U.S. FOOD & DRUG ADMINISTRATION

FDA Regulatory Roles and Initiatives for Controlled Substances

Annual Meeting of the National Association of State Controlled Substances Authorities (NASCSA)

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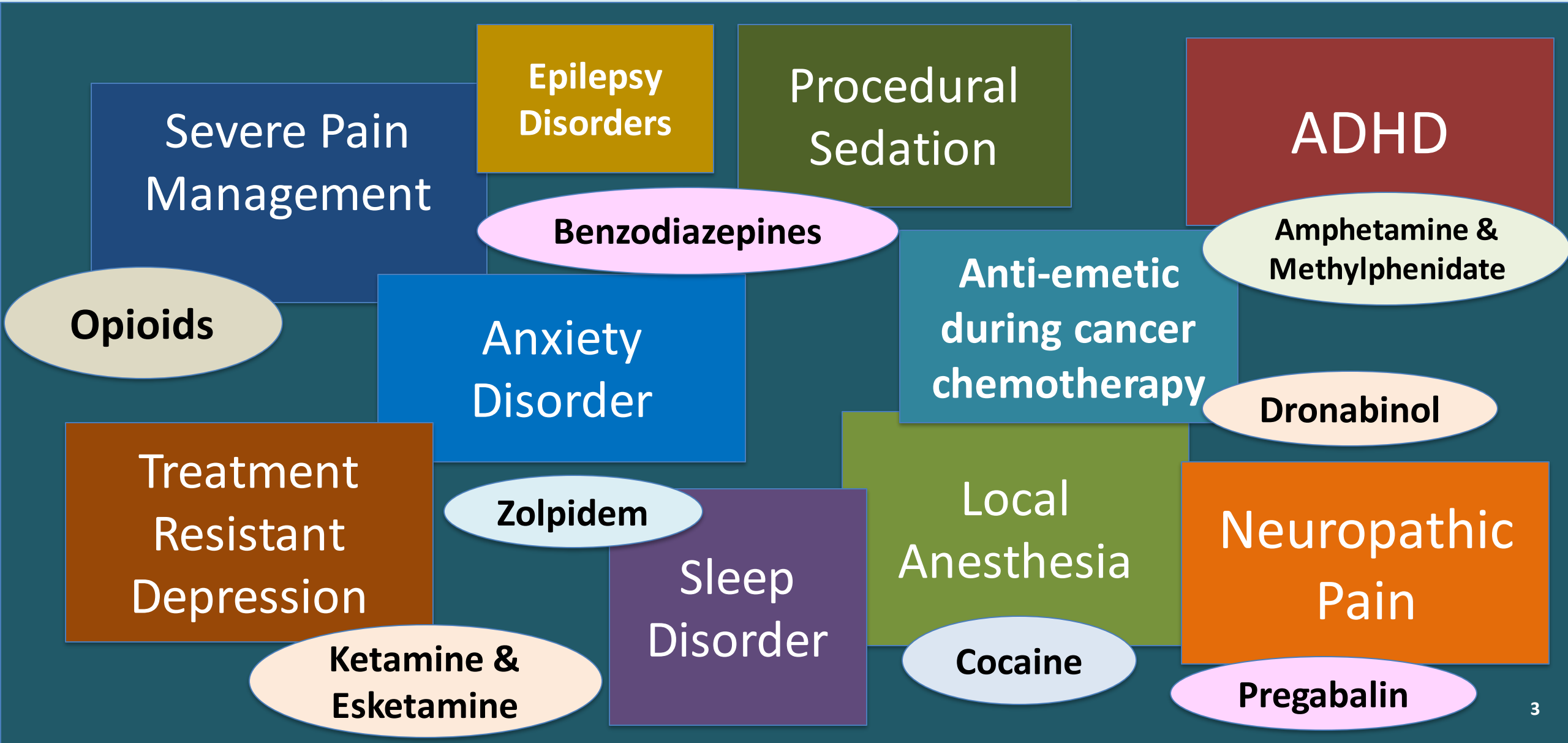
Dominic Chiapperino, PhD
Director, Controlled Substance Staff
Center for Drug Evaluation and Research
Food and Drug Administration

This presentation is intended to be informational.

