MEDICAL PROFESSIONAL LIABILITY IMPLICATIONS OF MEDICINAL CANNABIS

Wilson Elser partners:

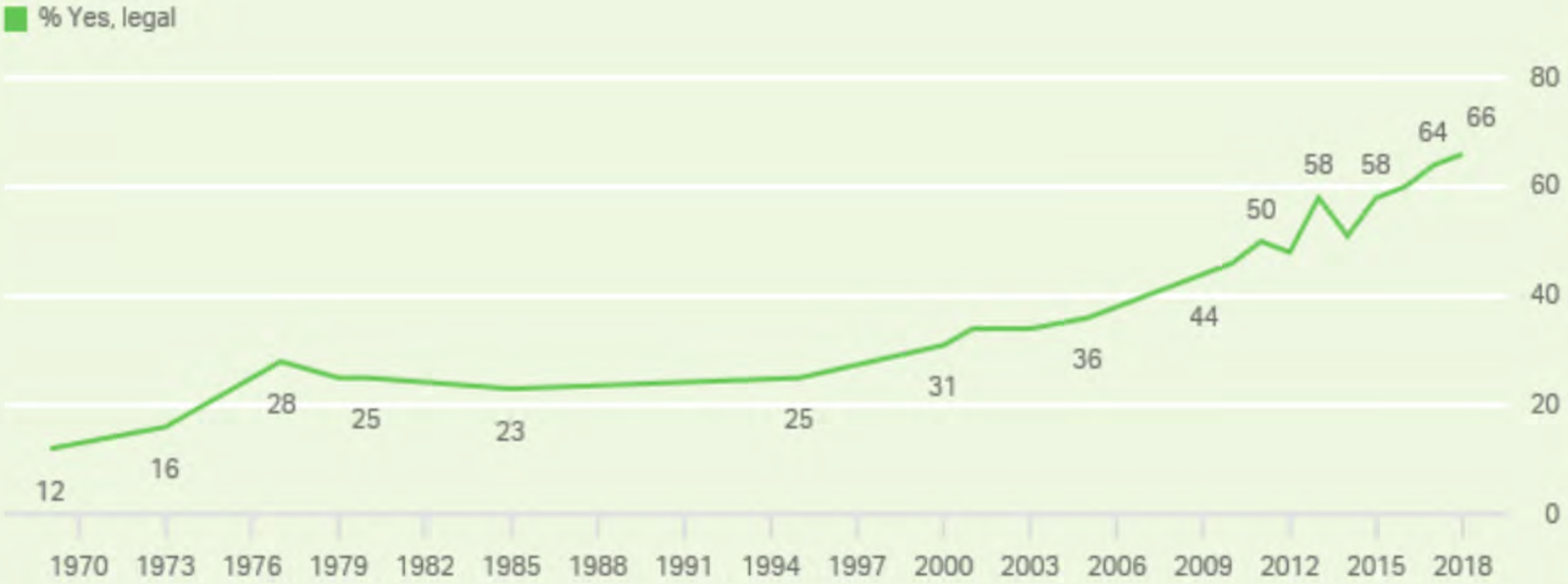
Ian Stewart Co-Chair Cannabis Practice Team

Lori Semlies Co-Chair Medical Malpractice & Healthcare Practice Team



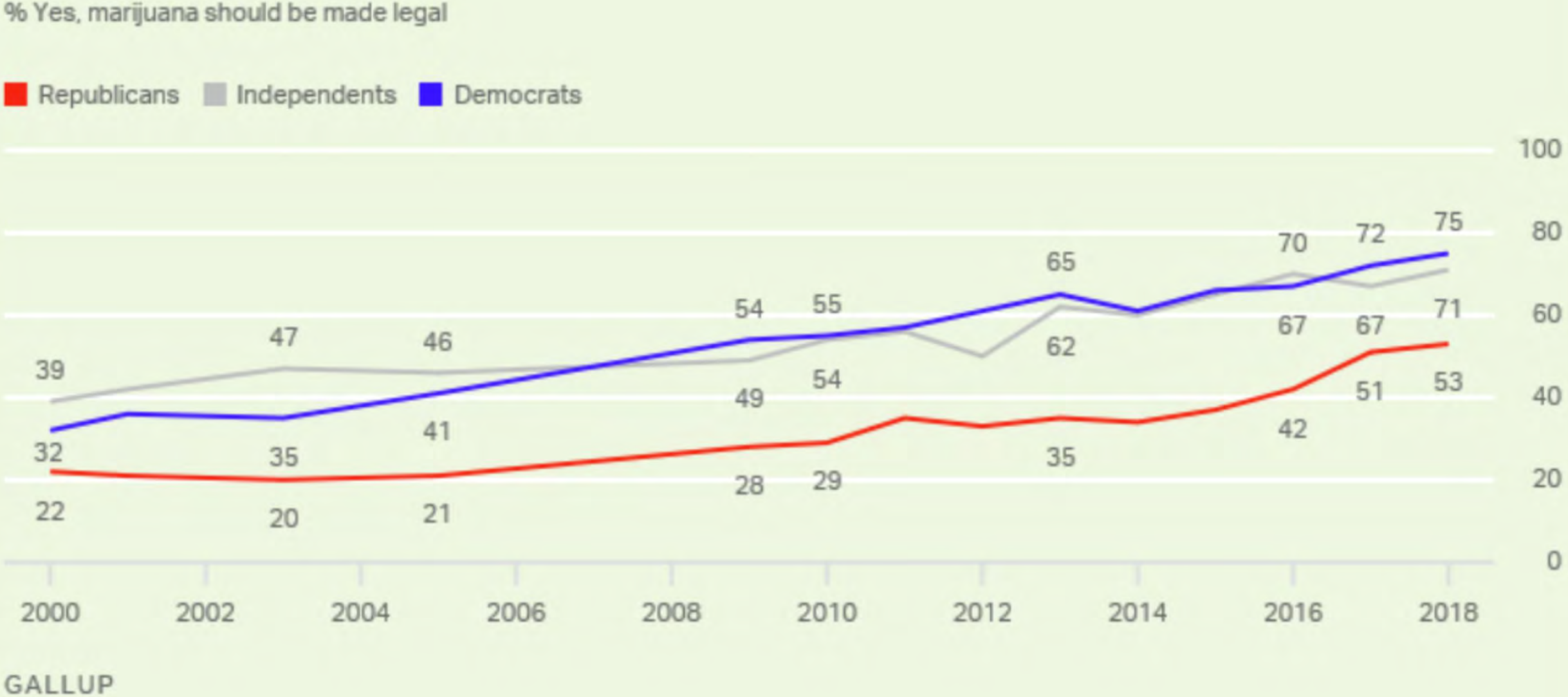
Support for Legalizing Marijuana Continues to Edge Up

Do you think the use of marijuana should be made legal, or not?

