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Where are we with marijuana and the smoking truth about vaping?

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Disclosure

- The presenter has no potential or actual conflicts of interest to disclose in association with this presentation.



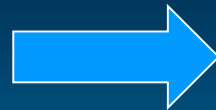
Objectives

- Examine the legal status and use of marijuana and its derivatives in the United States.
- Describe e-cigarettes & compare/contrast vaping and juuling and FDA stand on these products.
- Describe the impact that vaping and other pharmacological therapies for tobacco smoking cessation.
- Examine the adverse effects of using recreational e-cigarettes, marijuana, vaping, and juuling.
- Raise public awareness to prevent adolescents, teens, and adults from smoking e-cigarettes and tobacco products.



Background on Marijuana

- Comes from the plant *Cannabis Sativa* and *Cannabis Indica*
- Has been used for more than 4,000 years
- Earliest documentation of therapeutic use of marijuana dates back to the fourth century BC in China⁴



(2018). *Plants Profile for Cannabis sativa (marijuana)*. [online] Available at: <https://plants.usda.gov/core/profile?symbol=casa3> [Accessed 13 Dec. 2018] Plants.usda.gov.



Background on Marijuana

- Marijuana was listed in the US Pharmacopoeia from 1850- 1942
- In 1970, FDA listed marijuana as a scheduled I controlled substance⁷
- The Cannabis plant contains over 400 different chemical compounds
 - The two most common are:
 - Tetrahydrocannabinol (THC)
 - Cannabidiol (CBD)



Background on Marijuana

Cannabis Sativa

Tall thin stemmed with narrow leaves

Longer time to mature

Medicinal derivate with lower CBD levels

Medicinal derivate have higher THC levels

Cannabis Indica

Short stemmed with wide leaves

Faster growing and higher yields

Medicinal derivate have higher CBD levels

Medicinal derivate have lower THC levels



Background on Marijuana

- Cannabinoids is a term used to describe a compound that agonizes the cannabinoid receptors (CB)⁷
 - CB₁
 - Found in nervous system
 - CB₂
 - Located primarily in the peripheral system and recent data supports in the nervous system
 - Both receptors have also been identified in the T and B lymphocyte⁹
- The receptors are G protein linked neuromodulators that inhibits adenylate cyclase in a dose dependent manner⁷



Background on Marijuana

➤ THC

- A psychoactive component of marijuana⁷
- Short-term effects
 - Alters senses
 - Changes mood
 - Impairs cognitive functions
- Higher doses
 - Hallucinations, delusion, and psychosis
- Long-term effects
 - Impairment in cognitive function

➤ CBD

- Not a psychoactive but influences the body
- Short-term effects
 - Tiredness
 - Diarrhea
 - Change in appetite
 - Weight gain or loss
 - Decrease inflammation
 - Reduce pain
 - Reduce insomnia
- Long-term effects
 - Not well studied



Recreational Use

- Smoking is the most common use of marijuana
 - Joint/blunt, pipe, or a bong

- Assorted with food

- Mixed with a beverage as a tea

- Dabbing



Place in Medicine

- FDA has not approved marijuana safe and effective and remains a schedule I controlled substance

- FDA approved derivatives of marijuana:
 - Epidiolex[®] (Cannabidiol)

 - Marinol[®] and Syndros[™] (Dronabinol)

 - Cesamet[™] (Nabilone)



Epidiolex® (Cannabidiol)



The Daily Marijuana Observer. (2018). *EPIDIOLEX (cannabidiol) Oral Solution – the First FDA-approved Plant-derived Cannabinoid Medicine – Now Available by Prescri.* [online] Available at: <https://mjobserver.com/united-states/epidiolex-cannabidiol-oral-solution-the-first-fda-approved-plant-derived-cannabinoid-medicine-now-available-by-prescription-in-the-u-s/> [Accessed 14 Dec. 2018].



Epidiolex[®] (Cannabidiol)

- Approved for
 - Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome³

- Lennox-Gastaut Syndrome
 - Onset between the age of 2 years to 18 years of age

- Dravet Syndrome
 - Onset from infancy up to 2 years of age



Epidiolex[®] (Cannabidiol)

➤ Dosing³

- Initial: 2.5 mg/kg twice daily
 - Maintenance dose of 5 mg/kg may be increased after tolerating for 1 week
- Max dose: 10 mg/kg twice daily

➤ Adjustment³

- Moderate hepatic impairment (Child-Pugh class B)
 - Initial: 1.25 mg/kg twice daily, may increase after tolerating for 1 week to a dose of 2.5 mg/kg twice a day
 - Maintenance dose of 2.5 mg/kg
- Max dose: 5 mg/kg twice daily



