and
- · State agencies should monitor potential health impacts of increased access to CBD.

THERAPEUTIC EFFECTS

If medical marijuana were to be legalized in KS:

 Given the evolving nature of research on therapeutic benefits and potential harms of medical marijuana, consider authorizing state agency to specify qualifying conditions for patients to access medical marijuana

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DUI, TRAFFIC ACCIDENTS AND FATALITIES

If medical marijuana were to be legalized in KS:

- Provide education
- Require product labeling
- Conduct additional research to establish enforceable definition of impairment

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49

If medical marijuana were to be legalized in Kansas:

- · Provide education to public on risks of marijuana-related impairment;
- · Require education and materials for patients accessing medical marijuana;
- · Require product labeling on risks of marijuana-related impairment; and
- Conduct additional research to establish enforceable definition of impairment.

EXPOSURES

If medical marijuana were to be legalized in KS:

- Monitor emergency department visits and poison control center data for unintentional exposures
- Provide education
- Require product labeling
- Require child-resistant packaging
- Impose limits on number and types of edible products
- Require identification checks at dispensaries
- Impose age restrictions for access to dispensaries
- Prohibit the use of marijuana in public

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50

If medical marijuana were to be legalized in Kansas:

- Monitor emergency department visits and poison control center data for unintentional exposures;
- Provide education and materials through health care providers and dispensaries;
- · Require product labeling on risks of marijuana-related impairment;
- Require child-resistant packaging of marijuana products;
- Impose limits on number and types of edible products;
- · Require identification checks at dispensaries;
- · Impose age restrictions for access to dispensaries; and
- Prohibit the use of marijuana in public.

OPIOIDS

If medical marijuana were to be legalized in KS:

 State agencies should monitor potential impact of medical marijuana on opioid prescribing, morbidity and mortality

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THANK YOU Any questions?

Contact us at 785.233.5443 or visit our website at khi.org for additional information.













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