

Professions and Public Health Subcommittee

Tuesday, February 16, 2021
10:00 AM - 12:00 PM
Webster Hall (212 Knott)

Meeting Packet

Chris Sprowls
Speaker

Will Robinson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Professions & Public Health Subcommittee

Start Date and Time: Tuesday, February 16, 2021 10:00 am

End Date and Time: Tuesday, February 16, 2021 12:00 pm

Location: Webster Hall (212 Knott)

Duration: 2.00 hrs

Medical use of marijuana implementation update by Christopher Ferguson, Director, Office of Medical Marijuana Use, Florida Department of Health

Briefing on the effects of high-potency marijuana by Bertha Madras, PhD, Professor of Psychobiology, Harvard Medical School

This meeting will be live-streamed on https://thefloridachannel.org/. As no filed bills or draft legislation will be considered at this meeting, public testimony will not be solicited and seating will be limited to the Members, invited presenters, and the press. As always, you may contact any Representative prior to the start of the meeting. Contact information may be found at https://www.myfloridahouse.gov/Representatives.

NOTICE FINALIZED on 02/09/2021 4:06PM by Osborne.Erin

OMMU Presentation

Florida HEALTH

OMMU Office of MEDICAL MARIJUANA Use

FLORIDA DEPARTMENT OF HEALTH (DOH)

Office of Medical Marijuana Use

Low-THC Cannabis & Medical Marijuana

Florida's Official Source for Responsible Use.

OMMU Office of MEDICAL MARIJUANA Use

Office of Medical Marijuana Use

Medical Marijuana Program Update

Christopher K. Ferguson

Director

Office of Medical Marijuana Use

February 16, 2021

Medical Marijuana in Florida

2014: Medical marijuana was first legalized in Florida under the Compassionate Medical Cannabis Act of 2014. The act authorized a low tetrahydrocannabinol (low-THC) and high cannabidiol (CBD) form of marijuana for medical use by patients suffering from cancer or seizures.

2016: The 2016 Right to Try Act allowed patients with terminal illnesses access to low-THC cannabis and medical cannabis.

January 3, 2017: Amendment 2, which created Article X, section 29 of the Florida Constitution, went into effect. Amendment 2 expanded access to both low-THC cannabis and medical marijuana for a larger list of medical conditions.

June 23, 2017: Senate Bill 8-A, which implemented Article X, section 29 of the Florida Constitution by creating a unified regulatory structure, went into effect.

2019: Senate Bill 182, which authorized qualified physicians to recommend marijuana in a form for smoking for qualifying patients.

Florida HEALTH

OMMU Office of MEDICAL MARIJUANA Use

Medical Use of Marijuana

UNAUTHORIZED USE

- Marijuana that was not purchased or acquired from a MMTC.
- Use in a manner inconsistent with the qualified physician's certification.
- Transfer of marijuana to a person other than an authorized qualified patient or the qualified patient's caregiver on their behalf.
- Cultivation by anyone other than an approved MMTC (no home grow).

AUTHORIZED USE

- Medical marijuana *and* low-THC cannabis under 381.986., F.S., for all qualifying conditions.
- Medical use is the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a qualified physician.
- Medical marijuana is only provided through an approved MMTC.

Medical Use of Marijuana

Medical use means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does **NOT** include:

Use on any form of public transportation, except for low-THC cannabis not in a form for smoking	Use in any public place, except for low-THC cannabis not in a form for smoking	Use in a qualified patient's place of employment, except when permitted by his or her employer	Use in a state correctional institution, as defined in s. 944.02, or a correctional institution, as defined in s. 944.241	Use on the grounds of a preschool, primary school, or secondary school, except as provided in s. 1006.062	Use in a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis not in a form for smoking	The smoking of marijuana in an enclosed indoor workplace as defined in s. 386.203(5)

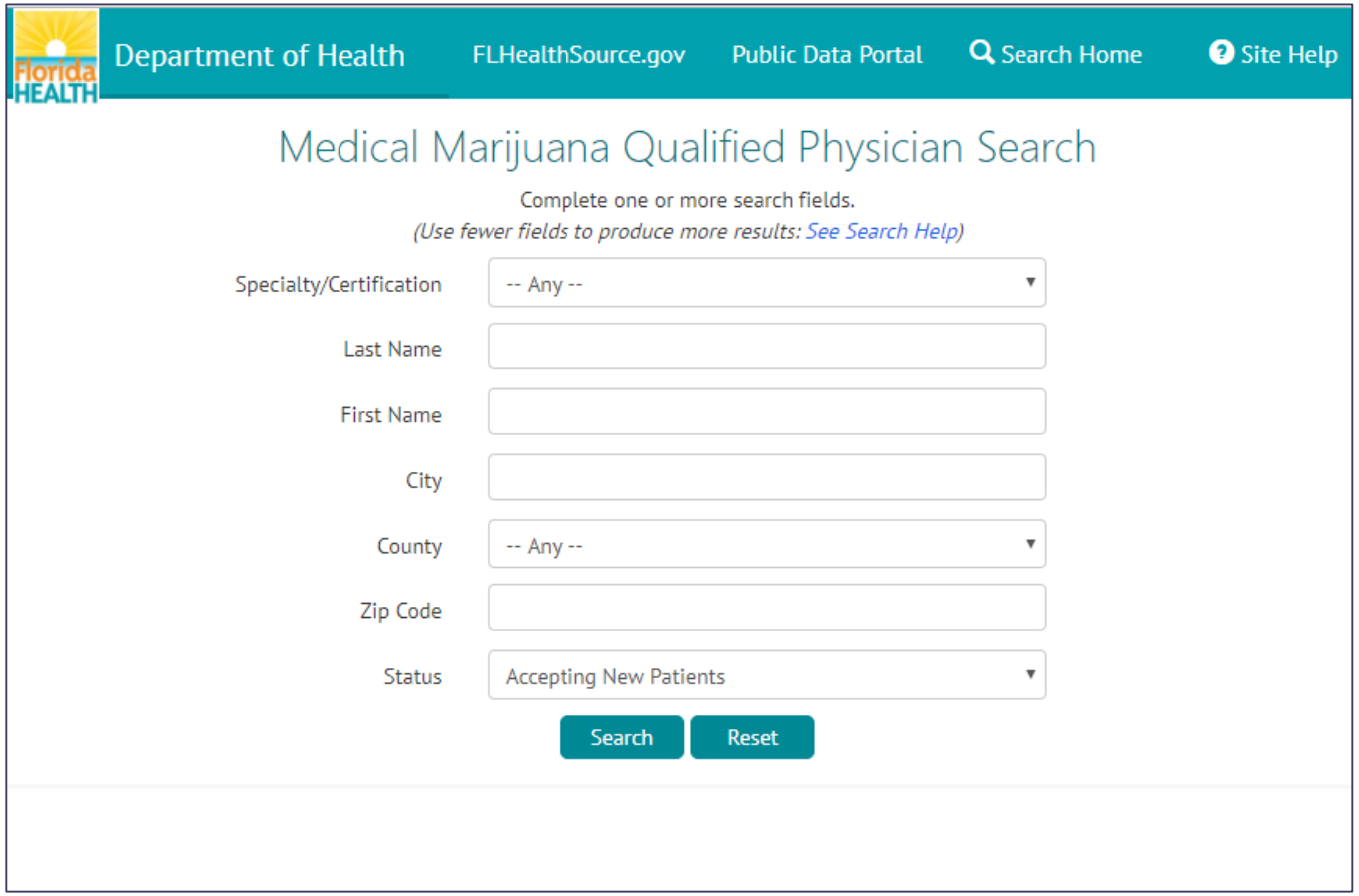
Qualifying Medical Conditions

- Cancer
- Epilepsy
- Glaucoma
- HIV
- AIDS
- Post-traumatic stress disorder (PTSD)
- Amyotrophic lateral sclerosis (ALS)
- Crohn’s disease
- Parkinson’s disease
- Multiple sclerosis (MS)
- Medical conditions of the same kind or class as or comparable to those above
- A terminal condition diagnosed by a physician other than the qualified physician issuing the physician certification
- Chronic nonmalignant pain caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition

Qualified Ordering Physicians

- Qualifying physicians must:
  - Have a clear/active license under Chapter 458, or 459, Florida Statutes.
  - Complete the required course and examination provided by the Florida Medical Association, and Florida Osteopathic Medical Association.

- Find a qualified physician using the online search tool:
  - https://knowthefactsmmj.com/



Qualified Physician Requirements

- Conduct a physical examination while physically present in the same room as the patient, conduct an assessment of the patient's medical history, and diagnose the patient with a qualifying medical condition.

- Determine that the medical use of marijuana would likely outweigh the potential health risks for the patient. If a patient is younger than 18 years of age, a second physician must agree with this determination.

- Determine if the patient is pregnant. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

- Review the patient's controlled drug prescription history in the Prescription Drug Monitoring Program database.

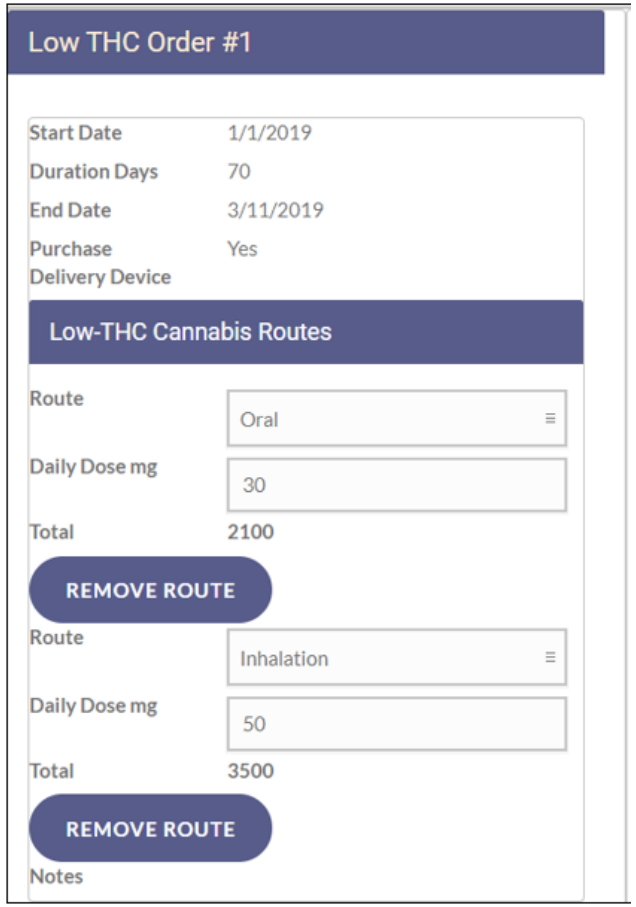
Qualified Physician Requirements

- Review the Medical Marijuana Use Registry and confirmed that the patient does not have an active physician certification from another qualified physician.

- Register as the issuer of the physician certification for the qualified patient in the Medical Marijuana Use Registry and enter the contents of the physician certification into the registry, including: the patient's qualifying condition, dosage, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

- Conduct an evaluation at least once every 30 weeks.

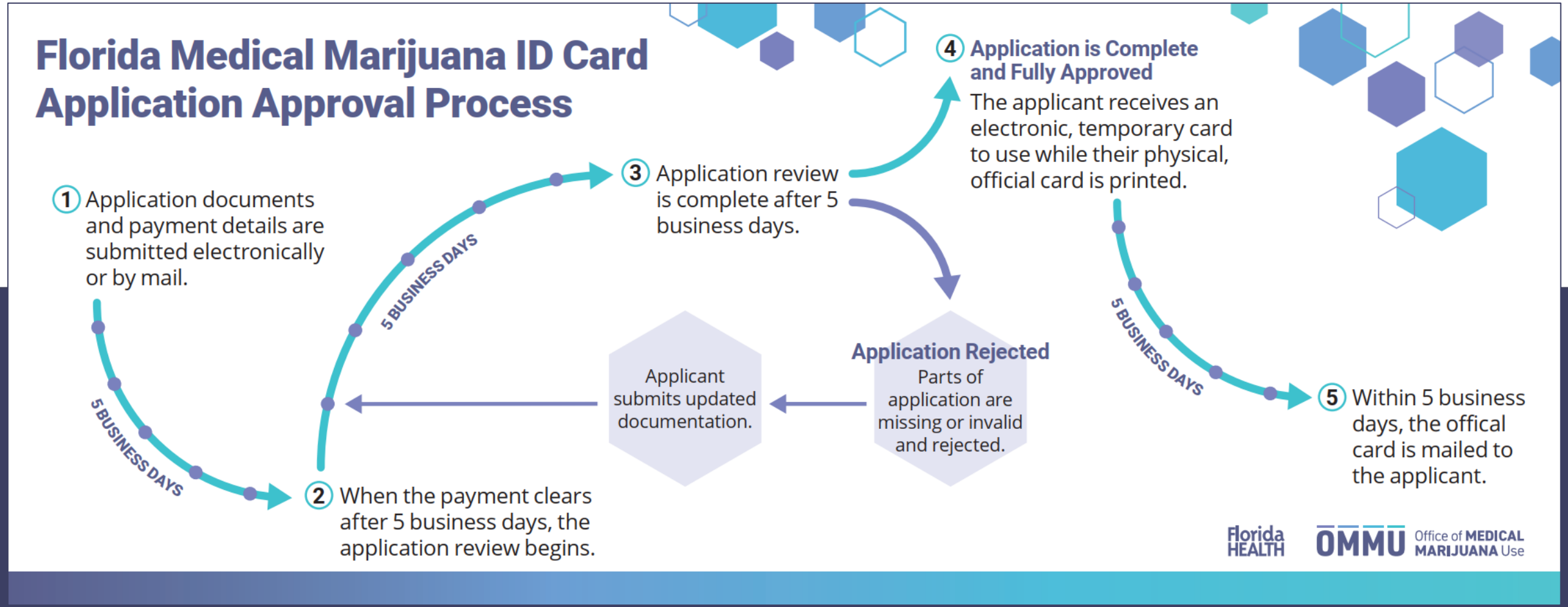
Physician Certifications



- A qualified physician may not issue a physician certification for more than three 70-day supply limits of marijuana or more than six 35-day supply limits of marijuana in a form for smoking (210 days).

- Contents of a Physician Certification:
  - Qualifying condition
  - Type: low-THC cannabis, medical marijuana
  - Route: Oral, edible, topical, sublingual, inhalation, suppository
  - Daily Dose: CBD, THC, Ounces of whole flower

Identification Card Process



Florida's Medical Marijuana Industry

MMTCs are vertically integrated, which means that each MMTC must cultivate, process, and dispense medical marijuana and low-THC cannabis

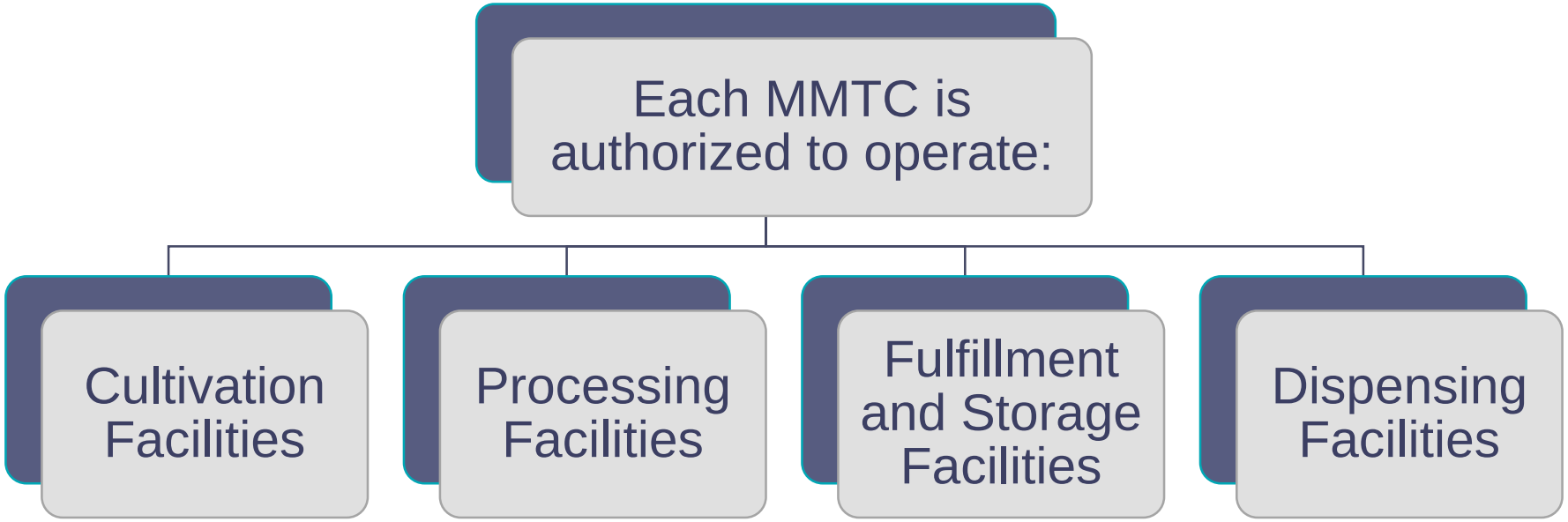
- MMTC Licensure Rolling Expansion:
  - By July 3, 2017, DOH must license any entity that holds an active, Dispensing Organization (DO) license under former Compassionate Use Act and which meets the requirements of s. 381.986.
  - By August 1, 2017, DOH must license any applicant whose application was scored but denied a license by DOH under the Compassionate Use Act, and which had an ongoing administrative or judicial challenge as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region.
  - DOH must license up to 10 MMTCs, including those licensed under bullet 2, one of which is a recognized class member of Pigford v. Glickman or In Re Black Farmers Litigation.
  - Upon reaching 100,000 patients in the registry, and for each additional 100,000 patients thereafter, DOH must license 4 more MMTCs within 6 months.
  - MMTCs must receive authorization from DOH to begin cultivating, processing, and dispensing.
  - As of April 1, 2020, there are no statutory limitations on the maximum number of dispensing facilities allowed.
  - MMTCs with dispensing authorization may deliver statewide.

OMMU Office of MEDICAL MARIJUANA Use

Florida's Official Source for Responsible Use.

KnowTheFactsMMJ.com

MMTC Authorization Phases



Prior to commencing operation at any facility, request an inspection and receive written approval from the Office of Medical Marijuana Use.