Epidiolex[®] (Cannabidiol)

- Severe hepatic impairment (Child-Pugh class C)³
 - Initial: 0.5 mg/kg twice daily, may increase after tolerating for 1 week to a dose of 1 mg/kg twice daily
 - Maintenance dose of 1 mg/kg
 - Max: 2 mg/kg twice daily
- Monitor
 - ALT, AST, and total bilirubin
- Adverse effects
 - Central nervous system
 - Dermatologic
 - Weight loss
 - GI
 - Anemia
 - Increase in liver enzymes
 - Asthenia



Marinol[®] (Dronabinol)



Akorn.com. (2018). [online] Available at:
http://www.akorn.com/documents/catalog/sell_sheets/17478-762-06.pdf
[Accessed 14 Dec. 2019].



Marinol® (Dronabinol)

- FDA approval to treat:⁶
 - Anorexia in patients with AIDS
 - Chemotherapy induced nausea and vomiting (CINV)



Marinol® (Dronabinol)

➤ Dosing Anorexia⁶

- Initial: 2.5 mg twice daily 1 hour prior to meals
 - May increase dose gradually based on response to medication
- Max dose: 20 mg per day



Marinol[®] (Dronabinol)

➤ Dosing CINV⁶

- Initial: 5 mg/m² 1 to 3 hours prior to chemotherapy, then 5 mg/m² per dose every 2 to 4 hours after therapy. Total of 4 to 6 doses per day⁵
 - May increase dose gradually based on response, increments of 2.5 mg/m²
- Max dose: 15 mg/m² per dose⁵



Syndros™ (Dronabinol)



Syndros.com. (2018). *SYNDROS | The First & Only FDA-Approved Liquid Dronabinol.* [online] Available at: <https://www.syndros.com/> [Accessed 14 Dec. 2018].



Syndros™ (Dronabinol)

- FDA approval to treat:¹⁰
 - Anorexia in AIDS patients
 - Chemotherapy induced nausea and vomiting (CINV)



Syndros™ (Dronabinol)

➤ Dosing Anorexia¹⁰

- Initial: 2.1 mg twice daily 1 hour prior to meals
 - May increase dose gradually based on response to the medication
 - Increments of 2.1 mg for the latest meal first, then may increase to 2.1 mg for both doses
- Max dose: 16.8 mg per day



Syndros™ (Dronabinol)

➤ Dosing CINV¹⁰

- Initial: 2.1 mg/m² 1 to 3 hours prior to chemotherapy, then 2.1 mg/m² per dose every 2 to 4 hours after therapy. Total of 4 to 6 doses per day ⁹
 - Dose rounded to nearest 0.1 mg
 - May increase dose gradually based on response to the medication
 - Increments of 2.1 mg/m² for the latest meal first, then may increase to 2.1 mg/m² for both doses
- Max dose: 12.6 mg/m² per dose⁹



Marinol® and Syndros™ (Dronabinol)

➤ Monitor

- Heart rate
- Blood pressure
- Worsening of symptoms

➤ Adverse effects

- Euphoria



Cesamet™ (Nabilone)



Cesamet.com. (2018). *Cesamet (nabilone): Dosing & Administration*. [online] Available at: <http://cesamet.com/hcp-dosing-and-administration.asp> [Accessed 15 Dec. 2018].



Cesamet™ (Nabilone)

- Approved for treating¹
 - Refractory nausea and vomiting associated with cancer chemotherapy who have failed other antiemetic treatments



Cesamet™ (Nabilone)

➤ Dosing¹

- Initial: 1 to 2 mg twice daily
 - May be used 2 to 3 times a day throughout chemotherapy regimen
 - Continue up to 48 hours after last chemotherapy dose
- Max dose: 6 mg per day divided into 3 doses

➤ Monitor

- Heart rate, blood pressure, and worsening of symptoms

➤ Adverse effects

- Central nervous system
- Xerostomia
- Visual disturbances



Marijuana Uses by the Medical Community

- FDA approval
 - AIDS wasting
 - Epilepsy
 - Cancer and chemotherapy-induced nausea

- Non-FDA approval
 - Neuropathic pain
 - Treatment of spasticity associated with multiple sclerosis