Opinions expressed in this presentation are those of the author and do not necessarily reflect the views and policies of the FDA.

Vital Medications but Significant Abuse Liability Risks and Harms to Be Mitigated



Characteristics of Scheduled Drugs

Psychotropic effects…. In particular, euphoria and intoxication

Often used outside of medical supervision

Often used nonmedically at higher doses - Greater toxicities and risk of overdose

Habit forming – Craving and addiction – Impaired control over drug use

Continued use despite adverse health and social consequences

Physical dependence – Producing withdrawal syndrome upon discontinuation

The potential for substitution among drugs used nonmedically - Fluidity in people switching between nonmedical use of prescription drugs and illicit drugs producing similar effects

Goals of Imposing Drug Controls Through Drug Scheduling

To reduce drug abuse and harms by mitigating the risk of drug diversion from legitimate channels, i.e., approved medical uses and new drug research, to illicit channels

To create a regulated "closed system" across the drug supply chain to the end user

The Drug Enforcement Administration (DEA) is the regulator of this closed system implementing the CSA

To place a substance within one of multiple drug schedules, which permits varying degree of regulatory controls, and also of criminal penalties for unlawful drug possession, manufacturing, and distribution/trafficking, commensurate with drug abuse risks

To balance legitimate access to drugs relative to the risks of diversion and drug abuse-related harms

Hierarchy of Controls on Drugs of Abuse

International controls

Relevant international drug control treaties:

- 1961 Single Convention on Narcotic Drugs (poppy, coca, cannabis plants)
- 1971 Convention on Psychotropic Substances (synthetic substances)

Federal controls in the U.S.

The Controlled Substances Act (CSA) provisions dictate domestic controls placed on drugs of abuse

- Required to keep the U.S. compliant with treaty obligations

State-level controls

Can be more stringent than federal controls but should not be less stringent.

The Schedules Under the Federal CSA

CRITERIA					
Abuse Potential	High	High	Low relative to CII	Low relative to CIII	Low relative to CIV
No Medical Use		Medical Use			
Lack of accepted safety under medical supervision		Psychological or Physiological Dependence			
		Severe Psych or Physical	High Psych or Moderate to low Physical	Ltd Psych or Physical relative to CIII	Ltd Psych or Physical relative to CIV

SCHEDULES	SCHEDULE I	SCHEDULE II	SCHEDULE III	SCHEDULE IV	SCHEDULE V
	Heroin Hallucinogens Marijuana Others	Opioids Barbiturates Cocaine Amphetamine Methylphenidate Methamphetamine PCP	Opioids (Codeine combinations, Buprenorphine) Barbiturates (combinations and products) Ketamine GHB Marinol Anabolic Steroids	Benzodiazepines and other depressants (Zaleplon, Zolpidem, Eszoplicone) Fenfluramine Modafinil Butorphanol Tramadol	Opioids in limited quantities and in combinations (Codeine, Dihydrocodeine, Difenoxin) Pregabalin Lacosamide

Relevant Classes of Scheduled Drugs

- Opioids
- Depressants
- Stimulants
- Hallucinogens
- Cannabinoids

CNS-active, rewarding effects

- Anabolic Steroids ← Desired physiological effects

Some of FDA's Regulatory Roles Relating to Controlled Substances

Ensure that abuse potential and dependence are investigated during IND stage, receiving full data package with NDA Submission

Approval of new Rx-only medications, and surveillance of use in post-market setting, for accurate labeling as to abuse liability

Utilize other tools to address drug safety and risks in post-market setting (REMS, PMRs, Enforcement actions)

Conduct "scientific and medical evaluations" of drugs to support the drug scheduling actions of DEA

Federal Drug Scheduling and FDA's Role

What other federal agencies have roles in the drug scheduling process?

What are the different pathways for drug scheduling placements, changes, or decontrol actions?

When is a scientific and medical evaluation required to support such actions? (Also known as an Eight Factor Analysis, or 8FA)

What circumstances can trigger a new 8FA for drug scheduling considerations?