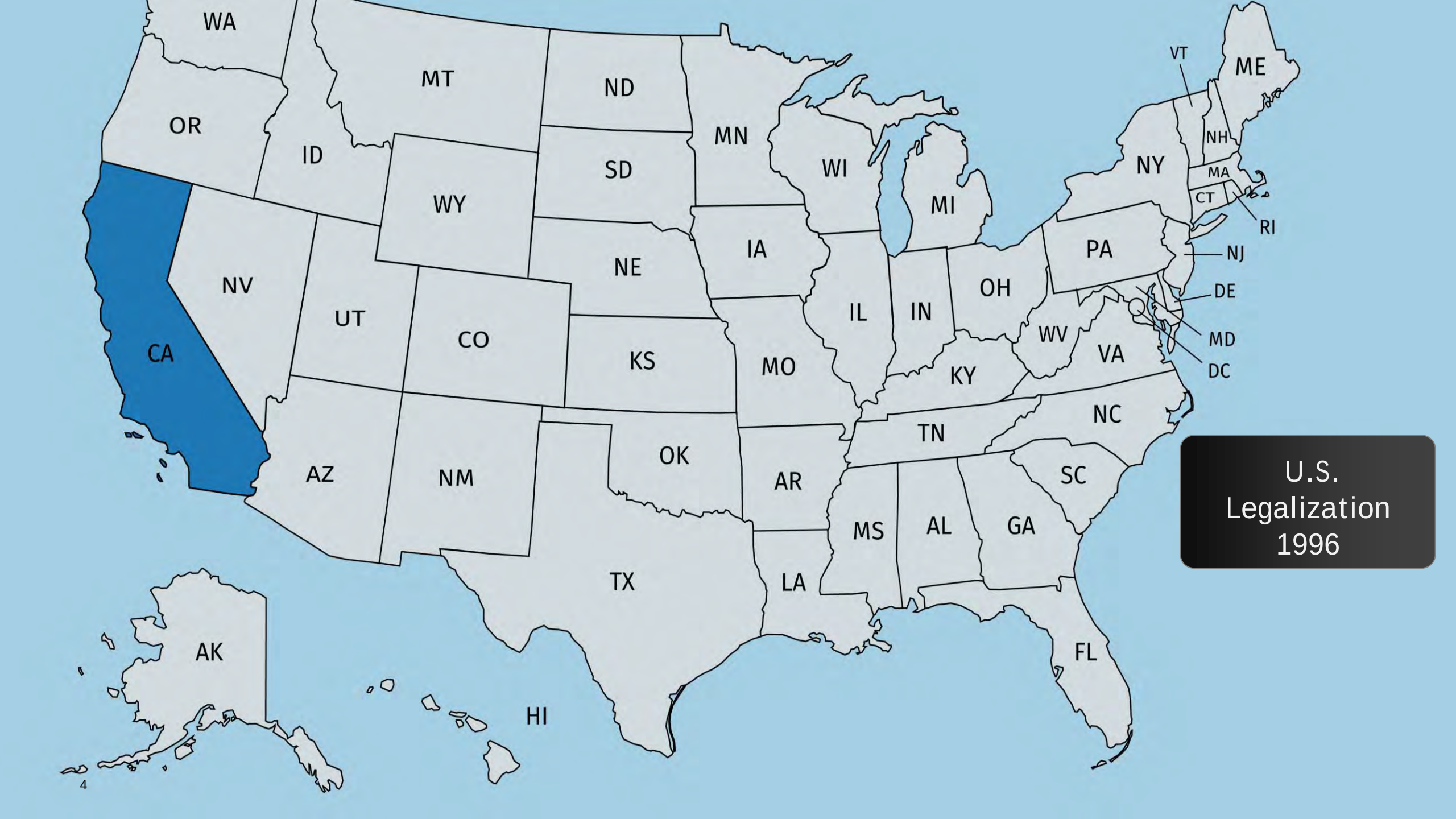


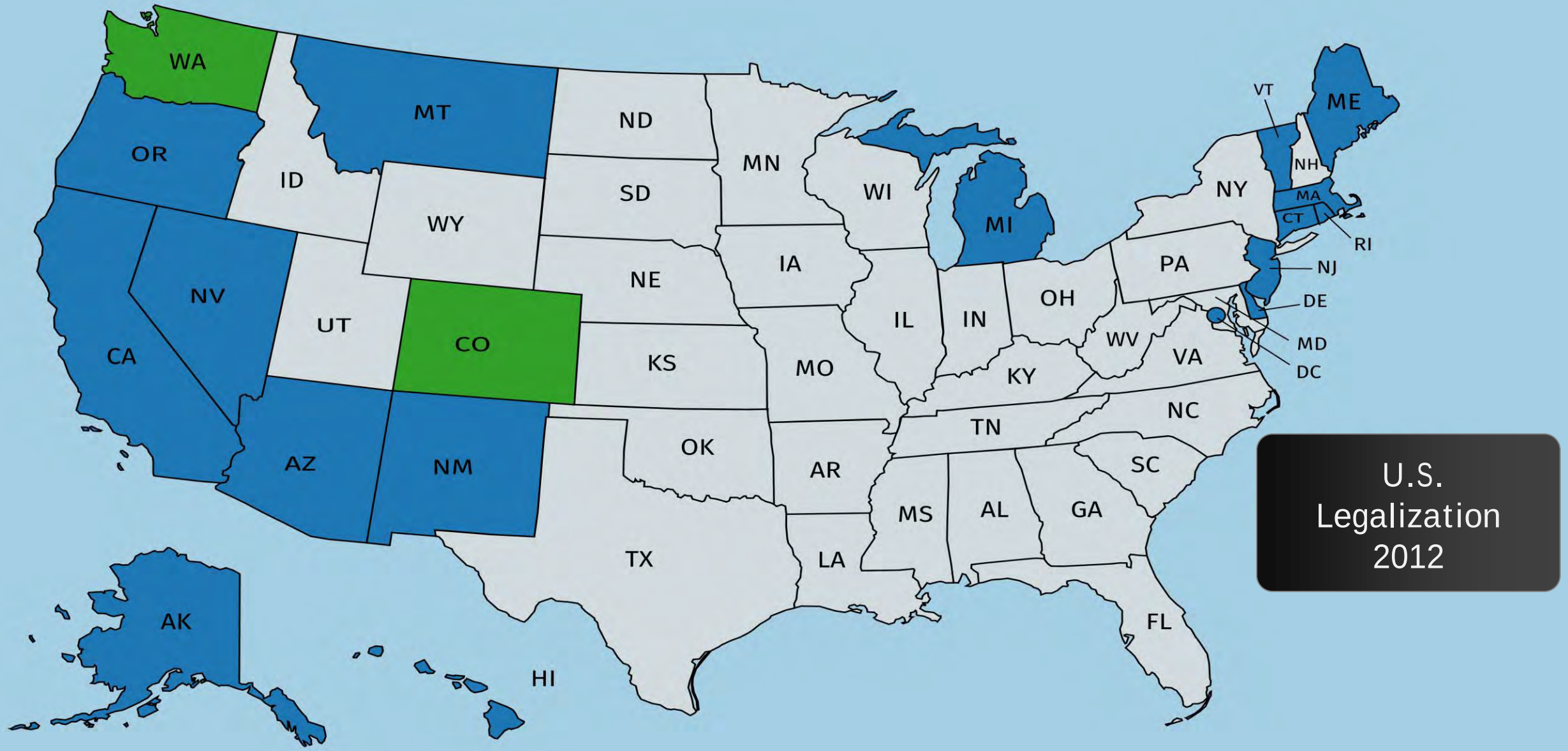
GALLUP

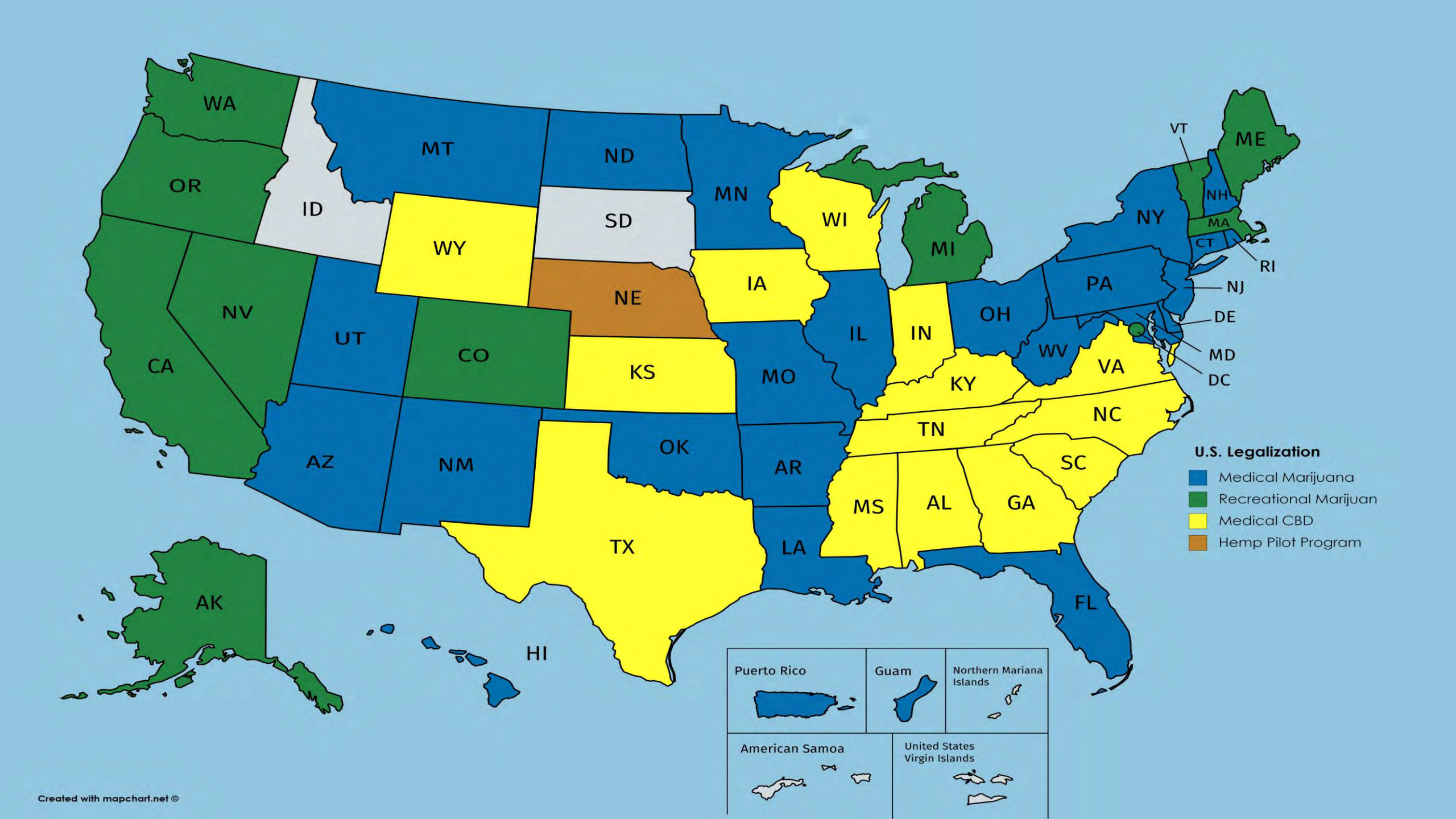
Majorities of All Political Identification Groups Continue to Support Legalization of Marijuana in 2018