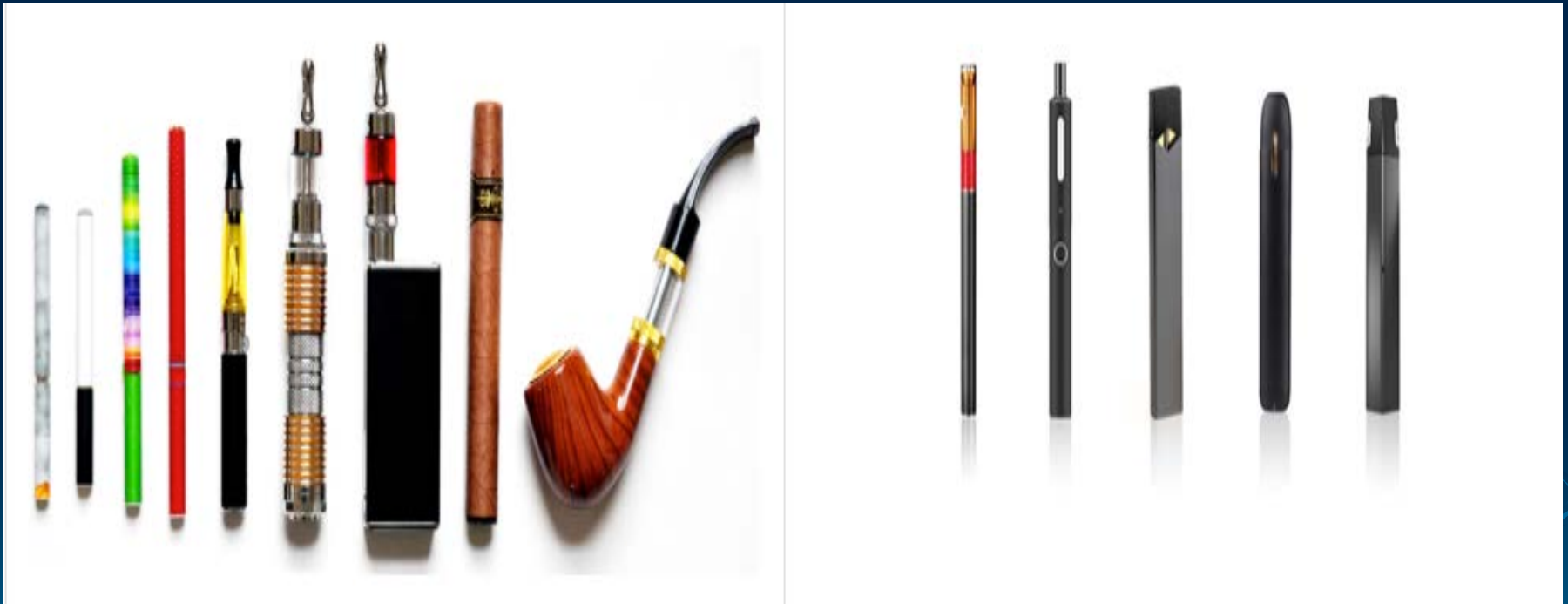


Status of Marijuana in United States

- The use of marijuana federally remains prohibited⁸
- Recreational approval:
 - Alaska, California, Colorado, District of Columbia, Maine, Massachusetts, Michigan, Nevada, Oregon, Vermont, and Washington
- Approved for Medical use:
 - Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Illinois, Louisiana (can not be smoked), Maryland, Minnesota, Missouri, Montana, New Mexico, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode island, Utah, West-Virginia (only for cannabis-infused products)



Vaping and Juuling



Devices, W. (2018). *What Parents Should Know About the Different Vaping Devices* | Center on Addiction. [online] Centeronaddiction.org. Available at: <https://www.centeronaddiction.org/e-cigarettes/recreational-vaping/what-parents-should-know-about-different-vaping-devices> [Accessed 15 Dec. 2018].



Vaping

- The act of using an electronic device to inhale or exhale an aerosol containing multiple chemicals
 - Nicotine
 - Propylene glycol (PG) and/or vegetable glycerin (VG) base
 - Flavoring agents
 - Water
- Think of vaping as an umbrella term for any device that is an electronic nicotine delivery system (ENDS)