Major Agency Roles for Scheduling Under the CSA

- Roles for the Department of Justice (DOJ) and Department of Health and Human Services (HHS)
  - Most DOJ roles (of the "Attorney General") are delegated to the DEA Administrator
  - Most HHS roles (of the "Secretary") are delegated to the Assistant Secretary of Health (ASH), and some further delegated to the FDA Commissioner
  - Some FDA responsibilities are delegated to CDER's Controlled Substance Staff (CSS), e.g., in drafting the Eight Factor Analysis (8FA)
  - In Drafting an 8FA, FDA will also consult with the National Institute on Drug Abuse (NIDA), and seek their concurrence on documents
  - The Office of the Assistant Secretary for Health is designated the signatory role within HHS to transmit scheduling recommendations to DEA

Possible Scheduling Actions Under the CSA

- **Addition/Placement** of a drug to one of the schedules (I, II, III, IV, or V)
  - Most common scheduling action, new approval or new street drug
- **Transfer/Rescheduling** of a drug from one schedule to another
  - E,g., hydrocodone combinations C-III to C-II; methaqualone C-II to C-I
- **Removal/Decontrol** of a drug from scheduling under the CSA
  - Naloxone (Narcan)
  - Naltrexone
  - Naldemedine

Opioid derivatives in C-II, but mu opioid antagonists with no abuse potential, all were evaluated under 8FAs and decontrolled

Different Pathways for Drug Scheduling

1) **New Legislation by Congress:** To alter controls or place new substances into control status
   - E.g., original CSA in 1970; anabolic steroids placed in Schedule III; cannabimimetic agents placed in Schedule I

2) **Temporary Scheduling Orders by DEA:** For a 2-year period, for an emergent substance with "imminent hazards to public safety" [21 U.S.C. 811(h)]
   - Permits time to evaluate the drug in an 8FA for a permanent action

3) **Permanent Scheduling Orders by DEA:** To achieve treaty compliance with drugs placed in a schedule of the 1961 Single Convention on Narcotic Drugs
   - Recently done for isotonitazene, an emergent, potent synthetic opioid

4) **Administrative Drug Scheduling Process:** Involves conducting an 8FA
   - Major roles for FDA, NIDA, HHS, DEA, and culminates in DEA rulemaking

8FAs in Administrative Drug Scheduling

- The 8FA process can be initiated by HHS and its agencies
  - Such as by FDA, e.g., when a new drug application (NDA) is under review for a new active ingredient with abuse potential that may warrant controls
- Can be initiated by DEA, for emerging street drugs
  - Often the case for DEA to request an 8FA from HHS for substances DEA has already temporarily controlled in Schedule I with an "order"
- Can be triggered by a petitioner, requesting a change in drug's control status
  - E.g., Cannabis rescheduling petitions to move cannabis out of Schedule I. Responses to petitions by DEA in 2016 were to deny petitions and maintain "Marihuana" in Schedule I

Statutory Basis for the 8FA Initiated Within FDA

For the administrative drug scheduling process requires HHS to conduct a "scientific and medical analysis" (a role delegated to FDA) by considering these Eight Factors [listed in 21 U.S.C. 811(c)]:

1. Actual or relative potential for abuse
2. Scientific evidence of pharmacological effect
3. Current scientific knowledge regarding the substance
4. History and current pattern of abuse
5. Scope, duration, and significance of abuse
6. Risk to public health
7. Psychic or physiological dependence liability
8. Immediate precursor of a substance already controlled

Data Typically Available for an 8FA

Type of Data	Drug Development	Emerging Street Drug
Chemical structure, synthesis	✓ Sponsor	✓ DEA, industry, online forums, or literature
Receptor binding/functional assays	✓ Sponsor	✓ DEA or literature
Animal drug discrimination	✓ Sponsor	✓ DEA or literature
Animal self-administration	✓ Sponsor	✓ DEA or literature
Human abuse potential study	✓ Sponsor	[rarely, literature]
Clinical program adverse events	✓ Sponsor	[rarely]
Medical use	✓ Sponsor	[rarely]
Actual abuse, harms	✓ Sponsor, DEA, or literature	✓ DEA, FDA/CDER/OSE, or literature
Trafficking/DEA seizures	[rarely, DEA]	✓ DEA or literature
Dependence/addiction	✓ Sponsor, literature	[rarely, literature]

A Definition of "Abuse Potential" Central to Drug Scheduling Decisions

In FDA's guidance for industry:

"Drug Abuse" is defined as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect.