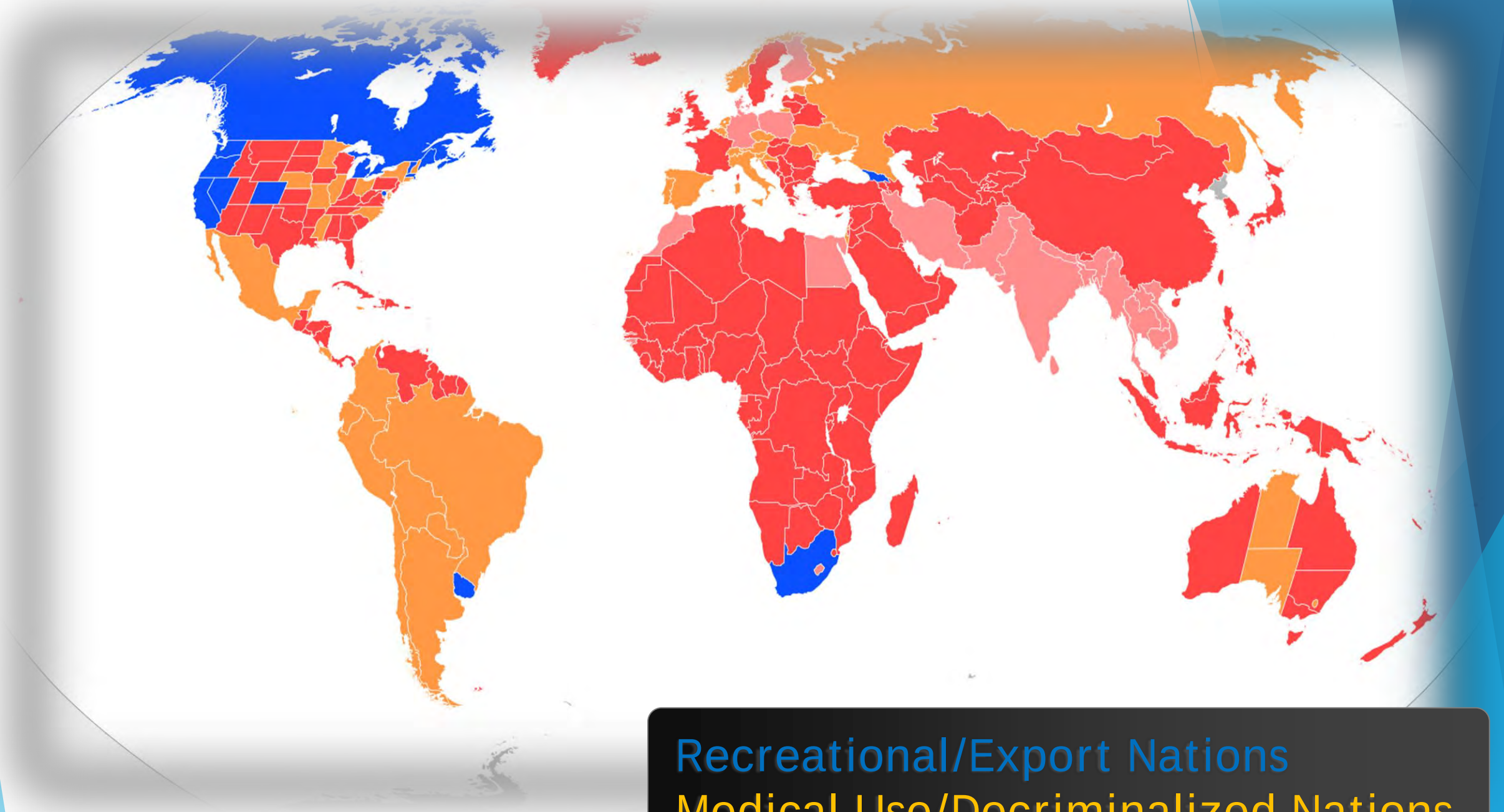


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U.S. Legalization 1996


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U.S. Legalization
Medical Marijuana
Recreational Marijuan
Medical CBD
Hemp Pilot Program
Puerto Rico
Guam
Northern Mariana Islands
American Samoa
United States Virgin Islands
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Recreational/Export Nations
Medical Use/Decriminalized Nations

International Trends to Watch

The 1961 Single Convention

- Cannabis as Schedule IV Substance

World Health Organization's 2019 Recommendation to the United Nations

- Reschedule Cannabis & THC
- Remove CBD Entirely

Hemp & CBD



The 2018 Farm Bill

Interstate Commerce

USDA and FDA Oversight

Qualifying Conditions:

- MOST LIBERAL STATES:

CA: "any other chronic or persistent symptom that substantially limits the ability of a person to conduct 1 or more of their major life activities"

Washington DC:

"any other condition that is chronic, cannot be effectively treated by ordinary measures"

Massachusetts:

"other debilitating condition as determined by the patient's qualifying physician"

MOST STATES' QUALIFYING CONDITIONS

- Only patients with one of the following severe, debilitating or life-threatening conditions:
- Cancer
- Glaucoma
- HIV or AIDS
- ALS, Parkinson's, MS, Huntington's disease, Tourette's, Muscular Dystrophy
- "damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity"
- Epilepsy
- Inflammatory bowel disease
- Neuropathy
- PTSD, ANXIETY
- Chronic pain

OPIOID REPLACEMENT?

NEW YORK:

"…or any condition for which an opioid could be prescribed (provided that the precise underlying condition is expressly stated on the patient's certification). Patients must also have one of the following associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain, severe nausea, seizures, or severe or persistent muscle spasms, PTSD or opioid use disorder (only if enrolled in a treatment program certified pursuant to Article 32 of the Mental Hygiene Law)."

The Endocannabinoid System (ECS)





Tetrahydrocannabinol



Cannabidiol



Cannabinol

CB1 receptors are primarily found in the brain and central nervous system, and to a lesser extent in other tissues.