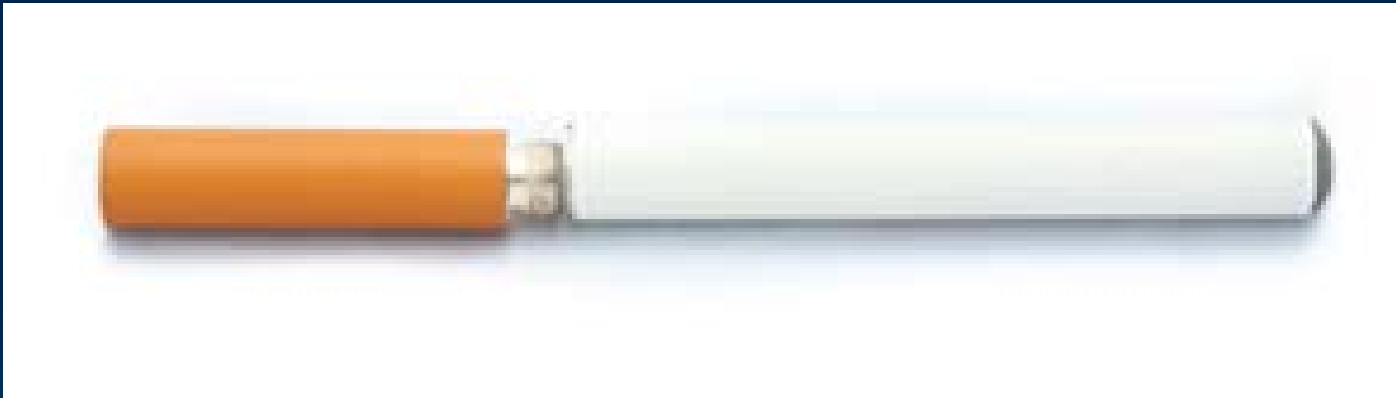
Vaping Devices

- Multiple device types that ranges from:
 - Device type/size
 - Electronic cigarettes/Cig-likes
 - Pen kits
 - Mechanical modified nicotine deliver system (MODs) kits
 - Juul
 - Nicotine content
 - 0-6 mg/mL
 - 3-12 mg/mL
 - 10-20 mg/mL
 - Throat hit
 - Soft, medium, and hard



Electronic Cigarettes/Cig-likes

- First generation of vaping devices



Devices, W. (2018). *What Parents Should Know About the Different Vaping Devices* | Center on Addiction. [online] Centeronaddiction.org. Available at: <https://www.centeronaddiction.org/e-cigarettes/recreational-vaping/what-parents-should-know-about-different-vaping-devices> [Accessed 15 Dec. 2018].



Pen Kits

- Second generation of vaping devices



Devices, W. (2018). *What Parents Should Know About the Different Vaping Devices* | Center on Addiction. [online] Centeronaddiction.org. Available at: <https://www.centeronaddiction.org/e-cigarettes/recreational-vaping/what-parents-should-know-about-different-vaping-devices> [Accessed 15 Dec. 2018].



Mechanical Modified Nicotine Deliver System (MODs) Kits

- Third generation
- Longer battery life than previous devices
- Delivers higher amounts of nicotine as compared to previous devices



Devices, W. (2018). *What Parents Should Know About the Different Vaping Devices* | Center on Addiction. [online] Centeronaddiction.org. Available at: <https://www.centeronaddiction.org/e-cigarettes/recreational-vaping/what-parents-should-know-about-different-vaping-devices> [Accessed 15 Dec. 2018].



Electronic Hookah

➤ Third generation



Devices, W. (2018). *What Parents Should Know About the Different Vaping Devices | Center on Addiction.* [online] Centeronaddiction.org. Available at: <https://www.centeronaddiction.org/e-cigarettes/recreational-vaping/what-parents-should-know-about-different-vaping-devices> [Accessed 15 Dec. 2018].



Juul

- The term Juuling has resulted from its growing popularity among users
- Similar to a USB
- Marketed in various flavors
- Easy to carry and recharged





Smoking Cessation

- Vaping may be safer compared to smoking cigarettes and other combustible tobacco products
 - Evidence from studies supports that vaping has less toxic elements than combustible products
- Long term effects are not known yet as this is a new trend
- For the youth this is a problem because we are introducing nicotine at an early age and their brains are still developing
 - Creating an addiction to these devices
- Heavy smokers may need to consider bigger device and larger PG percentage



Smoking Cessation

- Vaping is not approved among the guidelines as an aid for quitting
- Methods to stop smoking
 - Counseling
 - Pharmacological
 - Nicotine replacement products
 - OTC
 - Prescription
 - Non-nicotine replacement medication
 - Zyban[®] (Bupropion SR)¹²
 - Chantix[®] (Varenicline tartrate)²



Smoking Cessation

- Nicotine Patches

Cigarette use	Week 1-6	Week 7-8	Week 9-10
≤ 10 per day	14 mg	7 mg	None
> 10 per day	21 mg	14 mg	7 mg