Florida HEALTH

OMMU Office of MEDICAL MARIJUANA Use

OMMU Office of MEDICAL MARIJUANA Use

Office of Medical Marijuana Use

Program Update – By the Numbers

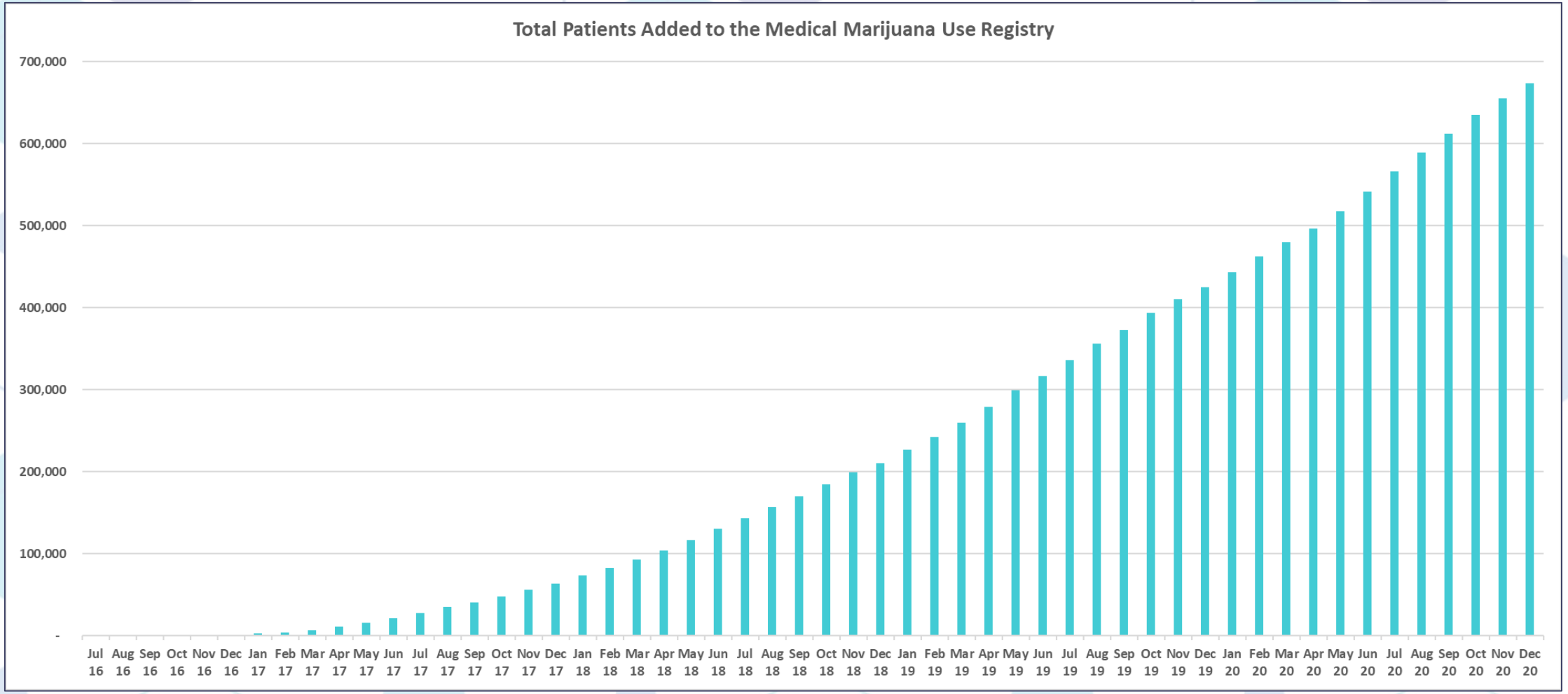
Qualified Ordering Physicians

- There are currently 2,708 qualified ordering physicians statewide.
- 2021 Data Review - Physician Certification Pattern Review Panel.
- Statewide from October 1, 2019, through September 30, 2020, there were 664,779 active physician certifications.
- 1,625 physicians issued certifications for 443,888 patients.

Medical Marijuana Use Registry Patient Adoption

Total Patient Adoption, per Year: **2016: 1,562** **2017: 62,451** **2018: 146,599** **2019: 214,088** **2020: 249,106**

Total Patient Adoption through December 31, 2020: **673, 806**



Active Medical Marijuana Patients

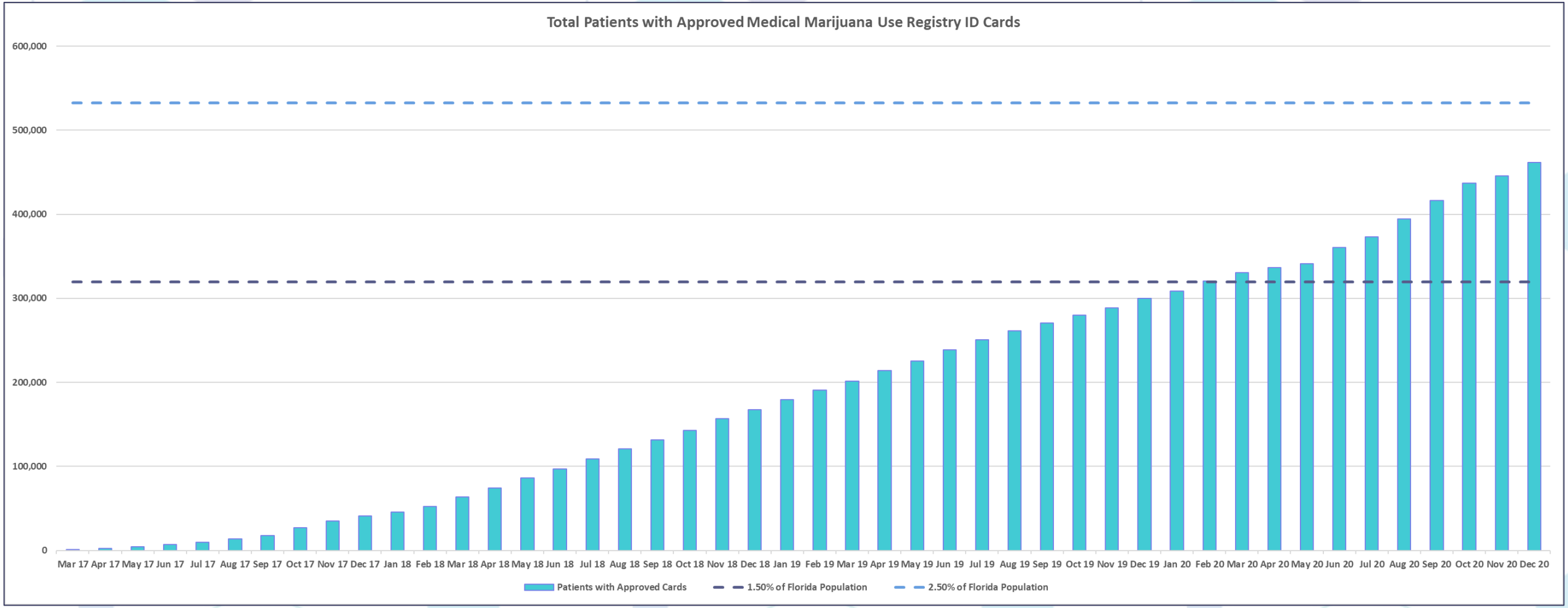
Total Active Patients at the End of Each Year:

2017: **41,295**

2018: **167,758**

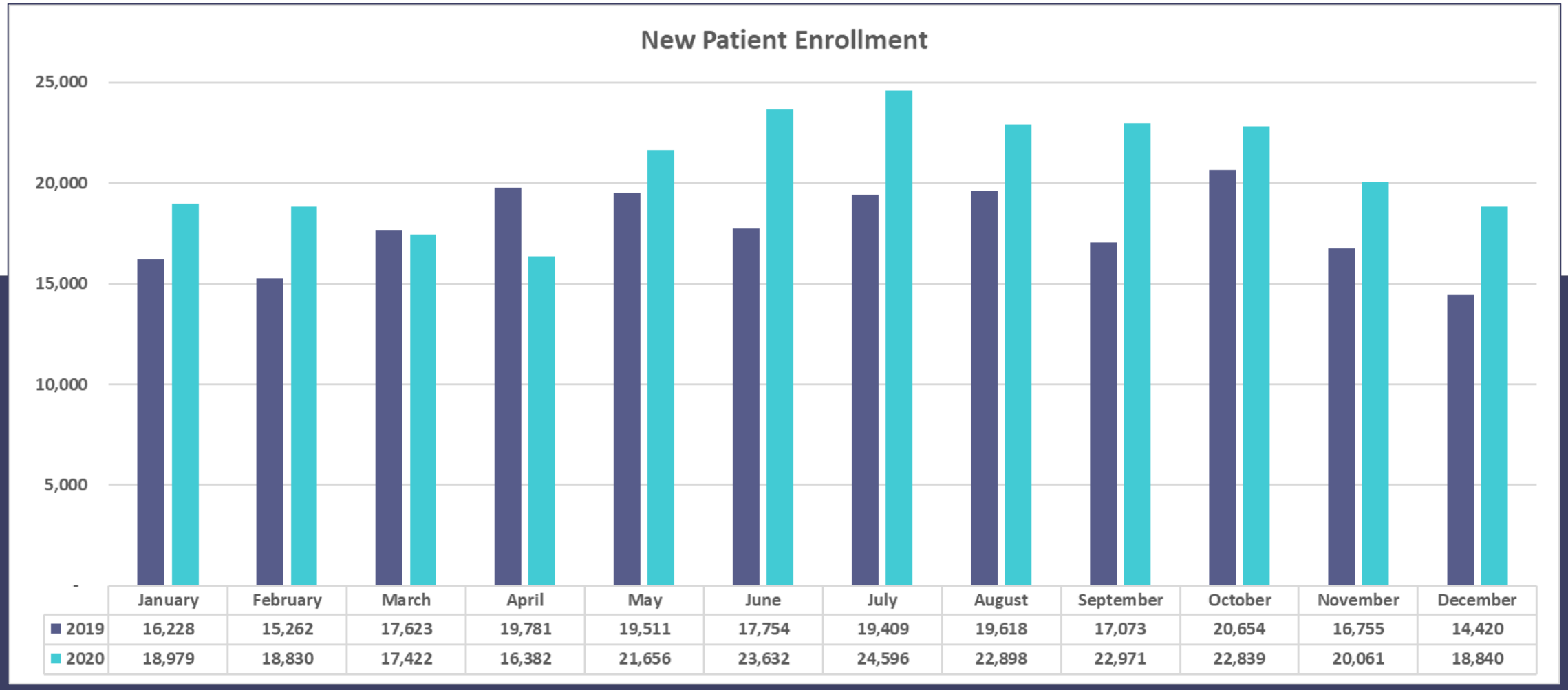
2019: **299,744**

2020: **461,599**



Comparison of New Patient Enrollment

Total Patient Enrollment, per Year: **2016: 1,562** **2017: 62,451** **2018: 146,599** **2019: 214,088** **2020: 249,106**

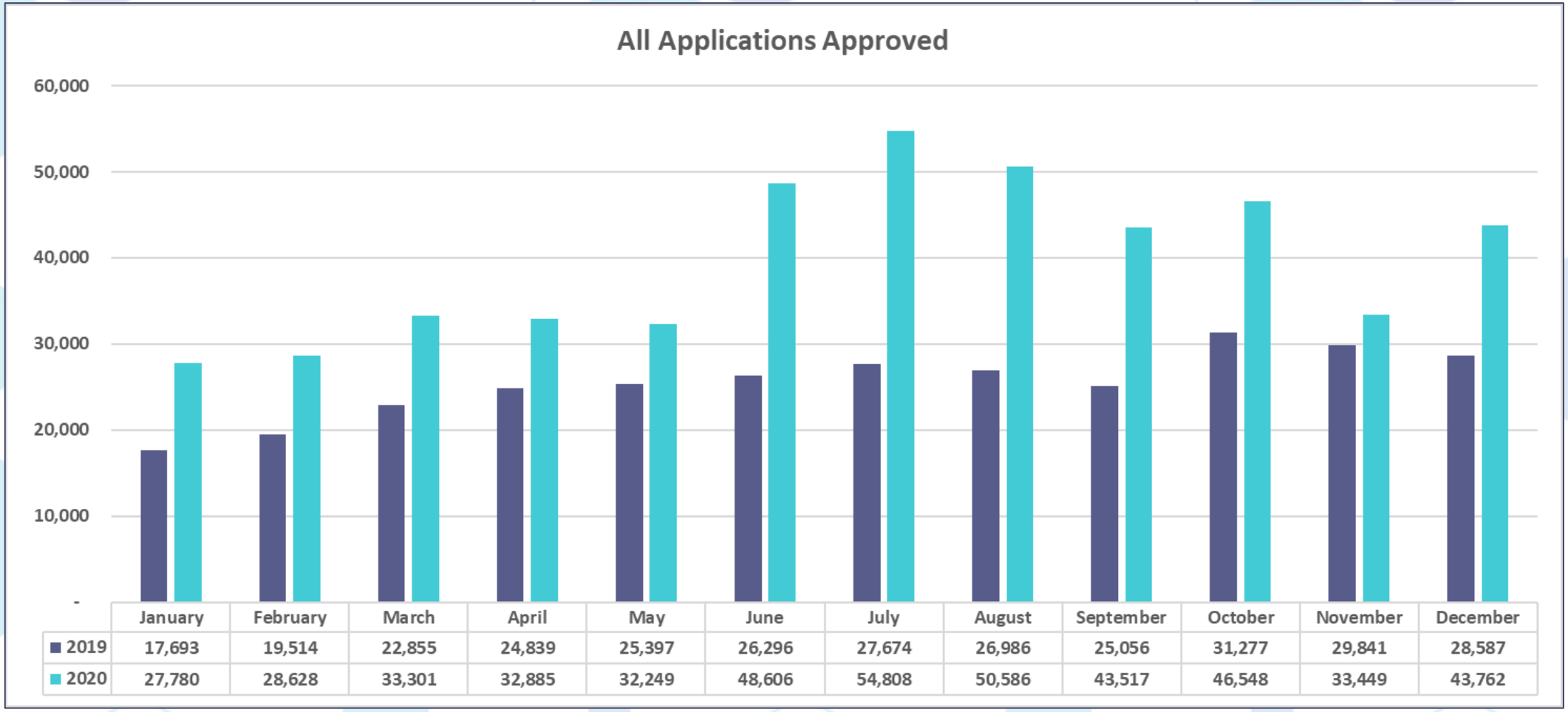


	January	February	March	April	May	June	July	August	September	October	November	December
2019	16,228	15,262	17,623	19,781	19,511	17,754	19,409	19,618	17,073	20,654	16,755	14,420
2020	18,979	18,830	17,422	16,382	21,656	23,632	24,596	22,898	22,971	22,839	20,061	18,840

Total Initial and Renewal Applications Approved

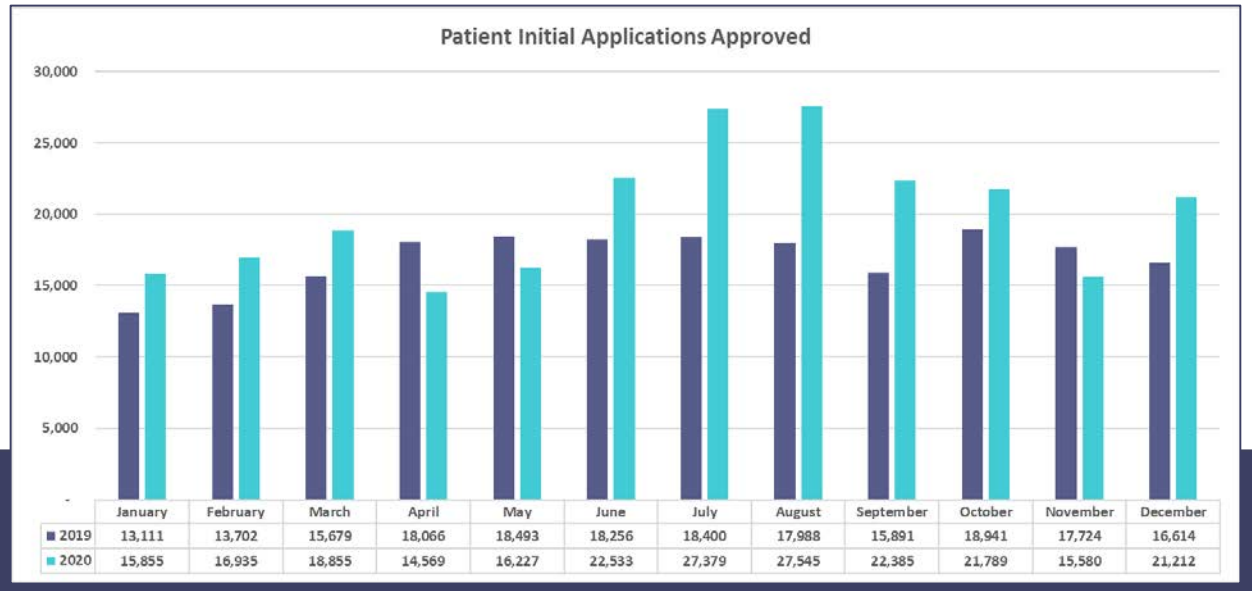
During 2019 the OMMU Approved **306,015** Patient / Caregiver Initial and Renewal Applications

During 2020 the OMMU Approved **476,119** Patient / Caregiver Initial and Renewal Applications



	January	February	March	April	May	June	July	August	September	October	November	December
2019	17,693	19,514	22,855	24,839	25,397	26,296	27,674	26,986	25,056	31,277	29,841	28,587
2020	27,780	28,628	33,301	32,885	32,249	48,606	54,808	50,586	43,517	46,548	33,449	43,762

Breakdown of Initial and Renewal Applications Approved



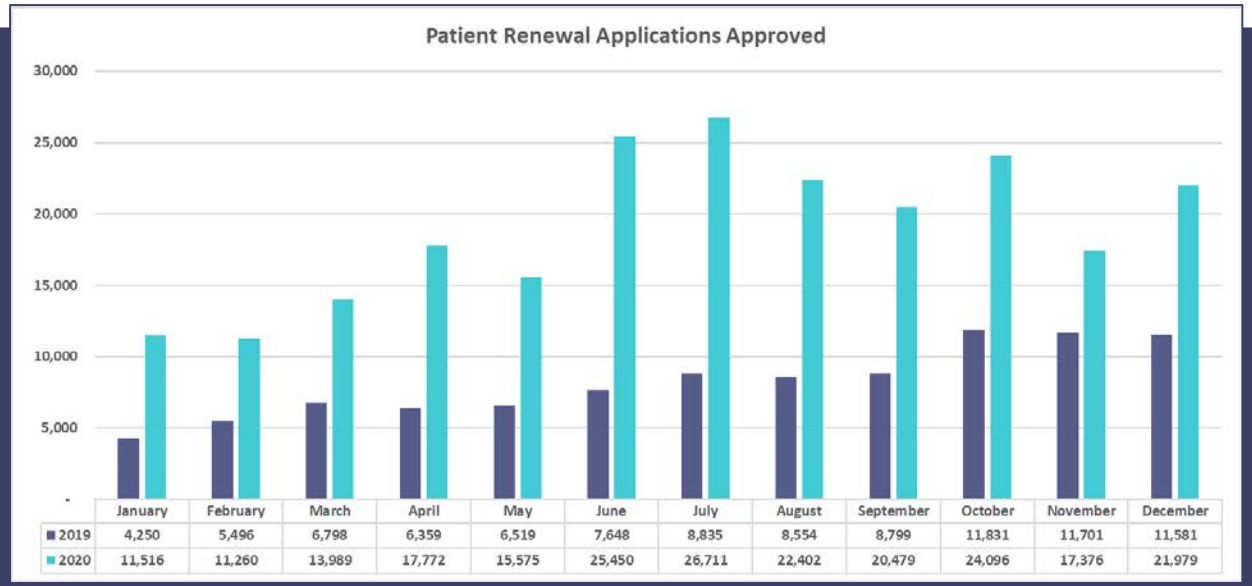
	January	February	March	April	May	June	July	August	September	October	November	December
2019	13,111	13,702	15,679	18,066	18,493	18,256	18,400	17,988	15,891	18,941	17,724	16,614
2020	15,855	16,935	18,855	14,569	16,227	22,533	27,379	27,545	22,385	21,789	15,580	21,212