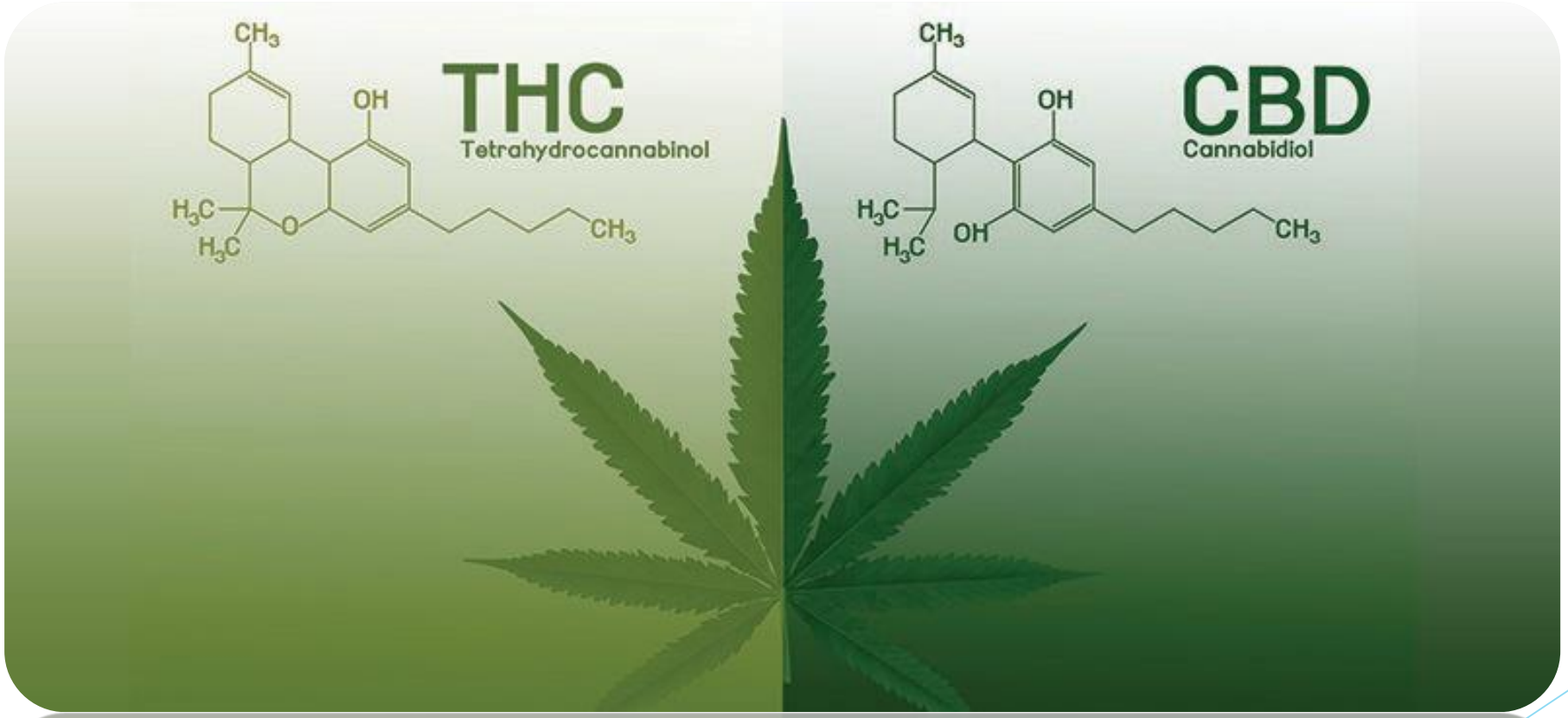


CBD does not directly fit CB1 or CB2 receptors but has powerful indirect effects still being studied.



CB2 receptors are mostly in the perepheral organs especially cells associated with the immune system.

THC vs CBD



Medical Uses for CBD

Epilepsy

In June 2018, the FDA approved Epidiolex, the first prescription medication to contain CBD.

Used to treat rare, difficult-to-control forms of childhood epilepsy.



Medical Uses for CBD

CBD is used to help with other various conditions:

- inflammation
- pain
- psychosis or mental disorders
- inflammatory bowel disease
- nausea
- migraines
- depression
- anxiety



Use of CBD - Malpractice Risk

- While the large majority of the science indicates CBD oil is safe for use and consumption, adverse effects have been seen with high doses.
- CBD is an inhibitor - it can act to keep other medications from being processed by the body as quickly as intended so the drug remains in the patient's system longer than anticipated causing unwanted side effects or potential for overdose. Here are some examples:

Steroids	Anesthetics
HMG CoA reductase inhibitors	Antipsychotics
Calcium channel blockers	Antidepressants
Antihistamines	Anti-epileptics
Prokinetics	Beta blockers
HIV antivirals	PPIs
Immune modulators	NSAIDs
Benzodiazepines	Angiotension II blockers
Antiarrythmics	Oral hypoglycemic agents
Antibiotics	Sulfonylureas

Potential Medical Uses for Marijuana/THC

- THC is used to help with conditions such as:
  - pain
  - muscle spasticity
  - glaucoma
  - insomnia
  - low appetite
  - nausea
  - anxiety



Potential Adverse Effects of Marijuana/THC

- Heart disease
  - Marijuana may cause rapid heartbeat, short-term high blood pressure and may increase the risk of heart attack.
- Weakened immune system
  - Cannabinoids in marijuana may weaken the immune system.
- Lung diseases
  - Long-term use of marijuana may aggravate lung problems. Regular, long-term marijuana use has been associated with lung cancer and also with several cases of an unusual type of emphysema.
- Seizure disorders
  - Marijuana can make seizure disorders worse in some people; in other people it may help to control seizures.

Medical Malpractice Exposure

DEVIATION FROM THE STANDARD OF CARE

(There is no established SOC-only Guidelines)

Common elements of Guidelines:

- An established physician/patient relationship
- Diagnosing qualifying condition & taking a complete history
- Informed consent discussion
- Treatment Plan and Monitoring
- Specialized assessment for substance abuse and mental health disorders
- Concerns in the elderly
- Documentation
- Conflicts of interest

Malpractice Risk

- Physicians are suddenly faced with having to know how cannabis can interact with other medications – EVEN IF THEY DO NOT CERTIFY FOR ITS MEDICAL USE
  - Example – Oncologist is working with a cancer patient who discloses use of cannabis for control of pain. Oncologist did not certify the patient for its use, but now needs to know how it could affect all of the other medications the patient takes for their cancer.
  - What if he/she prescribes a medication that is contraindicated with cannabis?
  - How will they educate themselves on those medications?
  - What is the effect of long term use of Marijuana?

Malpractice Risk

- Physicians are suddenly faced with patients asking them what they think about using cannabis
  - Example - General primary care physician is treating a patient with a diagnosis of severe rheumatoid arthritis. The patient is in constant pain and asks the doctor what she thinks about her using cannabis recreationally to ease the pain. The doctors says that it might be a good option for the patient to deal with her pain.
  - Patient obtains and uses cannabis as it is legal for recreational use
  - Patient has an adverse reaction to the cannabis and blames the physician saying that he/she said it was a good idea to use it.

Lack of Informed Consent

Drug interactions

Increased risk of falls

Short term memory impairment/ increased confusion

Driving risks

Pregnancy/breast feeding, fertility

Smoking increases risk of respiratory illnesses

Dependence/addiction

Impaired brain development

Increased risk of suicidal thoughts

Increase of symptoms of bipolar disorder

Other effects on underlying mental health disorders

Benefits & Alternatives:

- Intended and incidental (stimulates appetite)
- Alternatives: Opioids?
- Failure to offer it as a treatment option?

What Does "Medical Cannabis" Even Mean?