- Nicotine Gum

2 mg gum	4 mg gum
If 1 st cigarette smoked 30 minutes or later after waking up	If 1 st cigarette smoked within 30 minutes after waking up
Smoke < 25 cigarettes a day	Smoke > 25 cigarettes a day

Week 1-6	Week 7-9	Week 10-12
1 gum every 1 to 2 hours	1 gum every 2 to 4 hours	1 gum every 4 to 8 hours



Smoking Cessation

- Non-nicotine replacement medications
 - These agents serve as an aid to alleviate nicotine withdrawal symptoms and decreases the surges of dopamine, that is responsible for the reward associated with smoking

Drug	Day 1-3	After day 3
Zyban®	150 mg every morning	150 mg twice daily
Chantix®	0.5 mg daily	0.5 mg twice daily



Zyban[®] (Bupropion SR)¹²

- Side effects:
 - Xerostomia
 - Insomnia
 - Agitation
 - Headaches
- Black boxed warning:
 - Risk of suicidal thinking
- Contraindication¹²
 - Patients with seizure disorder
 - History of anorexia
 - Using within 14 days of discontinuing MAO inhibitors
 - Patients being treated with Zyvox[®] (Linezolid)



Chantix[®] (Varenicline tartrate)²

➤ Side effects:

- Nausea
- Insomnia
- Headache

➤ Dose adjustment²

- CrCl < 30 mL/minute initial: 0.5 mg once daily by mouth
- Max dose: 0.5 mg twice daily



Smoking Cessation

- Smoking is the leading cause of preventable death
 - 480,000 deaths per year in the US associated with smoking¹⁰
 - 6 million death per year world wide associated with smoking¹⁰
- Smoking of tobacco is linked to many health problems
 - Nicotine dependency
 - Cancer
 - Heart disease
 - Respiratory issues
 - Lung disease
 - Infertility in women



Quit Smoking

- Limited evidence that ENDS may be effective as an aid to promote smoking cessation
- No data to recommend vapes over approved products



Potential Harm of Vaping

- Bronchiolitis obliterans "Popcorn lung"
- Nicotine addiction
 - Not considered a carcinogen, but may lead to addiction to other tobacco products



Popcorn Lung



Judith Marcin, M. (2019). *Popcorn lung: Causes, symptoms, and treatment*. [online] Medical News Today. Available at: <https://www.medicalnewstoday.com/articles/318260.php> [Accessed 8 Jan. 2019].



Side Effects/Risks of Vaping

- Irritation to the eyes and throat
- Elevation of heart rate and blood pressure
- E-liquid poisoning if ingested
- Device battery explosions



Under 18 years of Age

- Evidence from the 2018 National Academies of Sciences, Engineering, and Medicine Report (NASEM) supported that the use of ENDS increases the risk of children and teenagers smoking tobacco
- Moderate evidence that ENDS use increases frequency and intensity of subsequent tobacco products



2nd Hand Smoking

- Less compared to combustible tobacco
- Vaping indoors increases the concentrations of particulate matter and nicotine in indoor environment



Public Awareness

- From the data it is apparent that vapes may be less harmful for adults that smoke, but this does not apply for children and adolescent
- According to the FDA many of adult smokers started at an early age⁵
 - 90% started before the age of 18
 - 95% started before the age of 21
 - 1% started after the age of 26



Data from the 2018 National Youth Tobacco Survey (NYTS)

- Information provided by a collaboration of the FDA and CDC
- The population of the survey were middle and high school students, regarding their use of ENDS⁵
 - 78% increase among high school students from 2017 to 2018
 - 48% increase among middle school students from 2017 to 2018
 - Total number of students using ENDS increased from 1.5 million to 3.6 million
 - 67.8% of those students used flavored ENDS



FDA

- FDA is aware of this alarming data and has created tools to address this problem
 - Launched a Youth Tobacco Prevention Plan
 - Launched the "The Real Cost" prevention campaign
 - Task force to crack down on retailers who are selling illegal ENDS to the youth
 - Partnered with Federal Trade Commission
 - Stricter flavoring policies for all flavored ENDS except for
 - Tobacco, mint, and menthol flavor



Take Home Points

- Use approved FDA methods for smoking cessation
- Long term effects of vaping is unknown
- Adolescents should avoid all tobacco and ENDS, as their developing brain does not benefit from nicotine



Questions





True or False

- The same therapeutic effects can be expected from CBD oil and THC.



Answer

X

• True

Correct

• False



True or False

- CBD oil has FDA approved indication for treating Dravet syndrome.



Answer

Correct

• True

X

• False



True or False

- Vaping does not cause addiction to nicotine.



Answer

X

• True

Correct

• False



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