2019 Total Patient Initial Applications Approved: **202,865**

2020 Total Patient Initial Applications Approved: **240,864**

2019 Total Patient Renewal Applications Approved: **98,371**

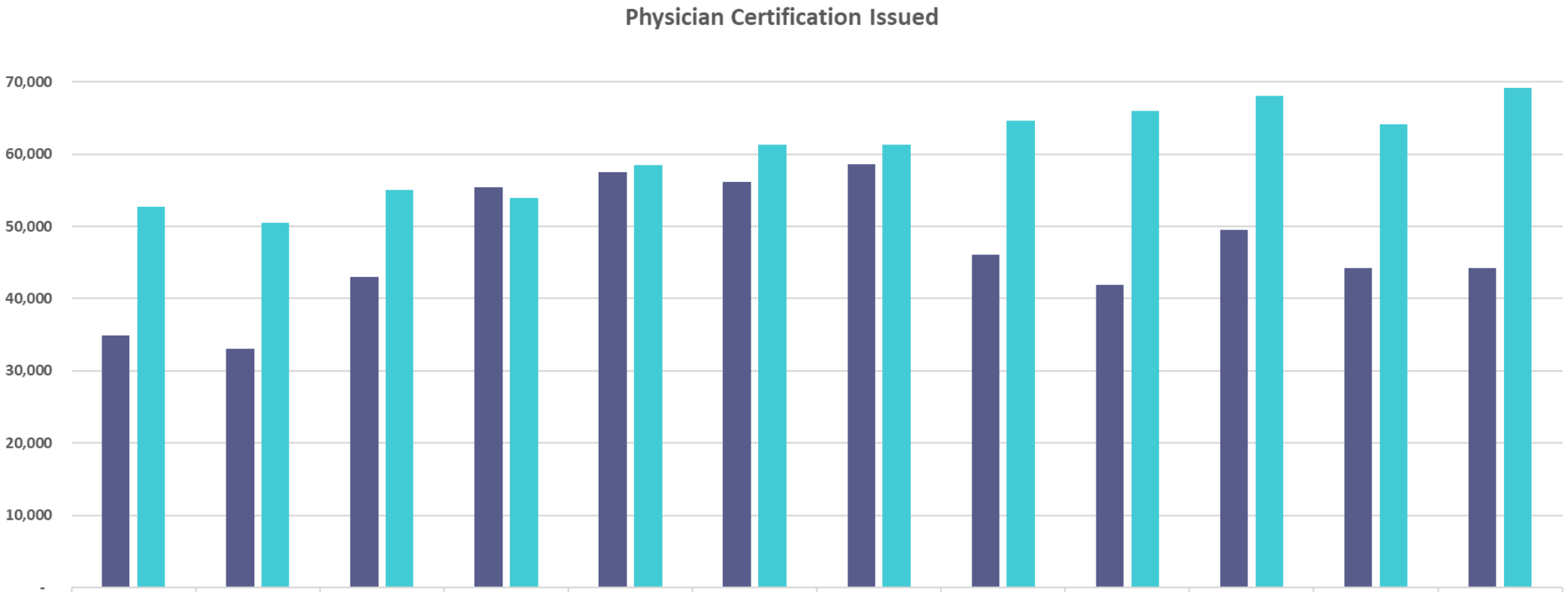
2020 Total Patient Renewal Applications Approved: **228,605**



	January	February	March	April	May	June	July	August	September	October	November	December
2019	4,250	5,496	6,798	6,359	6,519	7,648	8,835	8,554	8,799	11,831	11,701	11,581
2020	11,516	11,260	13,989	17,772	15,575	25,450	26,711	22,402	20,479	24,096	17,376	21,979

Comparison of Physician Certifications Created

Total Certifications Issued 2019: **564,562** Total Certifications Issued 2020: **725,298**



	January	February	March	April	May	June	July	August	September	October	November	December
2019	34,955	33,050	42,965	55,410	57,457	56,164	58,605	46,113	41,921	49,466	44,199	44,257
2020	52,744	50,476	55,086	53,975	58,486	61,263	61,268	64,583	65,964	68,080	64,141	69,232

Growth in Physician Certifications for Medical Marijuana Use

This table summarizes the growth in number of physician certifications, individual patients, and qualified physicians. Patient counts reflect distinct individuals; patients may have more than one certification in each time period.

	2019 Report 9 months January 1, 2018 through September 30, 2018	**2020 Report 12 months** October 1, 2018 through September 30, 2019	**2021 Report 12 months** October 1, 2019 through September 30, 2020	**Percent Increase (2019 to 2021)**
Certifications	169,573	460,469	664,779	292%↑
Individual Patients	113,847	291,865	443,888	232%↑
Qualified Physicians with Certifications	1,039	1,487	1,625	56%↑
All Qualified Physicians	1,838	2,556	2,700	47%↑

The greatest number of certifications were issued by a small percentage of qualified physicians. This ratio has been increasing.

- **2019**: 41% of certifications were issued by 4% of qualified physicians.
- **2020**: 61% of certifications were issued by 9% of qualified physicians.
- **2021**: 71% of certifications were issued by 12% of qualified physicians.

Trends in the total number and percentage of qualifying conditions reported in each data set.

Conditions listed in bold are the top three qualifying conditions reported by physicians.

	2019 Report 9 months January 1, 2018 through September 30, 2018		2020 Report 12 months October 1, 2018 through September 30, 2019		2021 Report 12 months October 1, 2019 through September 30, 2020	
Qualifying Condition	Number	Percent	Number	Percent	Number	Percent
(a) Cancer	16,602	9.8%	36,749	6.9%	51,420	4.6%
(b) Epilepsy	4,197	2.5%	8,698	1.6%	15,625	1.4%
(c) Glaucoma	3,319	1.9%	7,867	1.5%	10,834	1.0%
(d) Positive status for human immunodeficiency virus (HIV)	1,624	0.9%	3,861	0.7%	7,490	0.7%
(e) Acquired immune deficiency syndrome (AIDS)	279	0.2%	626	0.1%	1,661	0.1%
(f) Post-traumatic stress disorder (PTSD)	**40,005**	**23.6%**	**128,030**	**23.9%**	**406,542**	**36.3%**
(g) Amyotrophic lateral sclerosis (ALS)	223	0.1%	408	0.1%	9,564	0.9%
(h) Crohn's disease	3,312	1.9%	7,931	1.5%	23,006	2.1%
(i) Parkinson's disease	2,824	1.7%	4,888	0.9%	8,192	0.7%
(j) Multiple sclerosis (MS)	3,499	2.1%	6,760	1.3%	134,245	12.0%
(k) Medical conditions of the same kind or class as or comparable to those enumerated in paragraphs (a)-(j)	**46,434**	**27.4%**	**135,088**	**25.2%**	**273,979**	**24.4%**
(l) A terminal condition diagnosed by a physician other than the qualified physician issuing the physician certification	427	0.3%	870	0.1%	2,717	0.2%
(m) Chronic nonmalignant pain	**46,873**	**27.6%**	**193,941**	**36.2%**	**175,904**	**15.7%**
Total qualifying conditions reported:	169,618		535,717		1,121,179	
Total number of certifications:	169,573		460,469		664,779	
Total number of patients:	133,847		291,865		443,888	

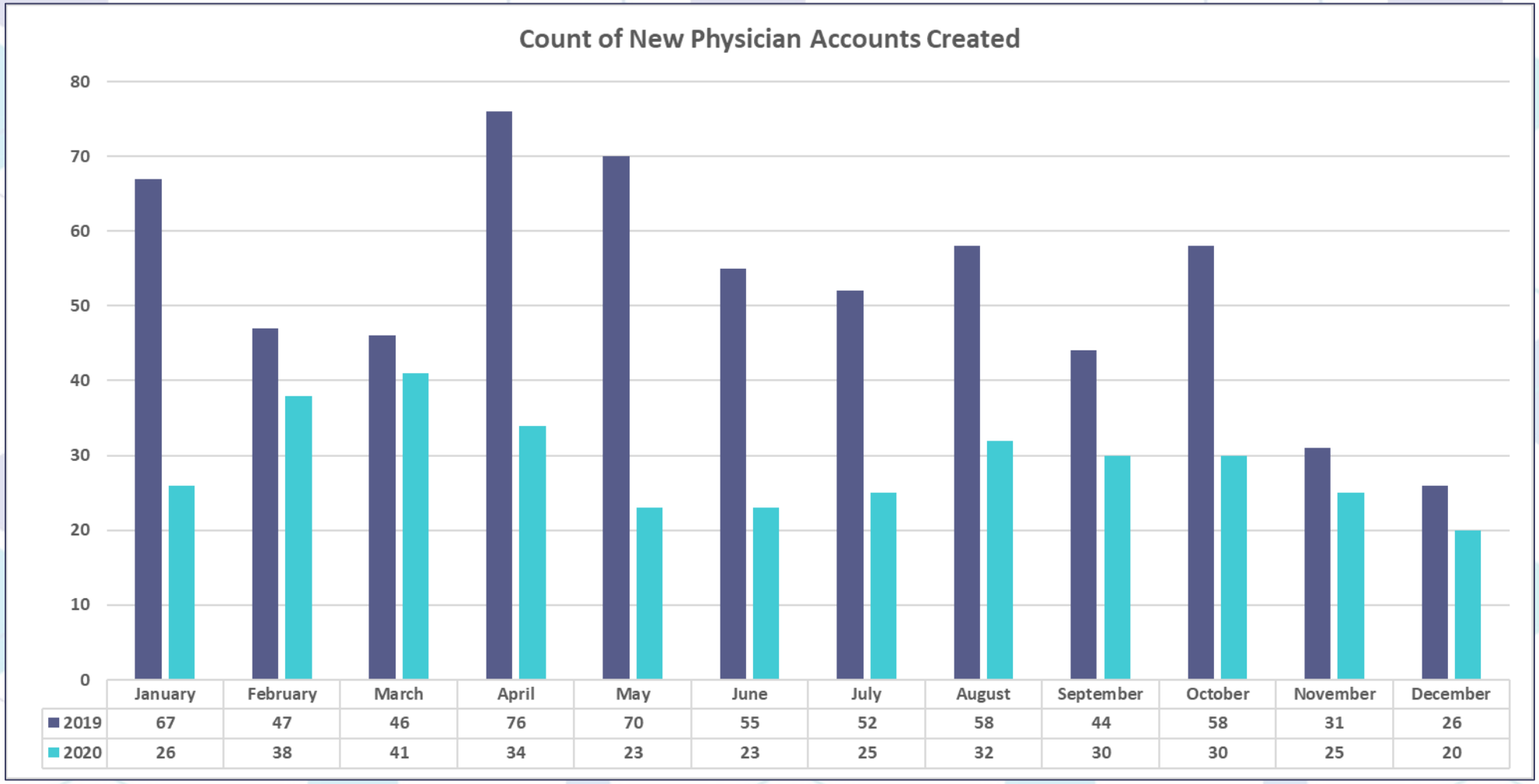
Total number of orders for Medical Marijuana, by route, in all certifications in each data set.

Edibles as a route of administration became available August 27, 2020.

Route	2019 Report 9 months January 1, 2018 through September 30, 2018	2020 Report 12 months October 1, 2018 through September 30, 2019	2021 Report 12 months October 1, 2019 through September 30, 2020
Edibles	_	_	199,677
Inhalation	340,199	407,855	1,837,293
Oral	295,170	376,350	1,827,093
Sublingual	46,303	98,005	1,027,120
Suppository	878	7,592	140,161
Topical	91,111	292,757	1,726,214

Comparison of New Physician Accounts Created

Physicians create their own accounts by self-registering. Physicians are only allowed to add patients and certifications if their license and education credentials are verified by Medical Quality Assurance.



	January	February	March	April	May	June	July	August	September	October	November	December
2019	67	47	46	76	70	55	52	58	44	58	31	26
2020	26	38	41	34	23	23	25	32	30	30	25	20

MMTC Product Offerings

Product Landscape

PRODUCT TYPES	COUNT OF: PROCESSED PRODUCTS TO MARKET	RANGE IN POTENCY THC CONTENT AS A % OF VOLUME	
		Lower Threshold	Upper Threshold
Balm	6	0.4%	0.9%
Body Oil	18	0.7%	1.2%
Capsule	67	0.5%	3.0%
Concentrate	72	63.0%	90.0%
Flower Cup	17	15.0%	28.0%
Inhaled (Crumble)	13	80.0%	90.0%
Inhaled (Rosin)	10	80.0%	90.0%
Inhaled (RSO)	18	60.0%	90.0%
Inhaled (Sauce)	3	80.0%	90.0%
Inhaled (Shatter)	17	80.0%	90.0%
Inhaled (Wax)	4	80.0%	90.0%
Inhaler	3	60.0%	87.0%
Kief	9	70.0%	85.0%
Lotion	24	0.3%	0.8%
Oil (Tincture)	108	1.3%	4.0%
Powder	3	95.0%	100.0%
Pre-roll	30	15.0%	28.0%
Resin	5	80.0%	90.0%
Suppository	9	1.3%	3.0%
Transdermal Patch	18	11.1%	90.0%
Vaporizer Cartridge	216	60.0%	87.0%
Vaporizer Disposable	20	75.0%	87.0%
Whole Flower	63	10.0%	28.0%

Physician Certifications

Top five physicians with the highest number of certifications in each dataset.

2019 Report 9 months January 1, 2018 through September 30, 2018			2020 Report 12 months October 1, 2018 through September 30, 2019			2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	Number of Certifications	Number of Patients	UID	Number of Certifications	Number of Patients	UID	Number of Certifications	Number of Patients
AU	4,888	4,114	AU	8,838	6,147	AY	16,604	7,022
J	4,405	2,854	BA	8,763	6,059	AZ	12,971	8,192
CF	3,173	2,906	J	5,665	3,390	BA	12,724	8,932
CG	3,046	2,012	AX	5,608	3,025	CY	6,412	4,777
AX	2,642	2,432	AV	5,184	4,035	BB	6,272	4,492

Medical Marijuana: Edibles

Top five physicians with the highest Average Daily Dose (mg).

2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	**Average Daily Dose (mg)**	**Number of Orders**
AP	8,449	184
AO	3,500	2
DF	2,900	30
DK	2,500	3
DH	2,000	2
Average with no outliers: 175 mg/day		

No data for Edibles in 2019 or 2020 Reports.
Edibles as a route of administration became available August 27, 2020.

Florida HEALTH

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Medical Marijuana: Inhalation

Top five physicians with the highest Average Daily Dose (mg).

2019 Report 9 months January 1, 2018 through September 30, 2018			2020 Report 12 months October 1, 2018 through September 30, 2019			2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**
A	362,231	235	A	593,778	302	X	25,290	6
Q	72,000	5	AT	127,216	6	DC	21,000	1
P	34,400	3	O	35,000	2	AJ	14,000	3
D	26,750	4	BD	21,000	3	AL	13,073	11
U	13,200	4	X	14,497	15	AA	11,635	23
Reported average: 1,098 mg/day			Average with no outliers: 193 mg/day			Average with no outliers: 225 mg/day		

Medical Marijuana: Oral

Top five physicians with the highest Average Daily Dose (mg).

2019 Report 9 months January 1, 2018 through September 30, 2018			2020 Report 12 months October 1, 2018 through September 30, 2019			2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**
A	384,592	235	A	575,251	302	AU	142,889	14,023
Q	72,000	5	P	93,132	28	AJ	14,000	3
BV	16,820	20	AT	22,480	6	AA	11,635	23
U	8,500	4	AA	14,000	3	A	10,000	6
BW	6,000	22	Q	12,158	29	DH	9,657	26
Reported average: 1,157 mg/day			Average with no outliers: 148 mg/day			Average with no outliers: 197 mg/day		

Medical Marijuana: Sublingual

Top five physicians with the highest Average Daily Dose (mg).

2019 Report 9 months January 1, 2018 through September 30, 2018			2020 Report 12 months October 1, 2018 through September 30, 2019			2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**
A	504,500	235	BE	55,909	34	DH	25,000	2
BW	20,000	22	A	55,223	302	AJ	17,500	2
BL	5,600	15	AA	14,000	3	A	10,000	6
BX	4,800	12	BD	9,650	3	DC	10,000	1
BF	3,655	43	BF	4,326	78	DD	7,000	3
Reported average: 630 mg/day			Average with no outliers: 140 mg/day			Average with no outliers: 189 mg/day		

Medical Marijuana: Suppository

Top five physicians with the highest Average Daily Dose (mg).

2019 Report 9 months January 1, 2018 through September 30, 2018			2020 Report 12 months October 1, 2018 through September 30, 2019			2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**
BY	19,998	530	U	2,400	3	AQ	4,800	4
BZ	2,000	21	BG	1,450	331	DI	3,500	2
CA	1,400	480	C	1,420	420	DF	2,750	12
CB	1,086	148	BH	1,350	350	DJ	1,750	6
CC	1,000	20	BI	1,200	31	U	1,620	5
Reported avg dose: 164 mg/day			Average with no outliers: 168 mg/day			Average with no outliers: 173 mg/day		

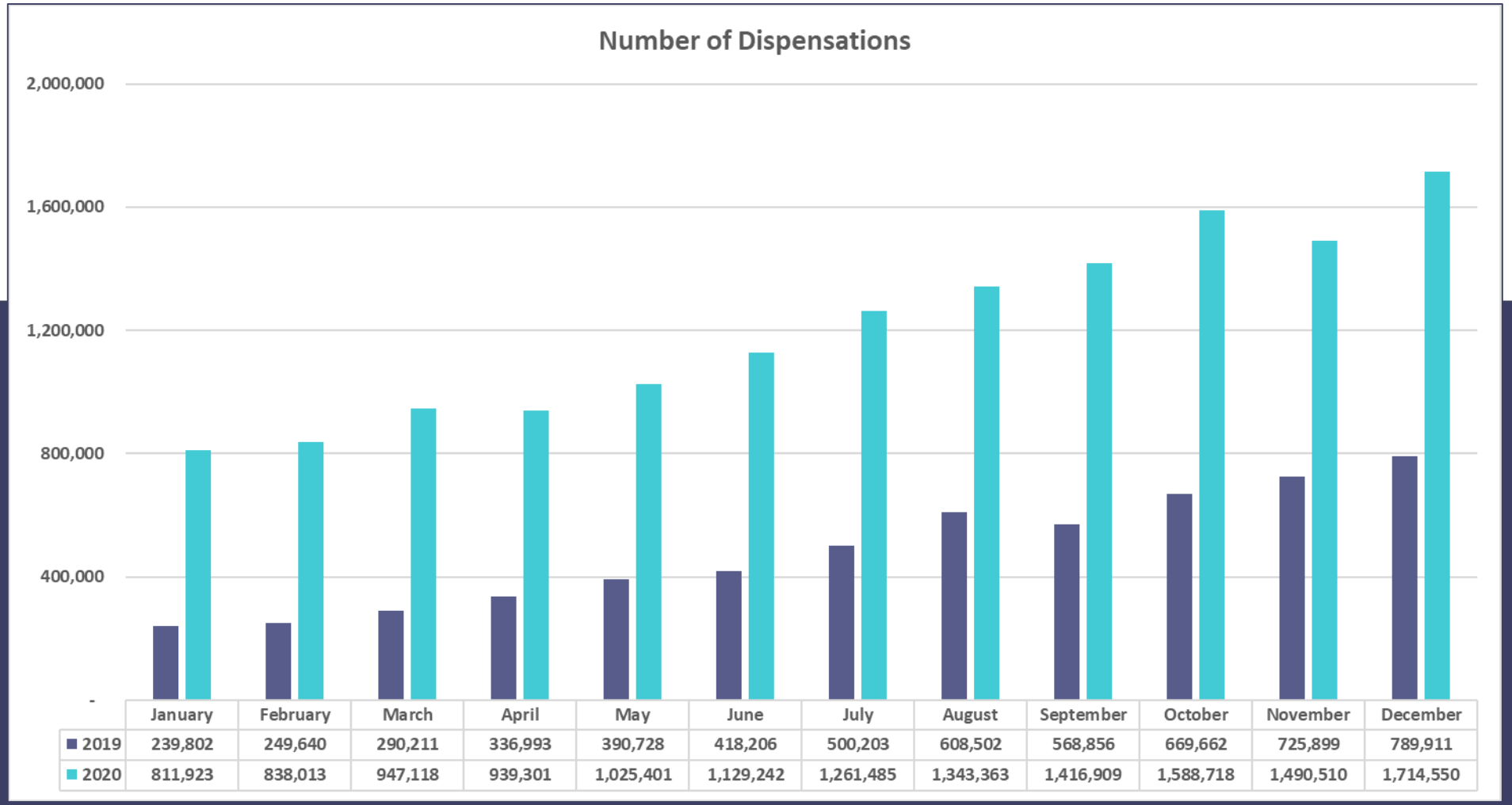
Medical Marijuana: Topical

Top five physicians with the highest Average Daily Dose (mg).