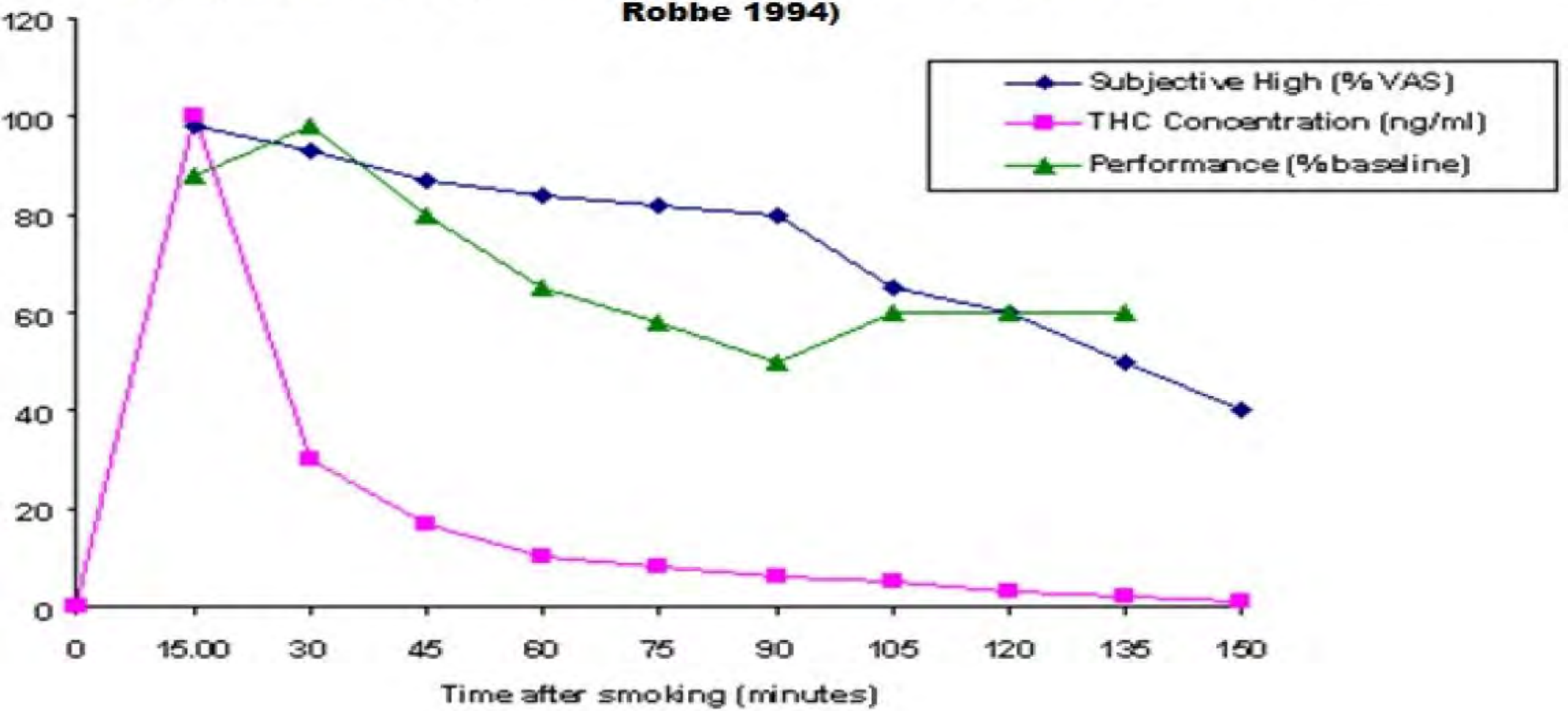
- NY and NJ
- Oils/Pens
- Tincture/drops
- Gels
- Capsules
- Inhalation where otherwise permitted
- NJ edibles only for under 18



Not All Products Are The Same

- Oral ingestion peaks in 1-6 hours and then has a 20-30 minute half life
- Inhalation peaks at 2 to 10 minutes and decline begins within 30 minutes
- Potency levels vary
- Ratio of THC to CBD and other cannabinoids varies

Time Course of Standardized THC Concentration in Plasma, Performance Deficit and Subjective High after Smoking Marijuana (Adapted from Berghaus et al. 1998, Sticht and Käferstein 1998 and Robbe 1994)

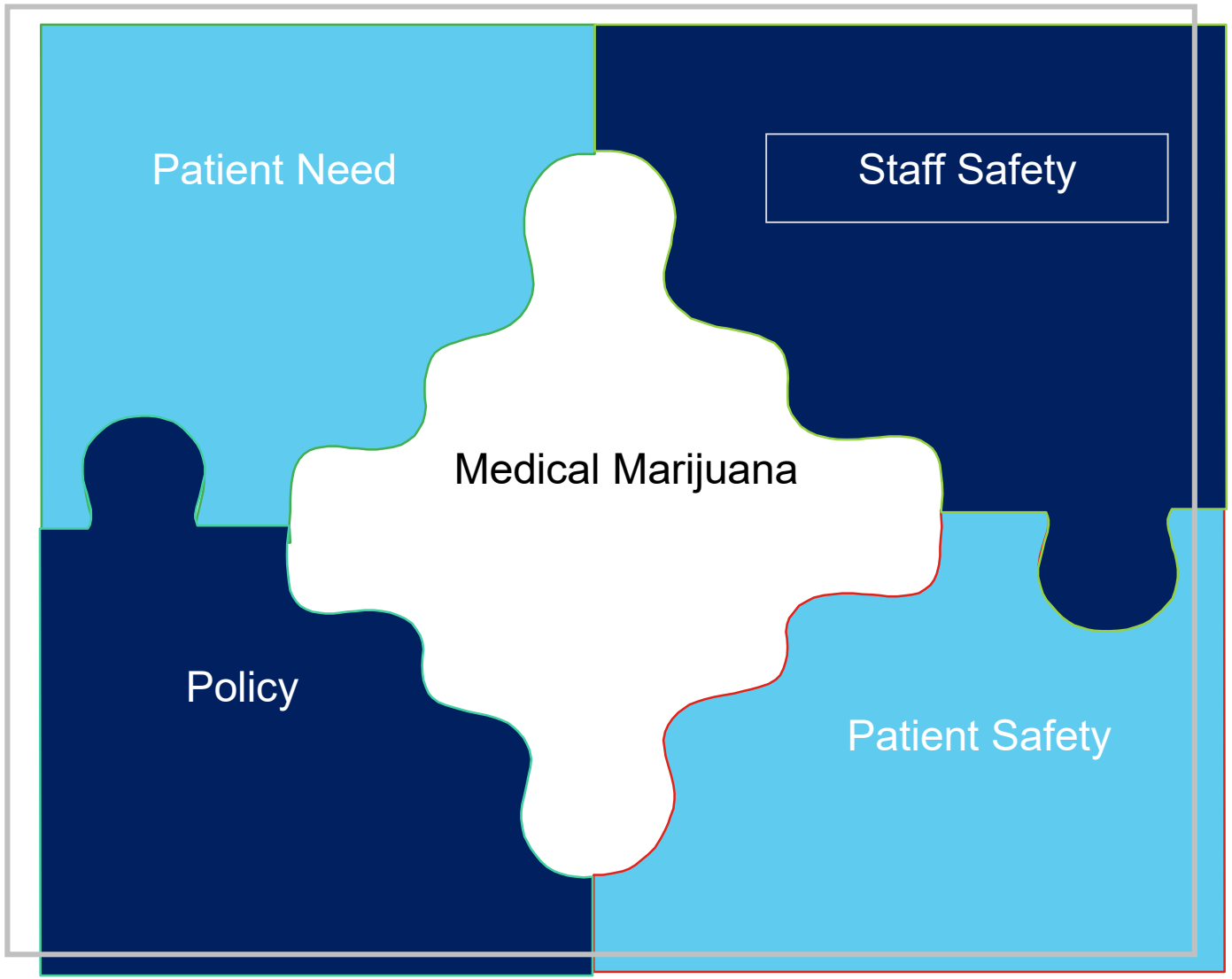



Driving impaired by marijuana doubles
the risk of traffic accidents and death.

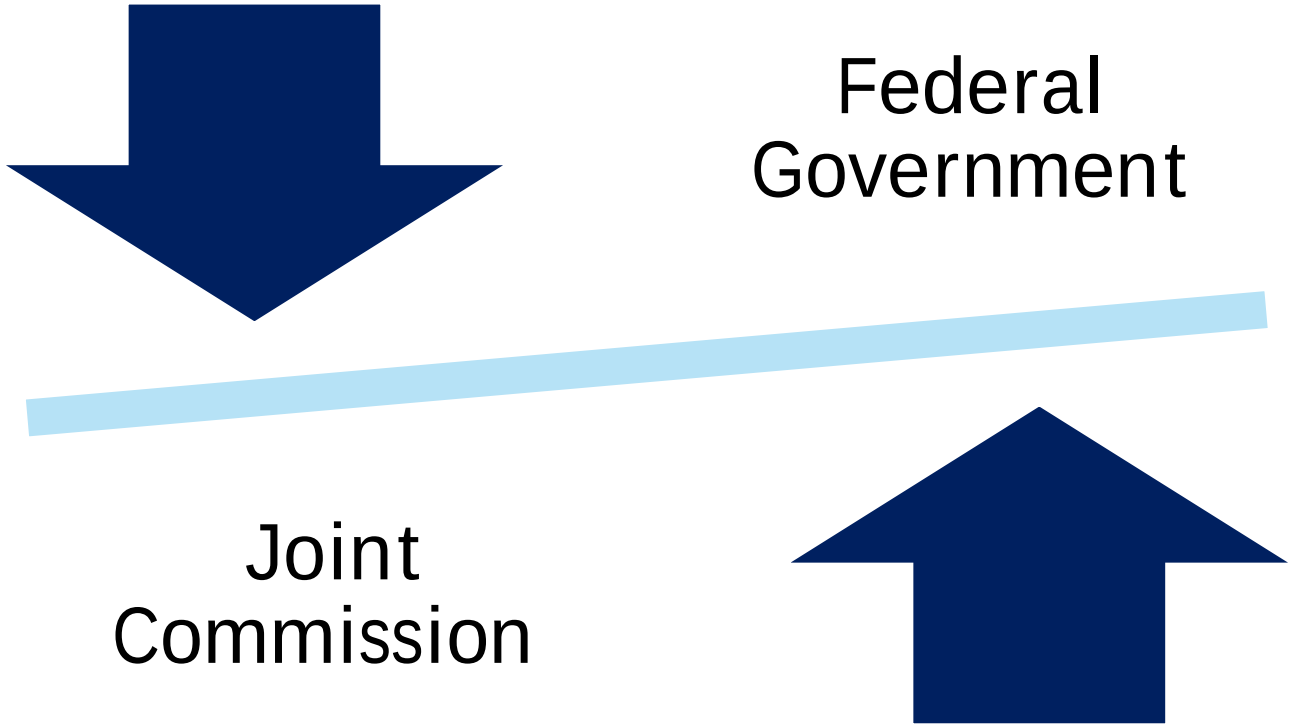
Canadian Pot Sobriety Test



Considerations for use in Hospital Setting



Balancing Act



Marijuana & Joint Commission

Joint Commission

The Joint Commission Standard MM.03.01.05 policy that states: "The hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners."[1]

This standard includes the following elements of performance:

- The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.
- Before use or administration of a medication brought into the hospital by a patient, his or her family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.
- The hospital informs the prescriber and patient if the medication brought into the hospital by patients, their families, or licensed independent practitioners is not permitted.

1. The Joint Commission. Revisions to the medication management standards regarding sample medications. December 18, 2013. http://www.jointcommission.org/assets/1/6/Sample-Medications_HAP.pdf.