2019 Report 9 months January 1, 2018 through September 30, 2018			2020 Report 12 months October 1, 2018 through September 30, 2019			2021 Report 12 months October 1, 2019 through September 30, 2020		
UID	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**	**UID**	**Average Daily Dose (mg)**	**Number of Orders**
A	709,991	235	A	558,287	302	DH	20,800	10
CD	280,000	3	X	50,400	15	AJ	17,500	1
BK	20,275	445	BD	20,600	3	A	10,000	6
U	9,000	4	BJ	10,599	128	AT	9,600	6
CE	4,661	93	U	8,400	3	AK	6,006	272
Reported average: 1,336 mg/day			Average with no outliers: 129 mg/day			Average with no outliers: 148 mg/day		

Count of Dispensations

MMTCs may only dispense the products a physician orders for their patient if the patient has an **Active** Medical Marijuana Use Registry ID Card



	January	February	March	April	May	June	July	August	September	October	November	December
2019	239,802	249,640	290,211	336,993	390,728	418,206	500,203	608,502	568,856	669,662	725,899	789,911
2020	811,923	838,013	947,118	939,301	1,025,401	1,129,242	1,261,485	1,343,363	1,416,909	1,588,718	1,490,510	1,714,550

MMTCs: Currently Licensed

Original Applicant	Current MMTC Licensee	d/b/a	Authorization Status
Costa Nursery Farms, LLC	Curaleaf Florida, LLC	Curaleaf	Dispensing Authorization
Chestnut Hill Tree Farm	DFMMJ Investments, LLC	Libery Health Sciences	Dispensing Authorization
Knox Nursery, Inc.	Spirit Lake Road Nursery, LLC	Fluent	Dispensing Authorization
Alpha Foliage Inc.	Alpha Foilage, Inc.	Surterra Wellness	Dispensing Authorization
George Hackney, Inc.	Trulieve Inc.	Trulieve	Dispensing Authorization
San Felasco Nurseries, Inc.	San Felasco Nurseries, Inc.	Harvest House of Cannabis	Dispensing Authorization
McCrory's Sunny Hill Nursery, LLC	McCrory's Sunny Hill Nursery, LLC	GrowHealthy	Dispensing Authorization
Tornello Landscape Corp	3 Boys Farm, LLC	One Plant	Dispensing Authorization
Loop's Nursery and Greenhouses, Inc.	VidaCann, LLC	VidaCann	Dispensing Authorization
Plants of Ruskin, Inc.	Plants of Ruskin, LLC	AltMed Florida	Dispensing Authorization
Sun Bulb Company, Inc.	Better-Gro Companies, L.L.C.	Columbia Care Florida	Dispensing Authorization
GST Enterprises, Inc.	MME Florida, LLC	MedMen	Dispensing Authorization
Keith St. Germain Nursery Farms, LLC	KSGNF, LLC	GTI Florida, LLC	Dispensing Authorization
Nature's Way Nursery of Miami Inc.	Acreage Florida, Inc.	The Botanist	Dispensing Authorization
Spring Oaks Greenhouses, Inc	Spring Oaks Greenhouses, Inc	The Source	Dispensing Authorization
Redland Nursery, Inc	D&D Accounting Services, LLC	-	Processing Authorization
Dewar Nurseries, Inc	Sanctuary Medicinals LLC	-	Dispensing Authorization
Tree King-Tree Farm, Inc	Tree King-Tree Farm, Inc	Cookies Florida, LLC	Initial Licensure
Perkins Nursery, Inc	Perkins Nursery, Inc	-	Dispensing Authorization
Bills Nursery, Inc	Bills Nursery, Inc	The Flower	Dispensing Authorization
Deleon's Bromeliads, Inc	Mount Dora Farms LLC	Green Dragon	Dispensing Authorization
Hart's Plant Nursery, Inc	Hart's Plant Nursery, Inc	Revolution Florida	Dispensing Authorization

MMTC Dispensing Locations

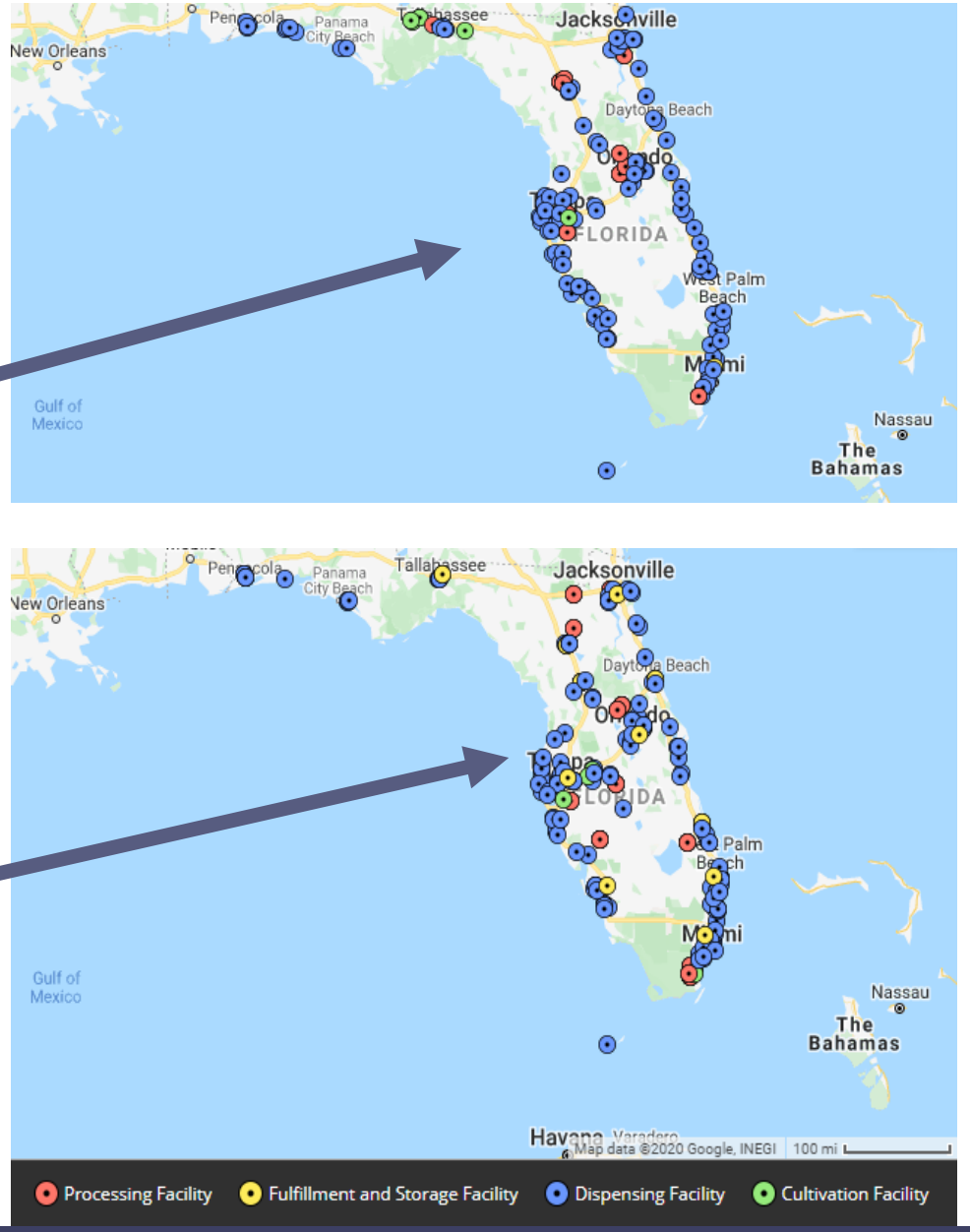
Each MMTC is vertically integrated and must cultivate, process, and dispense medical marijuana.

TOTAL FACILITIES			
Processing	F & S	Dispensing	Cultivation
27	20	313	36

- **Cultivation Facility** - Any area designated to be used for cultivation of marijuana.
- **Processing Facility** - Any area designated to be used for processing of low-THC cannabis and medical marijuana.
- **Fulfillment and Storage Facility (F&S) -** Any area designated, which is not open to the public, to be used for order fulfillment, shipping, transportation, or storage of low-THC cannabis, medical marijuana, and marijuana delivery devices.
- **Dispensing Facility** - Any area designated to be accessible by the public and where usable product and marijuana delivery devices will be dispensed at retail.

MMTC (Map 1)
One Plant
The Botanist
Surterra Wellness
Columbia Care Florida
The Flowery
Curaleaf
D&D Accounting Services, LLC
Liberty Health Sciences
Revolution Florida
GTI Florida, LLC
GrowHealthy
MedMen

MMTC (Map 2)
Green Dragon
Perkins Nursery, Inc
AltMed Florida
Harvest House of Cannabis
Sanctuary Medicinals LLC
Fluent
The Source
Trulieve
VidaCann



Certified Marijuana Testing Laboratory

381.986 (8)(e)11.d., F.S., requires an MMTC to test processed marijuana using a marijuana testing laboratory before it is dispensed. Testing results must indicate that: low-THC cannabis meets the statutory definition; THC potency meets statutory requirements; THC and CBD are labelled accurately; and the marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption.

Currently five Certified Marijuana Testing Laboratories (CMTL) licensed pursuant to section 381.988, Florida Statutes:

- Kaycha Davie
- Kaycha Gainesville
- ACS
- Modern Canna Science
- Green Scientific

Three additional applications are pending before DOH.

Rules Implementation

The Office of Medical Marijuana Use (OMMU) is charged with writing and implementing rules for medical marijuana. Currently, the OMMU has the following rules in effect:

Emergency Rules, Chapter 64, F.A.R.

CMTL Emergency Rules

- 64ER20-1 CMTL Definitions
- 64ER20-3 CMTL Testing
- 64ER20-4 CMTL On-Site Inspection
- 64ER20-5 Suspension and Revocation of CMTL Certification
- 64ER20-6 Standard Operating Procedures
- 64ER20-7 CMTL Testing Methods
- 64ER20-10 Quality Control Samples
- 64ER20-11 CMTL Calibration Standards
- 64ER20-12 CMTL Certificate of Analysis
- 64ER20-14 Requirements for CMTL Certification and Application
- 64ER20-15 CMTL Background Screening
- 64ER20-38 Submission of Product for Testing
- 64ER20-39 CMTL Sample Testing

MMTC Emergency Rules

- 64ER19-3 Pesticide Use on Medical Marijuana
- 64ER19-8 Renewal Application Requirements for MMTCs
- 64ER20-16 MMTC Marijuana Waste Management and Disposal
- 64ER20-17 MMTC Transition to Testing by Certified Marijuana Testing Laboratories
- 64ER20-31 Definitions
- 64ER20-32 MMTC Packaging and Labeling
- 64ER20-35 Standards for Production of Edibles
- 64ER20-36 MMTC Regulatory Compliance Testing
- 64ER20-37 MMTC Remediation

Chapter 64-4, F.A.C.

- 64-4.001 Definitions
- 64.4.002 Initial Application Requirements
- 64-4.004 Revocation of Dispensing Organization Approval
- 64-4.005 Inspection and Authorization Procedures
- 64-4.009 Compassionate Use Registry
- 64-4.011 Medical Marijuana Use Registry Identification Cards
- 64-4.013 Pesticide Use on Medical Marijuana
- 64-4.023 Medical Marijuana Treatment Center Variance Procedure
- 64-4.202 MMTC Inspection Procedures
- 64-4.208 MMTC Background Screening
- 64-4.210 MMTC Fines, Suspension, and Revocation

Annual Regulatory Plan

The OMMU expects to initiate rulemaking, not including emergency rulemaking, by July 1, 2021, to implement sections 381.986 and 381.988, F.S. The OMMU's 2020-2021 Annual Regulatory Plan contains the following rules:

64-4.001 Definitions
64-4.XXX Application for MMTC Licensure
64-4.013 Pesticide Use on Marijuana
64-4.XXX Dosing for Low-THC Cannabis and Medical Marijuana
64-4.XXX Medical Marijuana Treatment Center Change of Ownership Applications
64-4.XXX Caregiver Background Screenings
64-4.XXX Medical Marijuana Treatment Center Advertising and Signage
64-4.XXX Pigford and Black Farmers Class Application for MMTC Licensure
64-4.201 MMTC Licensure Renewal
64-4.205 Standards for Production of Edibles
64-4.206 Low-THC and Medical Marijuana Packaging and Labeling
64-4.207 MMTC Marijuana Waste Management and Disposal
64-4.209 Low-THC and Medical Marijuana Solvent Based Extraction and Related Products
64-4.211: MMTC Supplemental Licensure Fee
64-4.300 Certified Marijuana Testing Laboratory Definitions
64-4.301 Requirements for CMTL Certification and Application
64-4.302 Testing
64-4.303 On-Site Inspection
64-4.304 Suspension and Revocation of Certification
64-4.307 Standard Operating Procedures
64-4.308 Testing Methods
64-4.309 Submission for Product Testing
64-4.310 Sample Testing
64-4.311 Quality Control Samples
64-4.313 Certificate of Analysis
64-4.XXX CMTL Background Screening
64-4.XXX MMTC Transition to Testing by Certified Marijuana Testing Laboratories
64-4.XXX CMTL Fines
64-4.XXX CMTL Renewal
64-4.XXX Marijuana Delivery Devices
64-4.XXX MMTC Authorization Procedures
64-4.XXX Bonds and Financial Assurances
64-4.XXX MMTC Harvest Failure Procedures
64-4.XXX CMTL Audit Procedures for MMTCs
64-4.XXX Qualified Patient and Caregiver Suspension and Revocation
64-4.XXX Seed to Sale Tracking System
64-4.XXX MMTC Procedure for Recalls and Destruction of Marijuana Failing CMTL Testing
64-4.XXX Food Safety Good Manufacturing Practices Inspection Requirements and Renewal
64-4.XXX MMTC Website and Social Media Advertising
64-4.023 Medical Marijuana Treatment Center Variance Procedures
64-4.009 Compassionate Use Registry

OMMU Office of MEDICAL MARIJUANA Use

Thank you

Dr. Madras Presentation

Bertha K. Madras, PhD

PhD, Professor of Psychobiology, Harvard Medical School

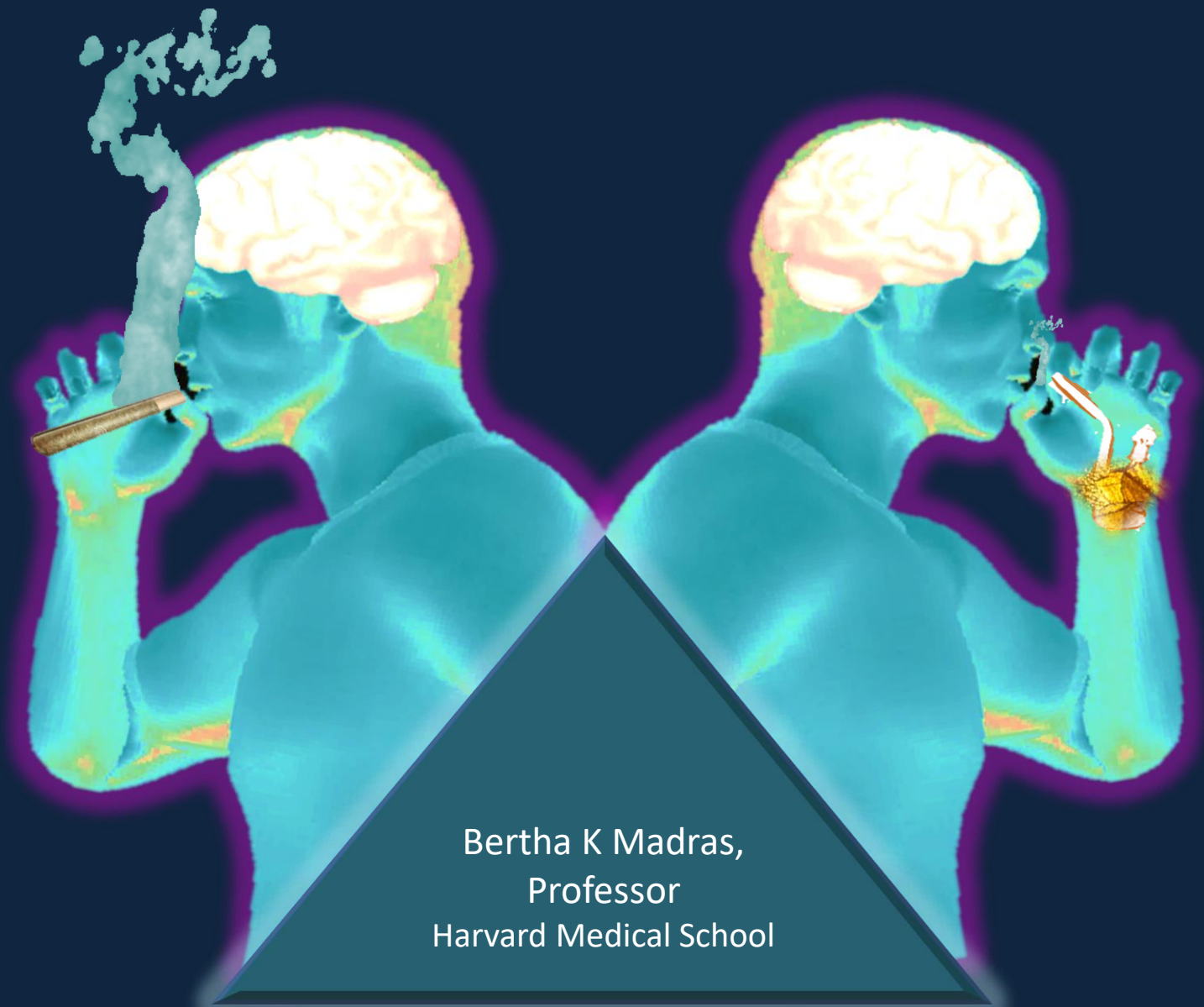
Biography



Bertha K. Madras, PhD, is a professor of psychobiology in the Department of Psychiatry at Harvard Medical School, with her office and laboratory at McLean Hospital. She is former Deputy Director for Demand Reduction (prevention, treatment) in the White House Office of National Drug Control Policy, Executive Office of President, a position unanimously confirmed by the US Senate. She served as one of six Commissioners (Gov. Chris Christie (NJ), Gov. Roy Cooper (NC), Gov. Charlie Baker (MA), former Congressman Patrick Kennedy, former Attorney General Pam Bondi (FL) on the President's Commission on Combating Drug Addiction and the Opioid Crisis.