Patient Need & Safety

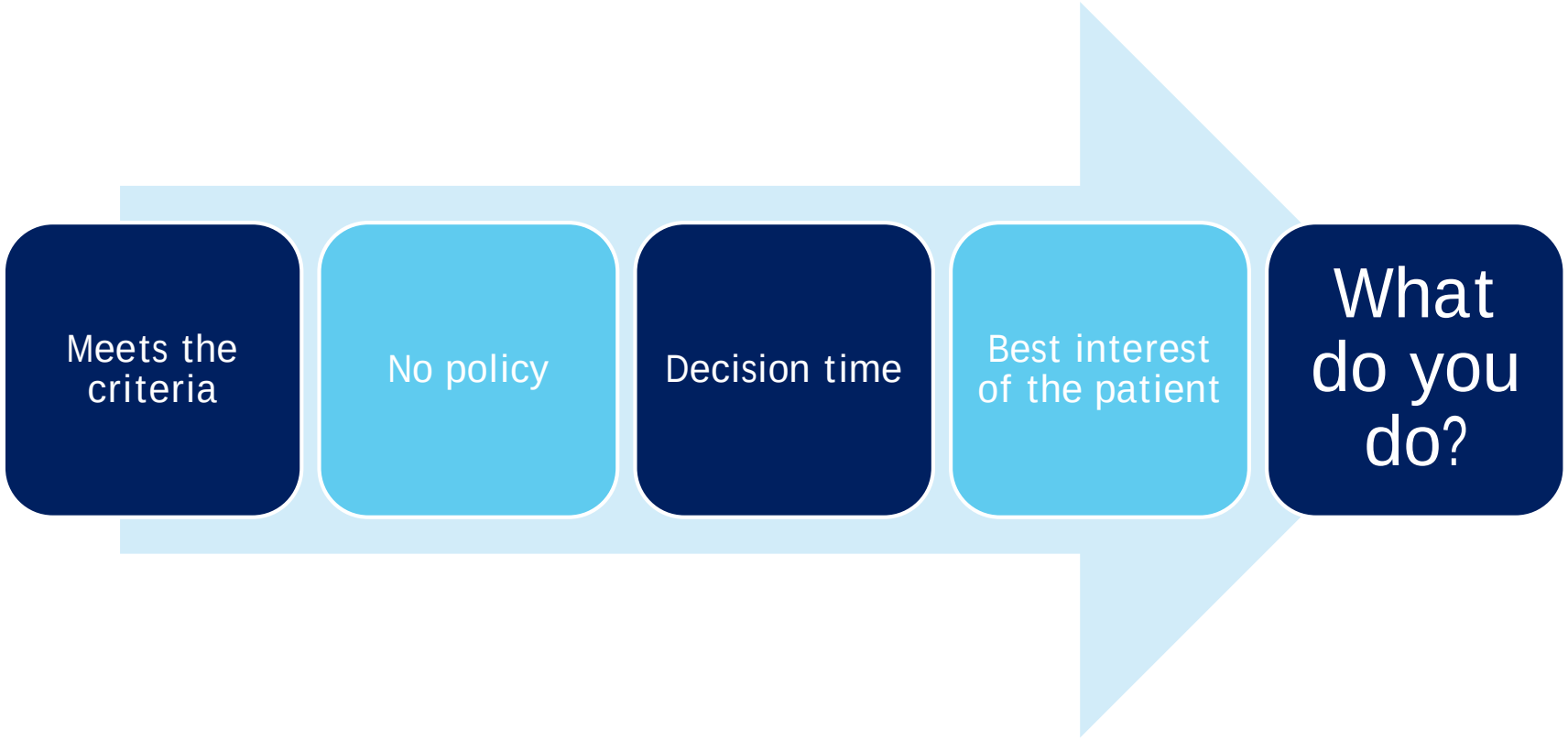
Patient comes through the door with medical marijuana – now what?

- Any patient who reports the use of medical marijuana at home and requests to use their medical marijuana while in the hospital will be asked for their New York State Department of Health Medical Marijuana Program ID card. A copy of the card will be scanned into the medical record.

- The patient or registered caregiver is responsible for the medication at all times.
- Only medical marijuana obtained from a NYS dispensary will be permitted in its original packaging.

- If at any time, the patient's clinical status suggests that the potential risk of using medical marijuana outweighs the potential therapeutic benefits of its use, the attending physician may state that the patient is not allowed to use medical marijuana during the hospital stay.

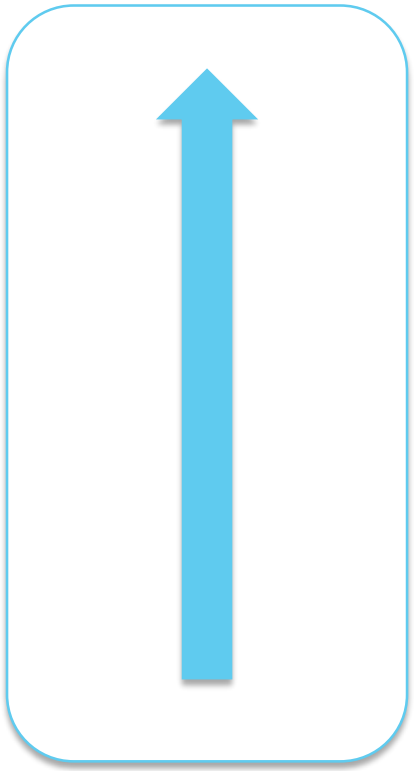
Patient comes through the door with medical marijuana – now what?



Turn a blind eye?



Patient Care & Safety



Claims and Lawsuits



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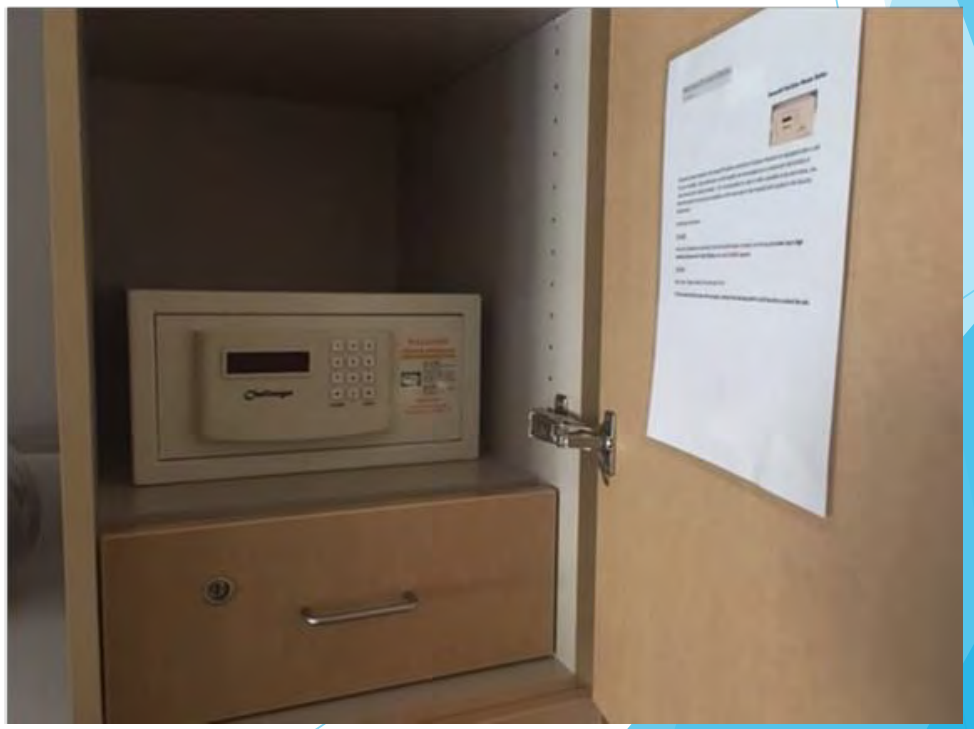
Sanctions & Fines

Some Ways to Lock it up…

- "The hospital is not responsible for storing or handling marijuana products. The medication will be secured in the patient's room."

- *Seems like a simple idea…Putting it into practice is not as easy as it seems.*







Questions?

www.wilsonelser.com/cannabis