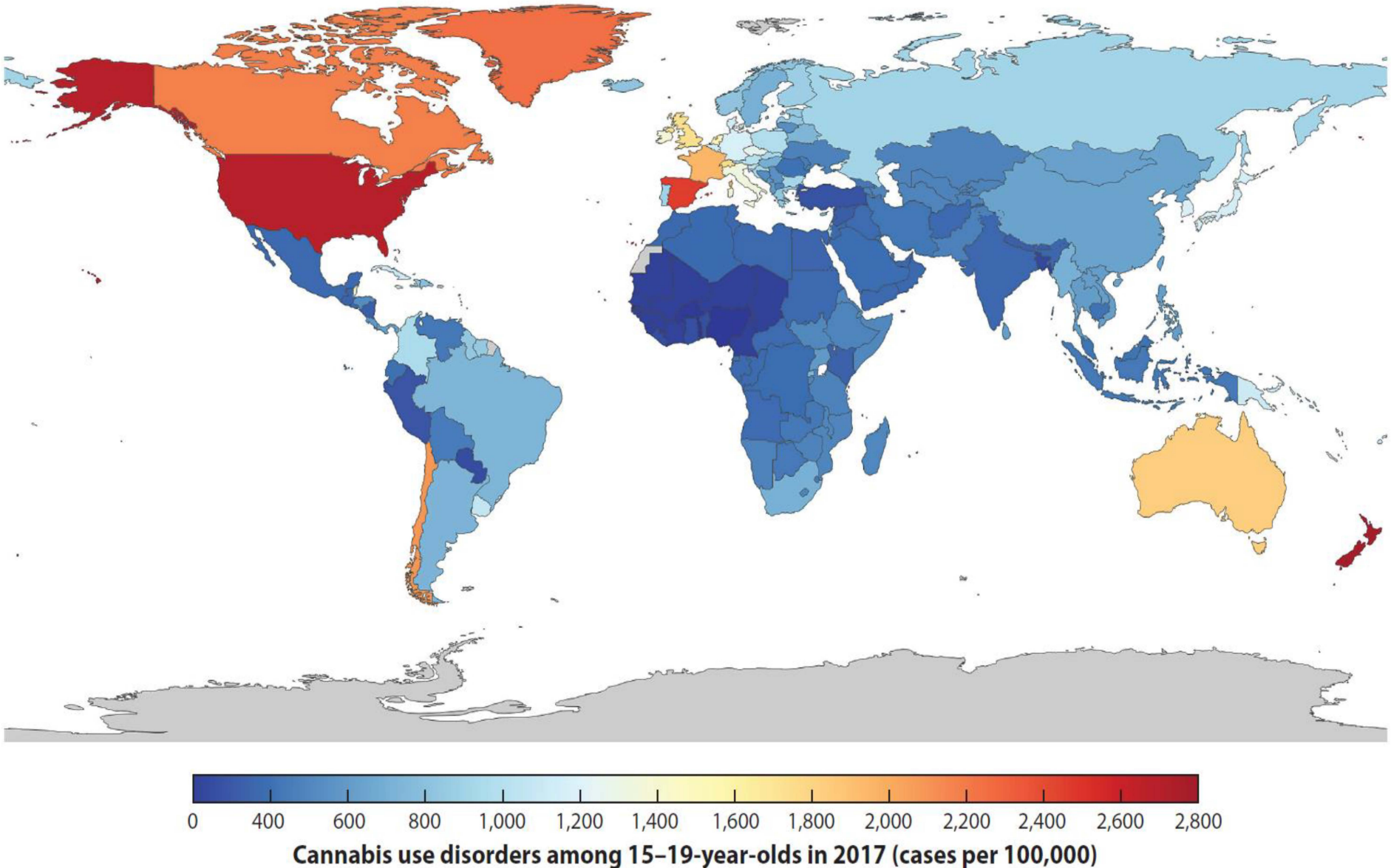
Her research focuses on addiction biology, and other neuropsychiatric diseases, with a recent focus on the developing adolescent brain. She holds 19 U.S. and 27 international patents for novel brain imaging agents and candidate therapeutics. In public service, she has delivered over several hundred public presentations globally, and developed a museum exhibit and a CD (licensed by Disney), with the Museum of Science, Boston. She is the recipient of, among others, an NIH MERIT award, The Innovator Award, NIDA Public Service Award, National Leadership Award, American Academy of Addiction Psychiatry Founders' Award. Her brain imaging agent altropane, was listed by The Better World Report in 2006 as "one of 25 technology transfer innovations that changed the world".

©High Potency Marijuana and Consequences



Bertha K Madras,
Professor
Harvard Medical School

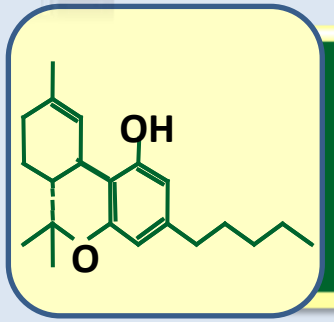
Prevalence of Cannabis Use Disorder 15-19 y



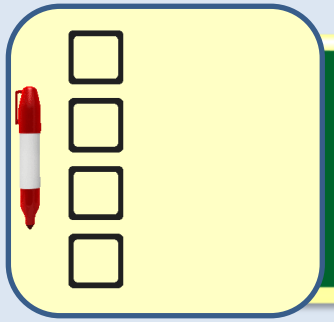
Hall et al 2020



Why Does Potency Matter?



What Does Marijuana Potency Mean?



Public Health Consequences: Known



Consequences to be determined

Why Does Potency Matter?

Higher potency, more drug effects, tolerance, addictive potential, others

Alcohol



Cocaine

Powder Cocaine.HCl



"Crack" Cocaine.$NaHCO_3$



Methamphetamine

Powder Meth.sulphate



Crystal Meth.HCl



Marijuana



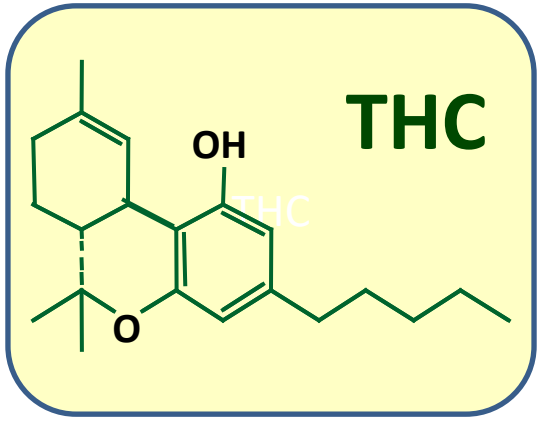




What Does Marijuana Potency Mean?

Cannabis Sativa Contains Many Chemicals

- **Plant: ~104 Phytocannabinoids, 200-300 terpenoids, flavenoids**
- **Synthetic cannabinoids: 1,000's made by chemists**
- **Endocannabinoids: Made by brain, body**



Δ^9-TetraHydroCannabinol (THC) in marijuana is key:

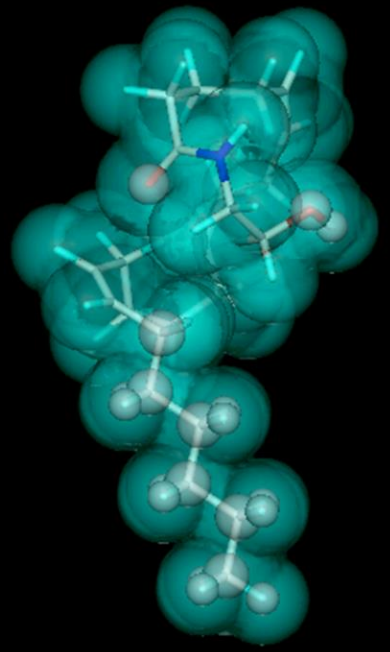
- **psychosis, cognitive impairment, euphoria, intoxication, motor impairment, addiction**

Huestis et al., 2001 Blockade of effects of smoked marijuana by the CB1-selective cannabinoid receptor antagonist SR141716. Arch Gen Psychiatry 58, 322-8.; Justinova et al., 2008; Blockade of THC-seeking behavior and relapse in monkeys by the cannabinoid CB(1)-receptor antagonist rimonabant. Neuropsychopharmacology 33, 2870-7. Carlini Kramer C. Effects of Cannabis sativa (marihuana) on maze performance of the rat. Psychopharmacologia. 1965 7, 175-81; Carlini et al., Effects of marihuana in laboratory animals and in man Br J Pharmacol. 1974;50:299–309; Masur et al., Effects of acute and chronic administration of cannabis sativa and (-) delta9-trans-tetrahydrocannabinol on the behavior of rats in an open-field arena. Psychopharmacologia. 1971;19(4):388-97.

What is THC? Why does %THC Matter?



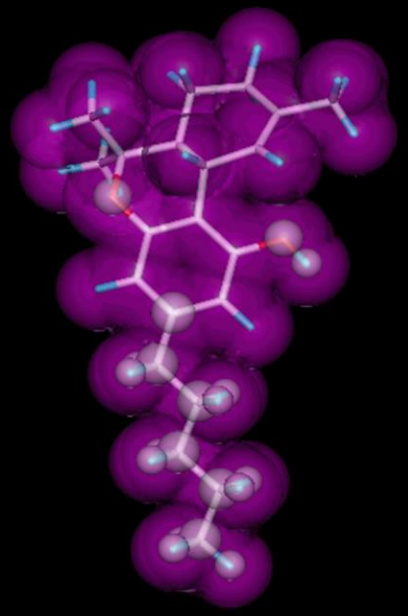
Made by the brain



Anandamide



Made by marijuana



THC

Models from BK Madras, W Mascarella: Museum of Science, Boston Exhibit

Legalization Arguments Made by Marijuana Lobby and Reality

1. *Regulations will Reduce Youth use: states with legal marijuana*

- past-month youth use is 40% higher
- past-year youth use is ~30% higher
- first-time youth use 30% higher compared to illegal states

2. *Marijuana will be less potent: potency has risen dramatically*

- Producers/retailers have incentive to increase %THC to reduce prices, increase profits
- Decreased prices, increased potency, more socially acceptable, increased users
- increased risks for adverse consequences

Arrival of New Marijuana

High THC Potency

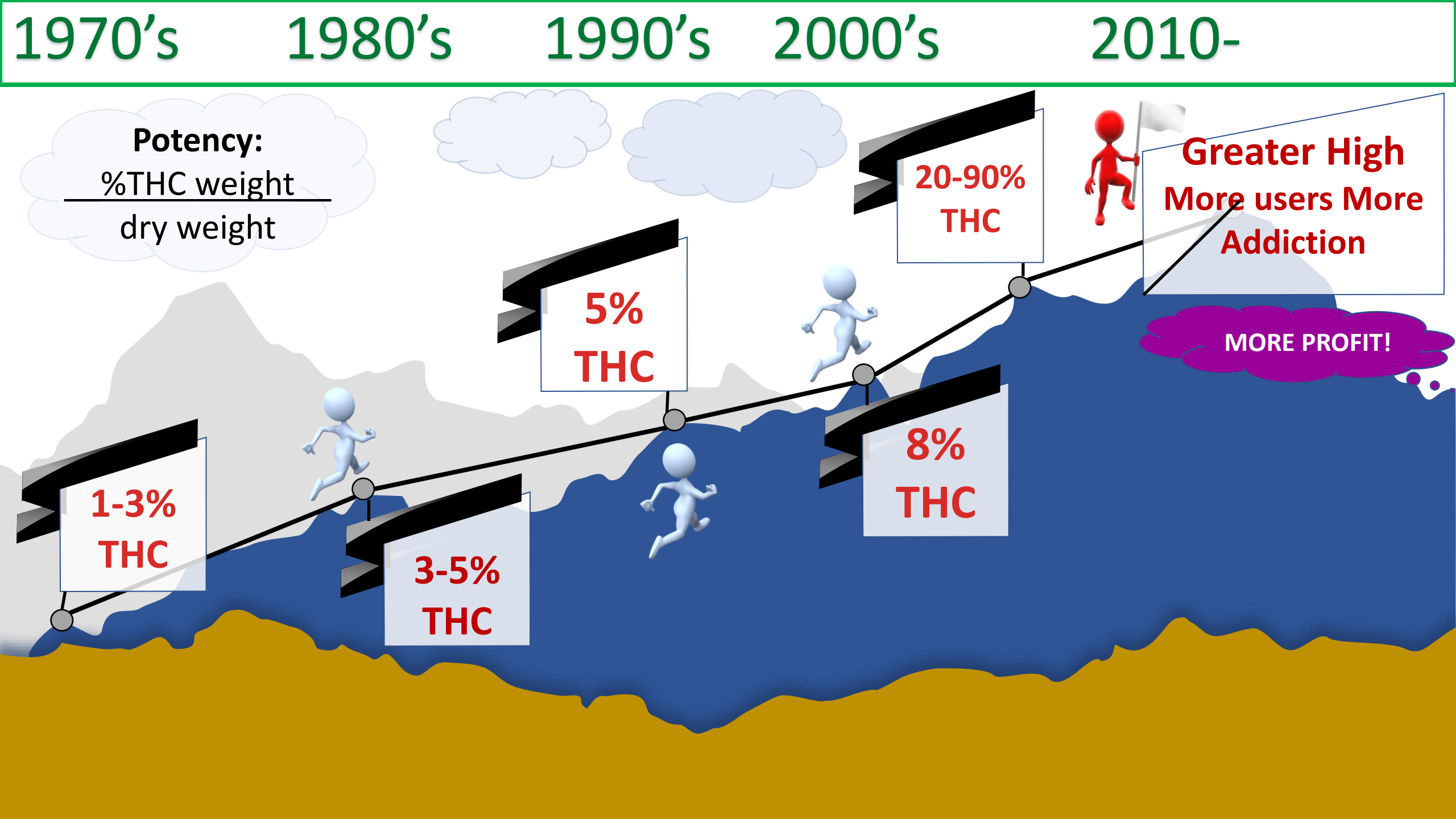
Wax, dabs, shatter

New Products

flower, high-potency extracts, edibles (gummy bears, candy, chocolates), infused beverages

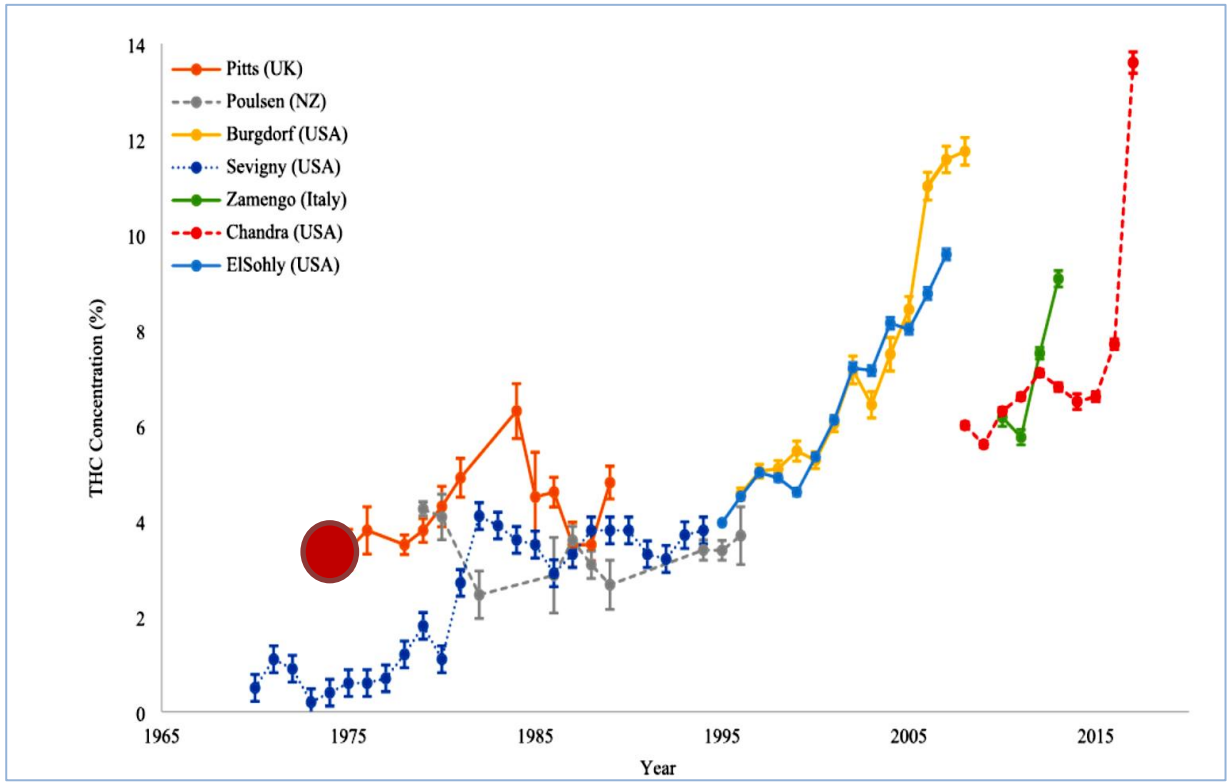
New Delivery System

Vaping

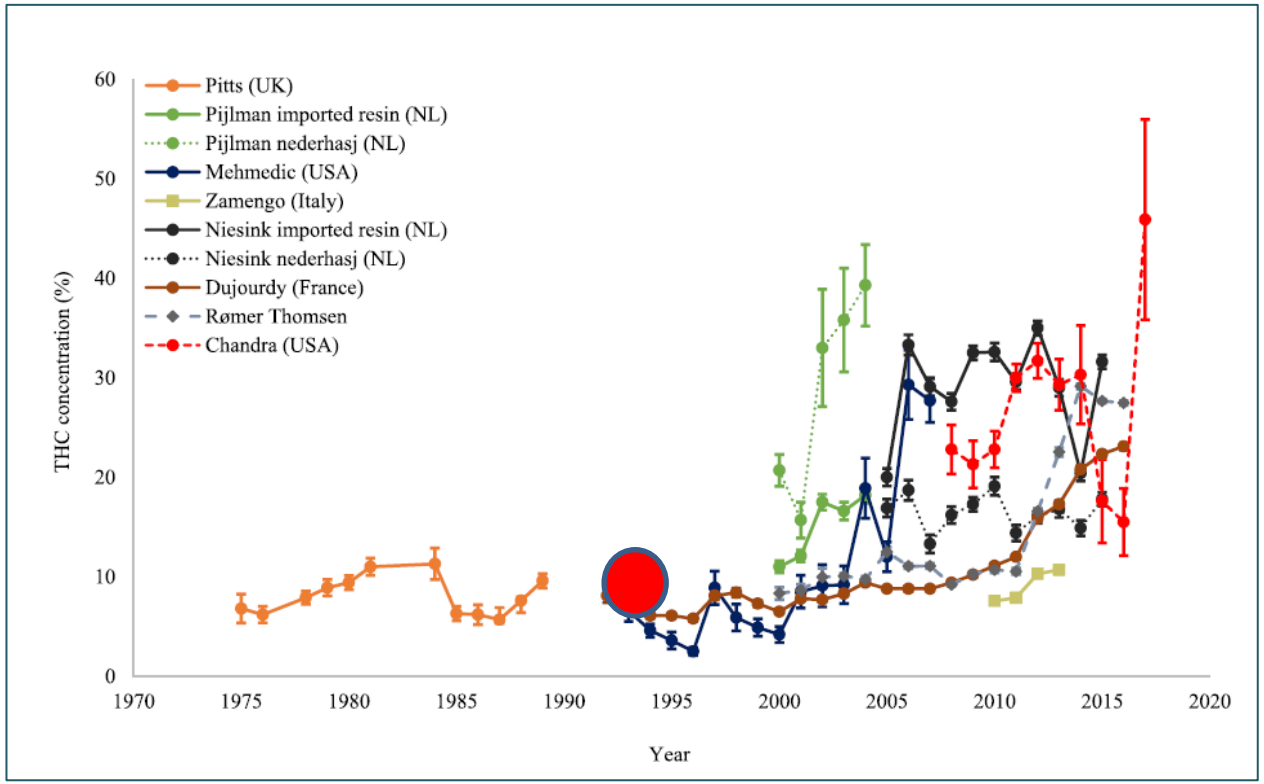

1970’s
1980’s
1990’s
2000’s
2010-
Potency:
%THC weight
dry weight
1-3% THC
3-5% THC
5% THC
8% THC
20-90% THC
Greater High
More users More Addiction
MORE PROFIT!

% THC in Cannabis Plant, Resins

Plant



Resins



Freeman TP, Craft S, Wilson J, Stylianou S, ElSohly M, Di Forti M, Lynskey MT. Changes in delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) concentrations in cannabis over time: systematic review and meta-analysis. Addiction. 2020 Nov 7.

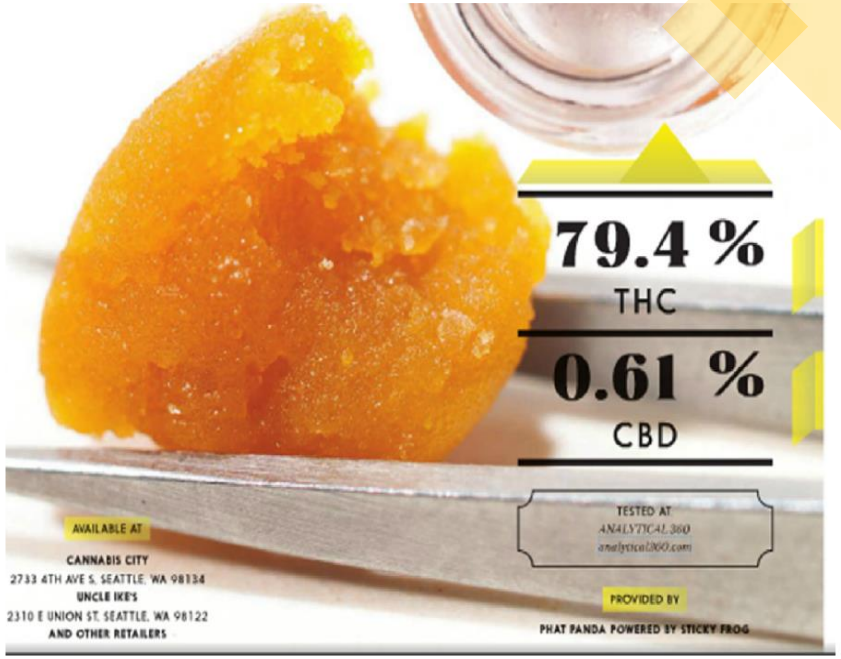
Forms of marijuana



Wilson J, Freeman TP, Mackie CJ. Effects of increasing cannabis potency on adolescent health. Lancet Child Adolesc Health. 2019 Feb;3(2):121-128. © Reproduced with permission from David Potter and Tom Freeman.

Washington State: Marketing of concentrates

- No cap for THC potency, or tax based on %THC
- Industry views concentrates as business op
- Farmers no need to produce appealing bud
- No mildew; more shelf stability than flower



- Delivery devices include vape-pens and dab-rigs
- Consumers choose wax, shatter, BHO, CO_2
- MJ advertised print, websites/social media, search engines

Carlini BH, Garrett SB, Harwick RM. Beyond joints and brownies: marijuana concentrates in the legal landscape of WA state. *Int J Drug Policy*. 2017;42: 26–29

The reality

Sale of extracts rise	• 70% +THC (21% of all sales in some states)
High potency	• preference of daily users (who account for most sales)
Cap %THC or tax based on %THC	• to reduce incentive, but no US state has adopted policy
Increased access to potent marijuana at low price	• likely to increase frequency of use
Profit-seeking legal industry	• Goal is to increase demand, users, frequent use

Public Health Consequences: Known

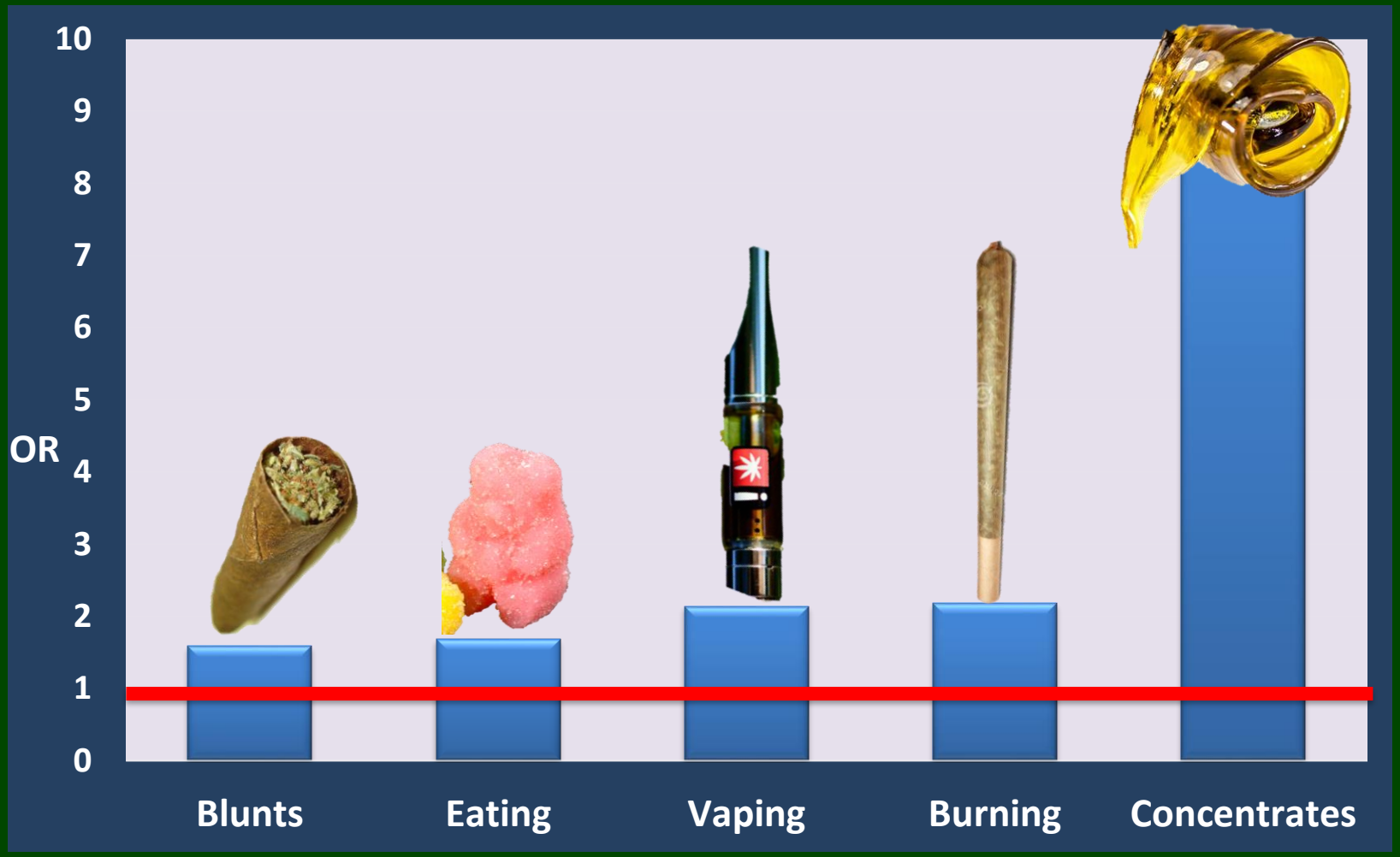
Specific to Youth

- Continued high frequency use
- Addiction
- Psychiatric symptoms
- Use of other drugs

General

- More addiction
- Psychosis
- Hospitalizations
- Traffic accidents
- Childhood exposures

% THC and Adolescent Risk for Continued or High Frequency Marijuana Use



Concentrates

- **Highest risk of continued use**
- **Highest risk of high frequency use**

Barrington-Trimis, JL, Cho J, Ewusi-Boisvert E, Hasin, D, Unger JB, Miech RA, Leventhal AM. Risk of Persistence and Progression of Use of 5 Cannabis Products After Experimentation Among Adolescents. JAMA Network Open January 24 2020

AZ Youth Who Use Concentrates

8th-, 10th-, and 12th-graders:

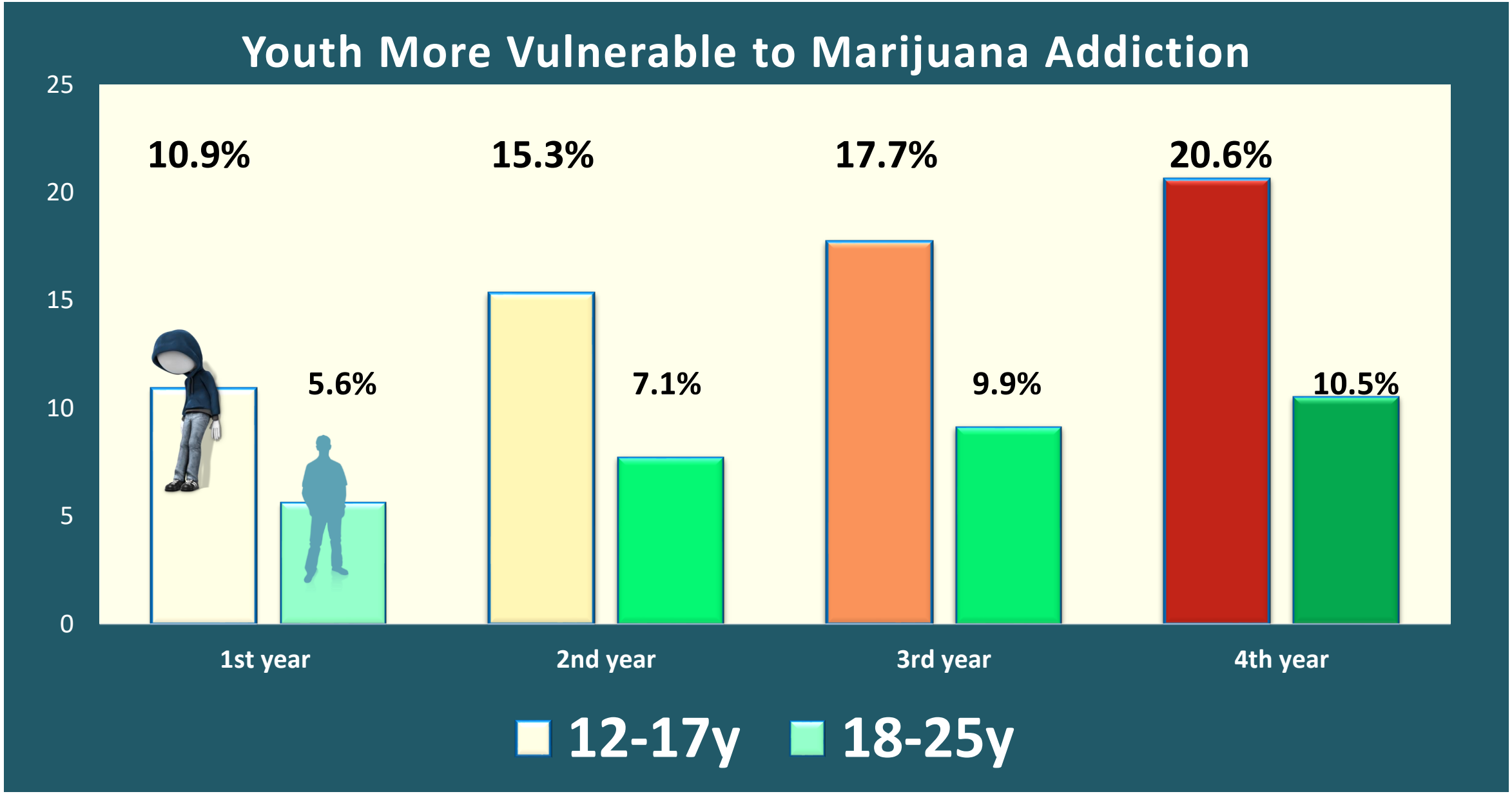
- 33% reported lifetime marijuana use
- 24% reported lifetime concentrate use
- 74% of all lifetime cannabis users had used concentrates



Compared with adolescent non-users or cannabis users not using concentrates, concentrate users were more likely to:

- Smoke
- Use e-cigarettes
- Use alcohol, other drugs before age 17
- Use other drugs
- Experience more risk, fewer protective factors for substance use problems

Meier MH, Docherty M, Leischow SJ, Grimm KJ, Pardini D. Cannabis Concentrate Use in Adolescents. Pediatrics. 2019 Sep;144(3):e20190338.

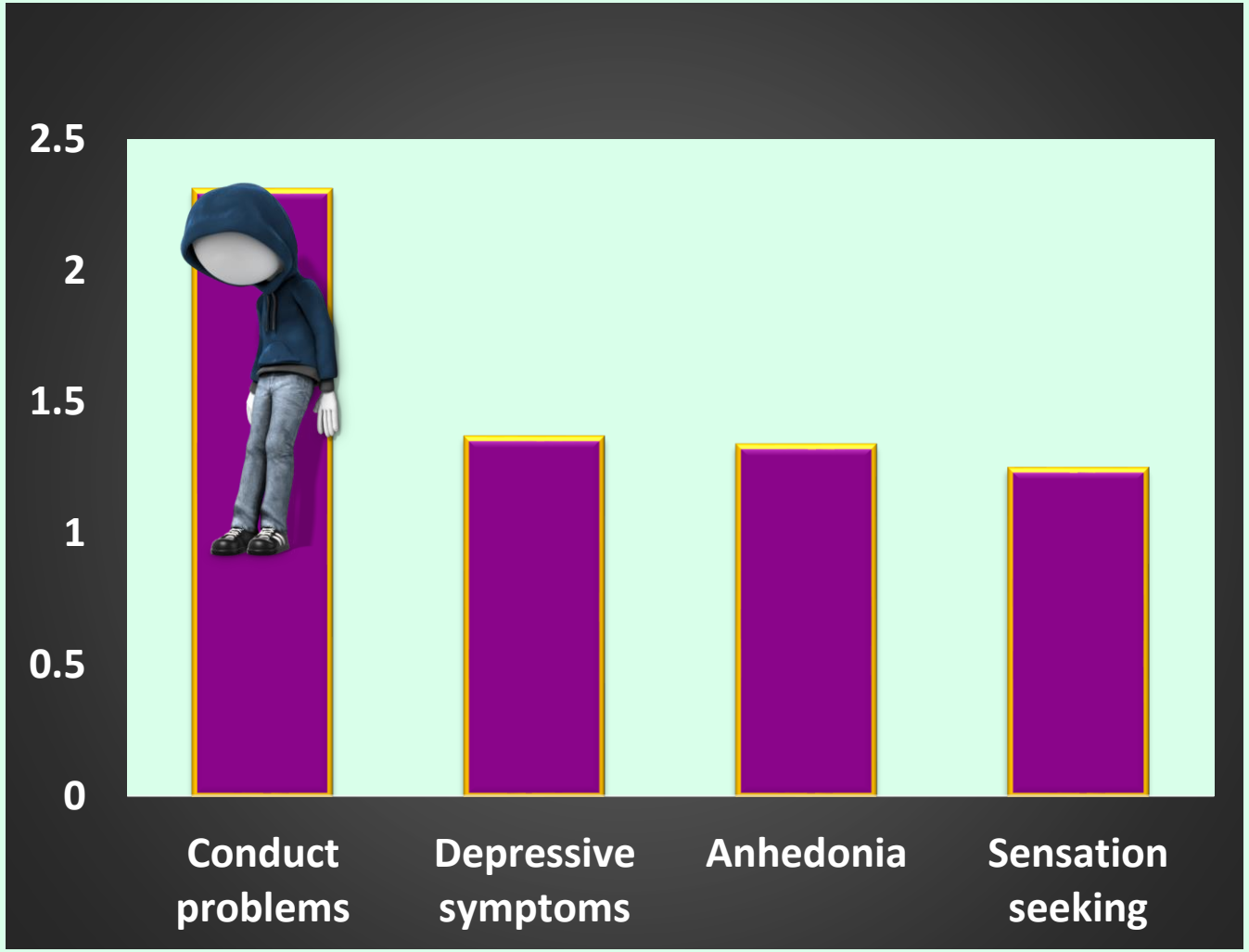


Han B, Compton WM, Blanco C, Jones CM. Time since first cannabis use and 12-month prevalence of cannabis use disorder among youth and emerging adults in the United States. Addiction. 2019 Apr;114(4):698-707

12-month prevalence of cannabis use disorder among US youth aged 12-17 and emerging adults aged 18-25 varied by time since first cannabis use. (n=100,000 12 -25; Past 12-month cannabis use disorder was assessed using DSM-IV criteria

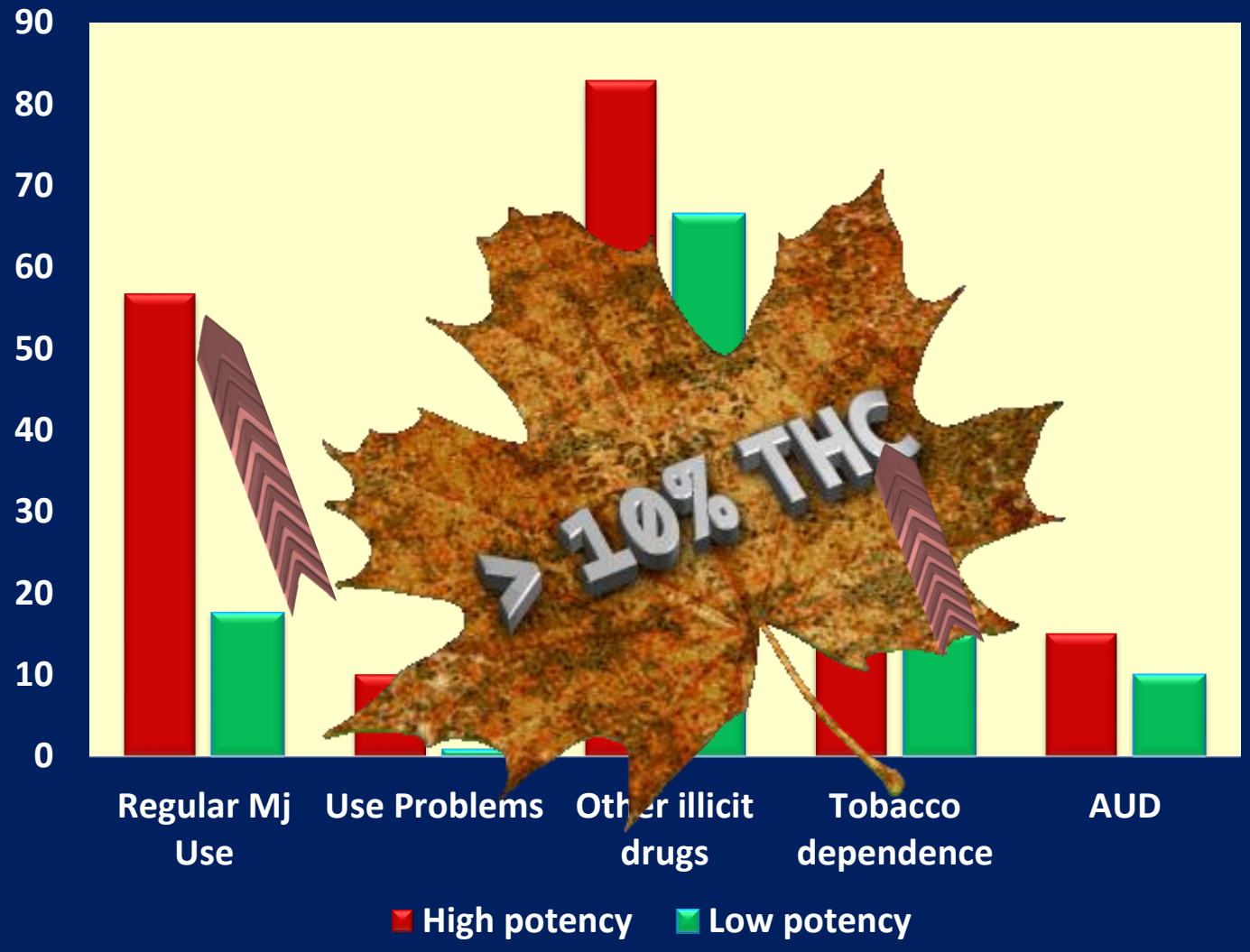
Edibles and Vaporized Marijuana Associated with Psychiatric Symptoms in Adolescents

- Psychiatric symptoms associated use of combustible, edible, vaporized marijuana
- Psychiatric symptoms higher in poly-product use



Leventhal AM, Bae D, Kechter A, Barrington-Trimis JL. Psychiatric comorbidity in adolescent use and poly-use of combustible, vaporized, and edible cannabis products. *J Psychiatr Res*. 2020;124:91-98.

High vs Low Potency Adolescent Marijuana Use

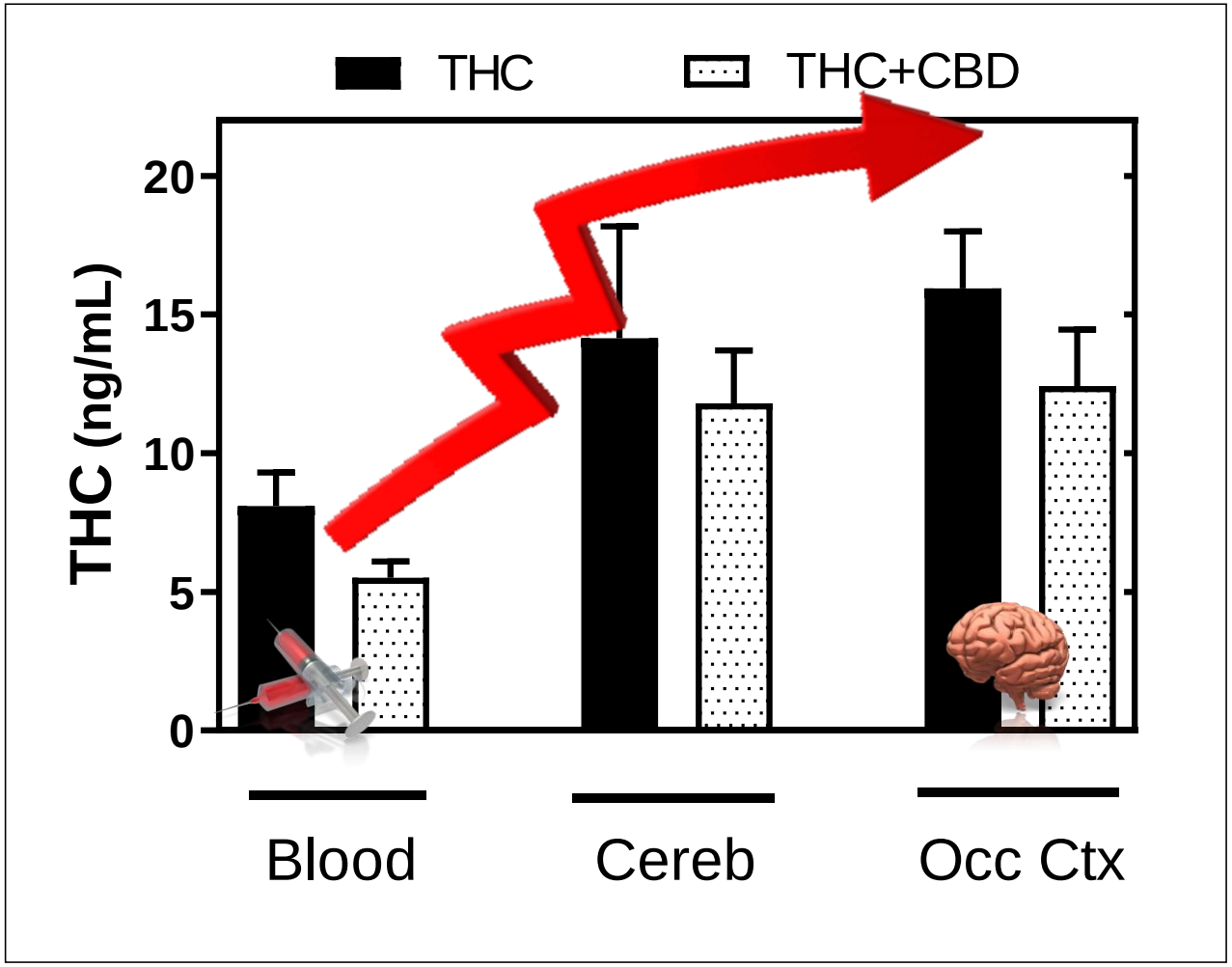


High potency vs low potency

- More regular marijuana use
- More use problems
- More use of other drugs
- More tobacco dependence
- More alcohol use disorder

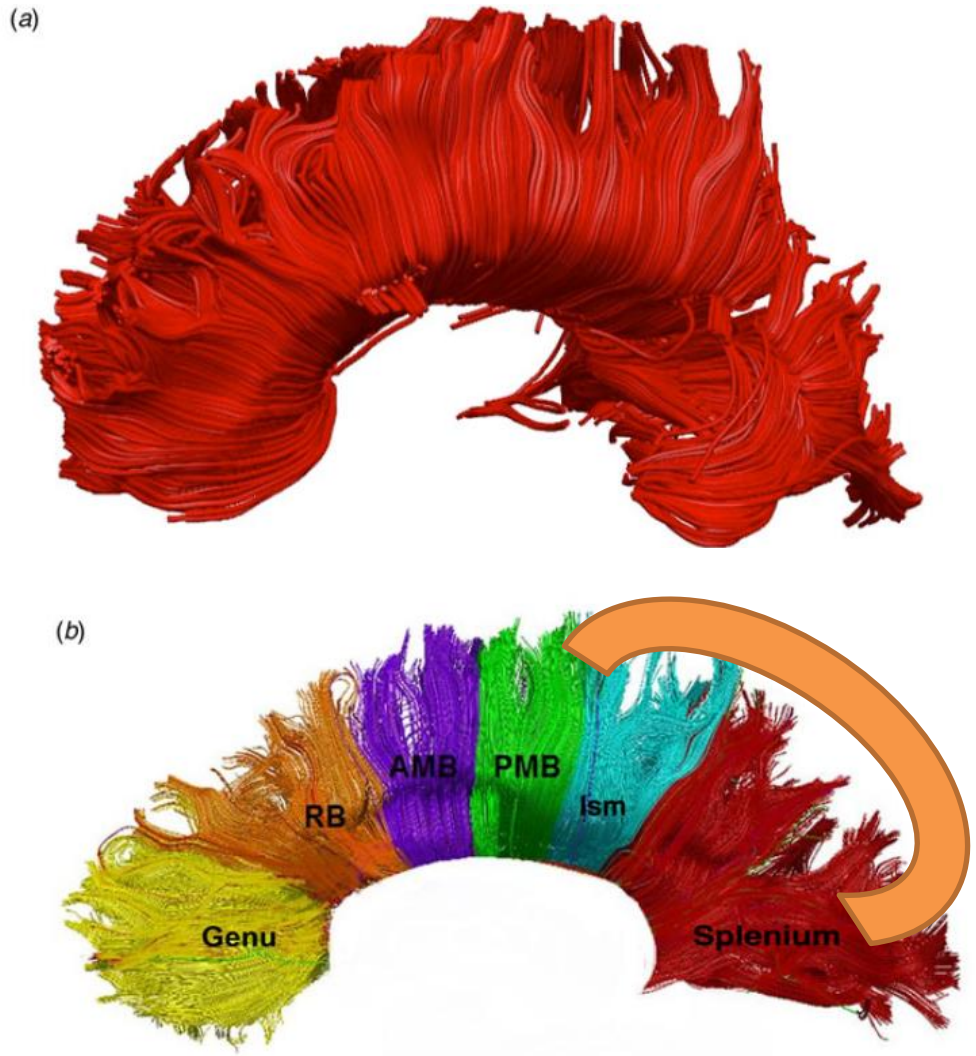
Hines LA, Freeman TP, Gage SH, et al. Association of High-Potency Cannabis Use With Mental Health and Substance Use in Adolescence [published online ahead of print, 2020 May 27]. *JAMA Psychiatry*. 2020;e201035.

THC Accumulates in Brain With Daily High THC Doses



Withey SL, Bergman J, Huestis MA, George SR, Madras BK. THC and CBD blood and brain concentrations following daily administration to adolescent primates [published online ahead of print, 2020 Jun 18]. *Drug Alcohol Depend*. 2020;213:108129.

Brain Changes with High THC Marijuana Use



- Corpus callosum (CC), rich in CB1 cannabinoid receptors during neurodevelopment
- CC is critical for connecting left-right hemispheres of the brain

- **Frequent high-potency marijuana use is associated with disturbed callosal microstructural organization in users with or without psychosis**

Rigucci S, Marques TR, Di Forti M, Taylor H, Dell'Acqua F, Mondelli V, Bonaccorso S, Simmons A, David AS, Girardi P, Pariante CM, Murray RM, Dazzan P. Effect of high-potency cannabis on corpus callosum microstructure. Psychol Med. 2016 Mar;46(4):841-54.

Marijuana potency (%THC) is associated with first time entry into treatment for CUD



In U.S.

Higher potency marijuana products associated with increasing marijuana use disorder

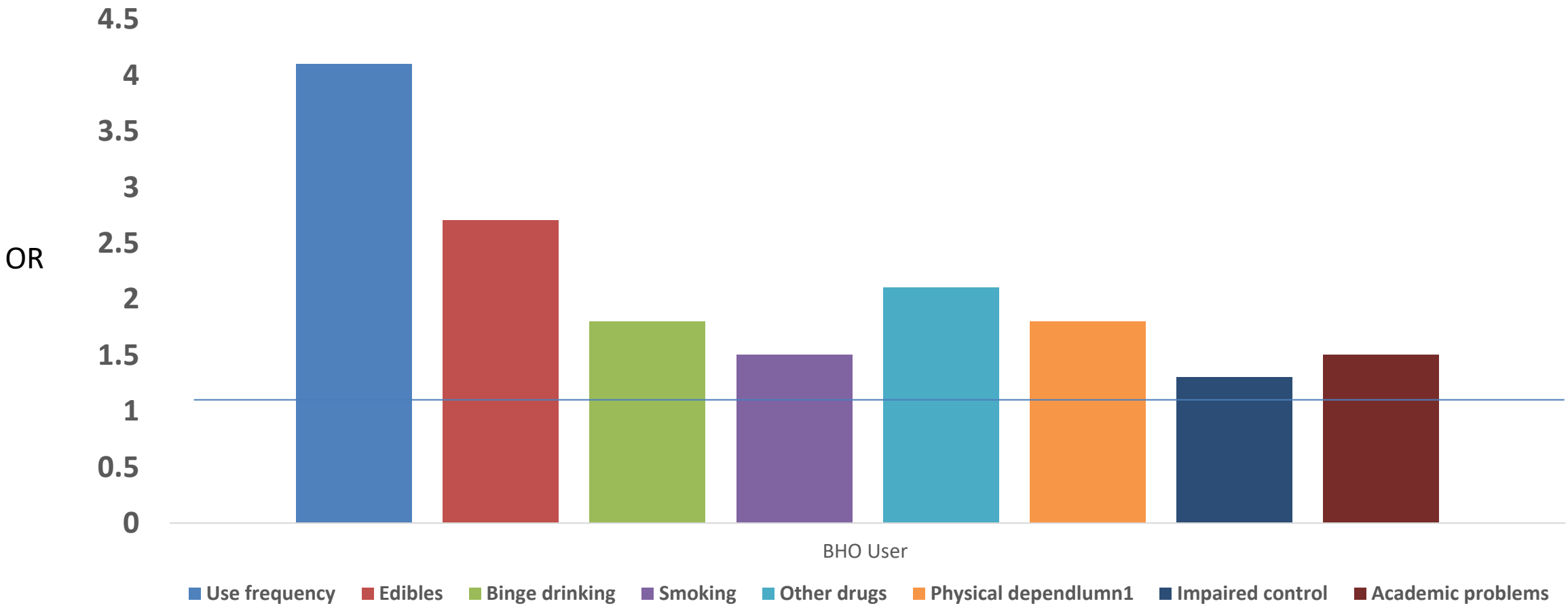
Higher potency products increase risk for progression from use to marijuana use disorder

Adolescents: Past-year marijuana use disorder significantly increased

In adults 26+, past-month marijuana use and past-year daily or almost daily marijuana use significantly increased in adults aged 26+ (NSDUH, 2019)

Freeman TP, van der Pol P, Kuijpers W, Wisselink J, Das RK, Rigter S, van Laar M, Griffiths P, Swift W, Niesink R, Lynskey MT. Changes in cannabis potency and first-time admissions to drug treatment: a 16-year study in the Netherlands. Psychol Med. 2018 Oct;48(14):2346-2352

Problems Associated with Use of Butane Hash Oil (~ 50-60% THC) Among College Students before adjusted OR



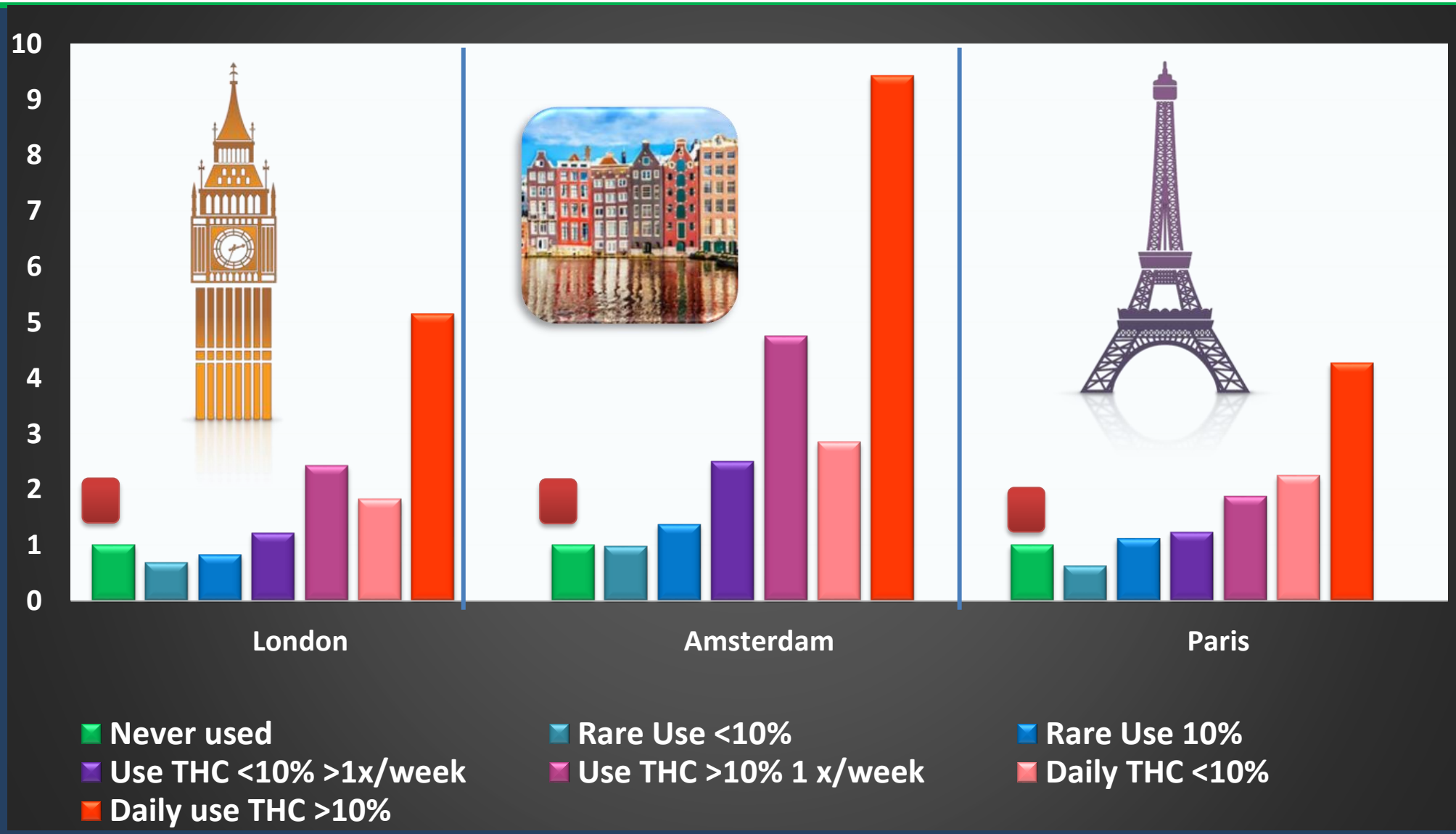
Meier MH. Associations between butane hash oil use and cannabis-related problems. Drug Alcohol Depend. 2017 Oct 1;179:25-31.

% THC, Frequency of Use Higher Risk for Psychotic Disorders

A "Tale" Of 3 Cities (Actually 11 Sites)

Di Forti et al

Lancet Psychiatry 2019 May;6(5):427-436.



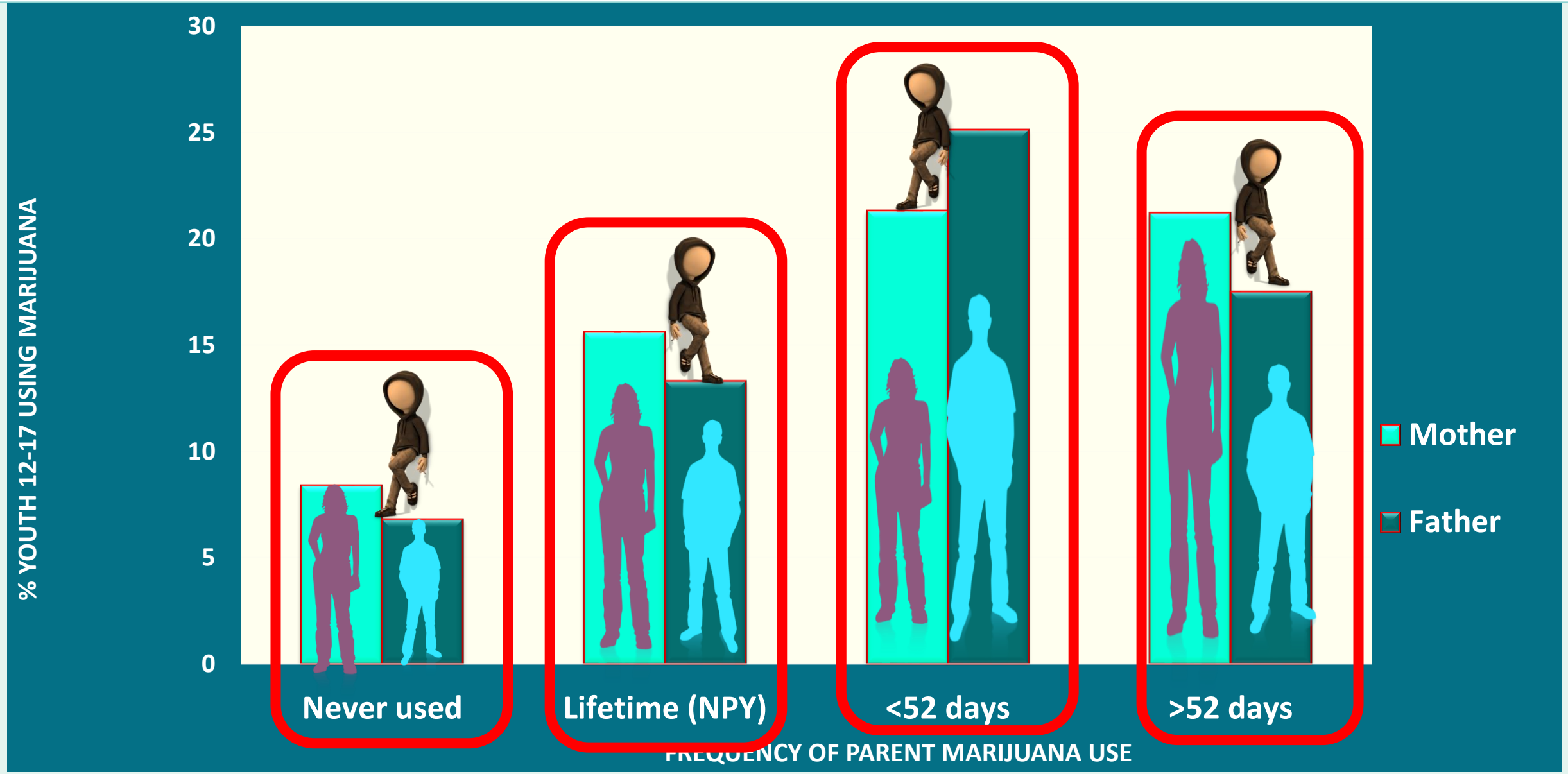
Dose-response:

- van Os J, et al 2002;
- Henquet C, et al 2005;
- Moore THM et al: 2007;
- Haney and Evins, 2016;
- Marconi et al 2016;

High THC Potency Associated With Higher Risk for

- Psychosis
- Lower age of schizophrenia
- Impaired brain function, driving
- Use of other drugs, other effects
- More use, higher risk for addiction

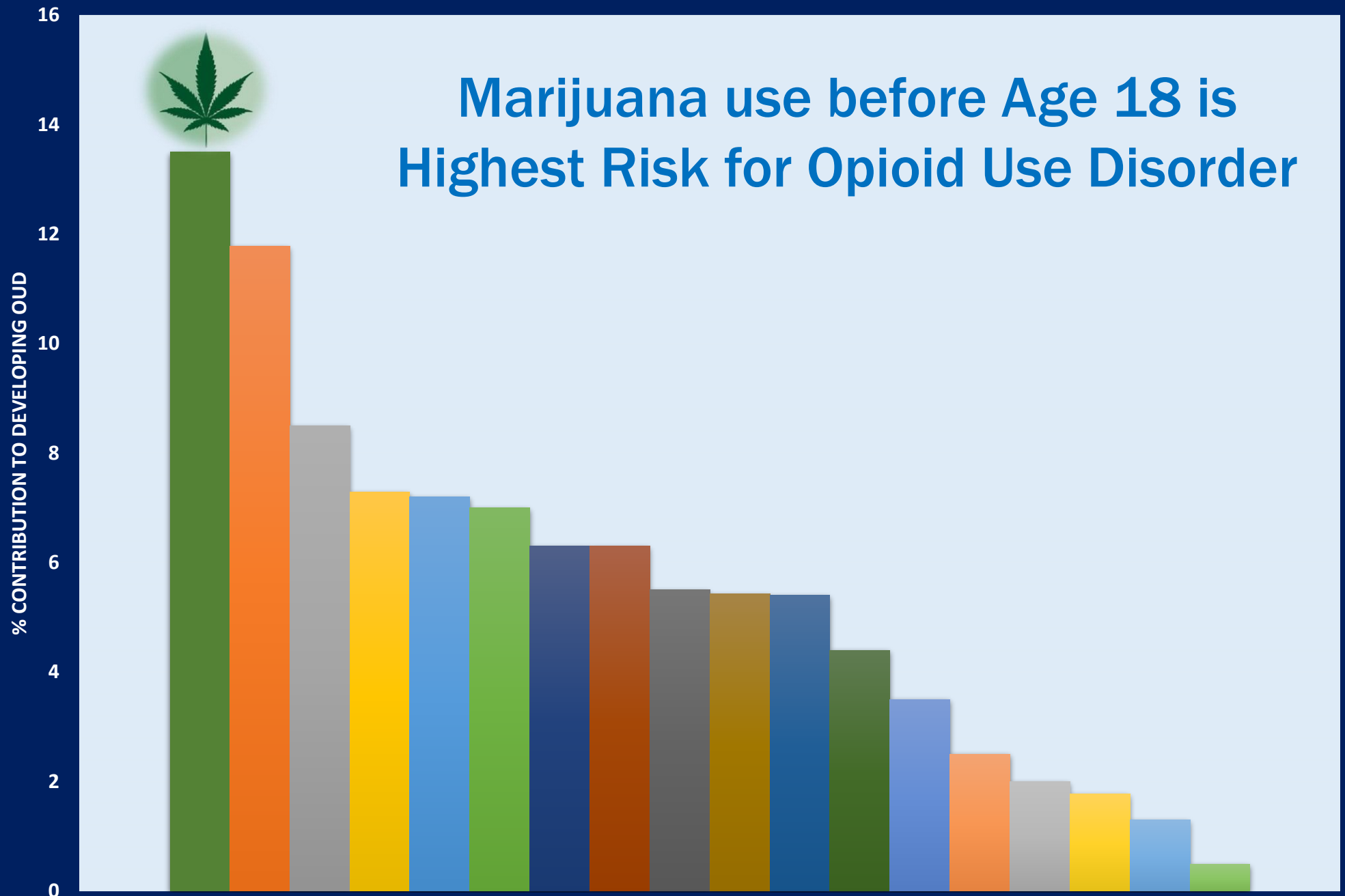
If Mothers or Fathers Use Marijuana Offspring 12-17 y More Likely to Use Marijuana



Marijuana-related hospitalizations (CO) Increased After Legalization Due to:

Marijuana	• abuse and dependence
Mental illness	• marijuana-related code increased 5X faster than mental illness without marijuana code 2012 - 2014
Largest increases	• diagnoses of schizophrenia, other psychotic disorders, suicide and intentional self-harm, mood disorders
Motor vehicle accidents, injuries	• related to cannabis abuse data mixed
Head injuries	• due to falls
Hyperemesis	• 46% increase in the incidence of cyclic vomiting was reported between 2010 and 2014
Childhood poisonings	• exposures to candies, pastries
Severe burns	• users who tried to extract THC from cannabis oils

Marijuana use before Age 18 is Highest Risk for Opioid Use Disorder



Adway S. Wadekar. Understanding Opioid Use Disorder (OUD) using tree-based classifiers Drug and Alcohol Dependence 208 (2020) 107839

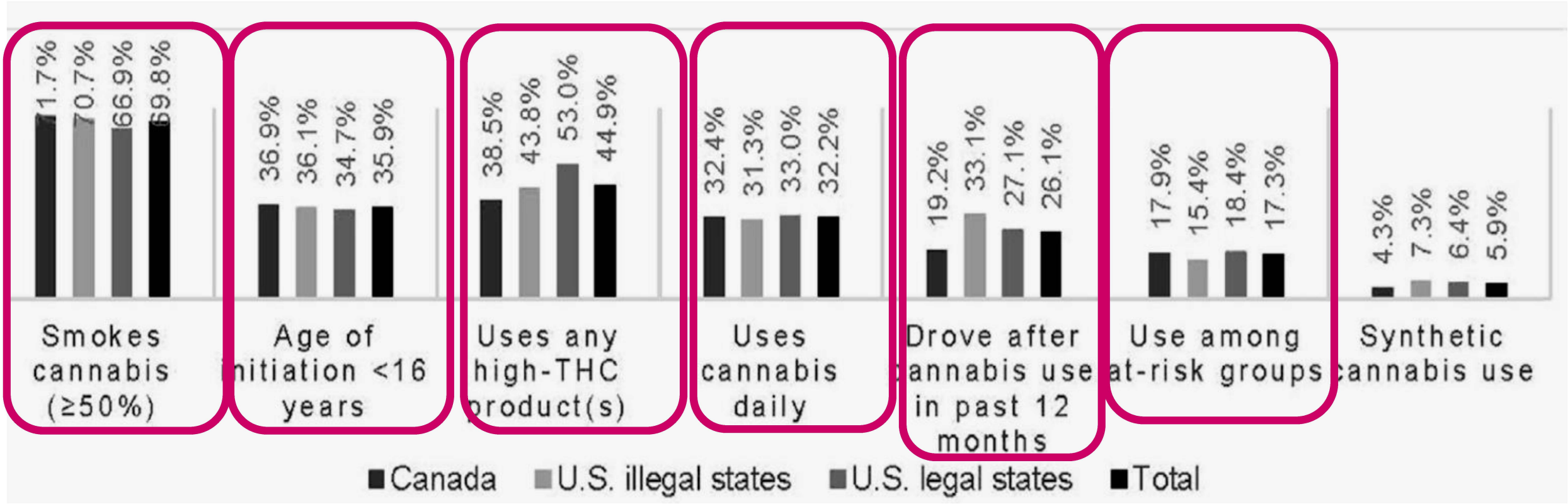
Lower-Risk Cannabis Use Guidelines (LRCUGs)

- Abstain from cannabis use if possible
- Choose low-strength: lower THC content or higher CBD: THC.
- Do not use synthetic cannabis products
- Avoid smoking cannabis
- Avoid deep inhalation
- Don’t drive or operate machinery after using cannabis
- Avoid cannabis if pregnant or a personal or family predisposition toward psychosis or substance abuse
- Avoid combining the risky behaviors listed

Fischer et al., Am J Public Health. 2018;108(5):e2]. Am J Public Health. 2017;107(8):e1–e12.

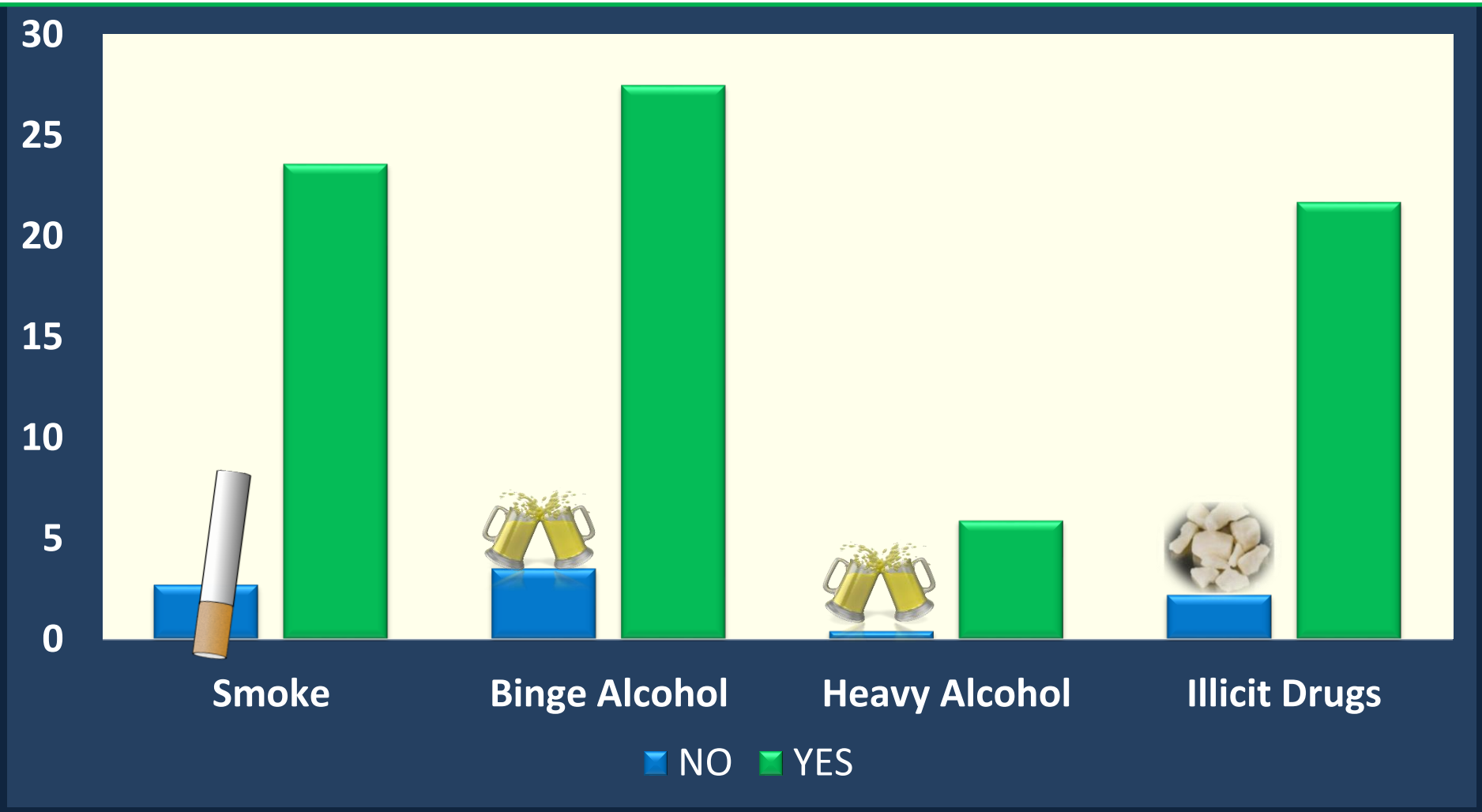
Prevention Messages and Reality

(Past 12 month use)



Goodman S, Fischer B, Hammond D. Lower-Risk Cannabis Use Guidelines: Adherence in Canada and the U.S. Am J Prev Med. 2020 Dec;59(6):e211-e220.

Use of Other Substances Much Higher in Adolescent Marijuana Users



Data from Dupont, Han, Shea, Madras. Preventive Medicine 113: 68-73, 2018. [Graph prepared by BK Madras] Past month use of alcohol, tobacco and illicit drugs, among youth aged 12-17, by marijuana status (past month unadjusted prevalence; n = 17,000; data from Table 1). Y-axis: past month prevalence in %)

Consequences to be determined



Consequences high potency?

- Workplace?
- Car accidents, fatalities?
- Fetal development? heightens the health risk of vulnerable groups associated with sensitive landmarks in brain development, pregnancy, children, adolescents, young adults
- Impact on cognitive impairment of older adults
- Impact greater with concurrent use of marijuana, alcohol?
- Heavy smoking may increase cardiovascular disease risk in young or middle-aged men?

Marijuana Consequences: Magnified by high THC?



Brain changes



Addiction

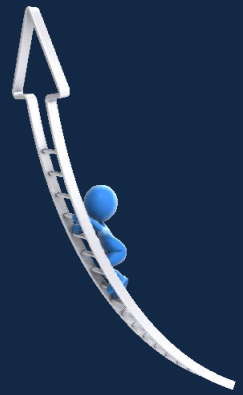


Deficits Cognition

Short term memory loss

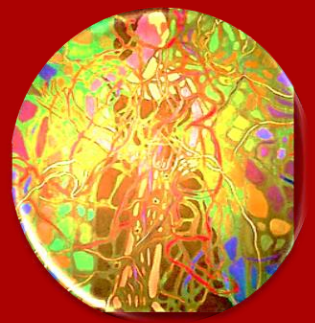
IQ decline

Poor school performance



Amotivation

Higher school drop-out



Psychiatric diseases

Psychosis

Depression

Anxiety



Safety

Decreased reaction time
Impaired motor coordination,

- In 2019 Surgeon General Jerome Adams warned the risks of physical dependence, addiction, other negative consequences *increase with exposure to high concentrations of THC and younger age of initiation*

- Higher doses of THC are more likely to produce anxiety, agitation, paranoia, and psychosis.

- "These harms are costly to individuals and to our society, impacting mental health and educational achievement and raising the risks of addiction and misuse of other substance."

Stuyt E. The problem with the current high potency THC marijuana from the perspective of an addiction psychiatrist. *Mo Med* 2018; 115(6):482-486; Chandra S,et al., New trends in cannabis potency in USA and Europe during the last decade (2008-2017) *Eur Arch Psychiatry Clin Neurosci.* 2019; 269(1): 5-15.; Smart et al., (2017) Variation in cannabis potency and prices in a newly legal market: evidence from 30 million cannabis sales in Washington state. Addiction, 112: 2167– 2177; Morean et al., Predictors of Adult E-Cigarette Users;
Office of the Surgeon General, U.S Surgeon General's Advisory: Marijuana Use and the Developing Brain. Available at:hhs.gov/surgeongeneral/reportsandpublications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

Summary

Brain is maturing until mid-20s to 30	• Cannabinoids unsafe for fetus, adolescent, young adult, especially potent marijuana
High Potency Marijuana	• "New" marijuana poses a greater risk than old marijuana; no evidence it is necessary
High potency marijuana	• Associated with more brain changes, addiction, psychosis, hospitalizations
Marijuana and Opioids	• Evidence is weak that it reduces opioid use • States put opioid users at risk by endorsing MJ
% THC	• Limit % THC • Tax on basis of % THC

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