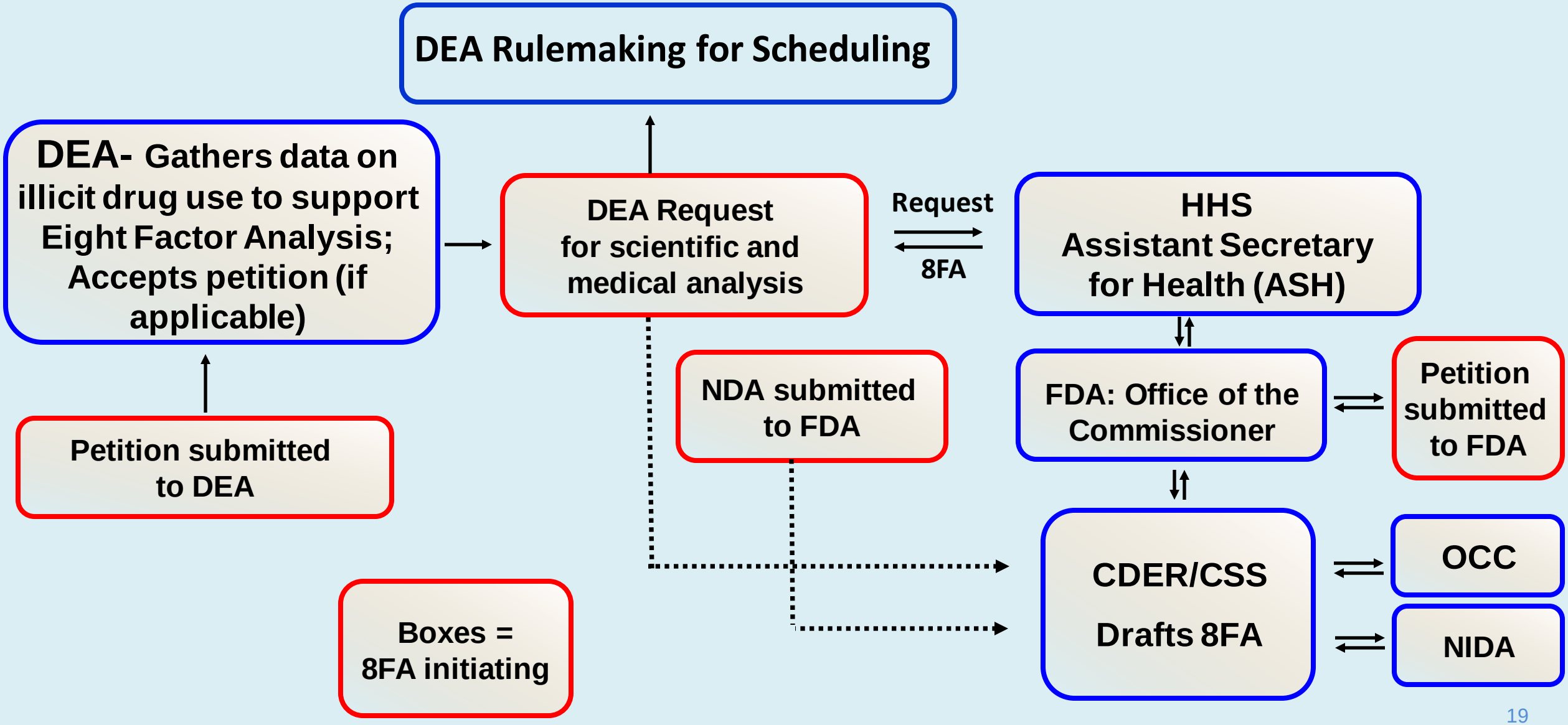
Therefore, *"abuse potential"* refers to the likelihood that abuse will occur with a particular drug product or substance with central nervous system (CNS) activity.

Examples of such psychoactive CNS effects include euphoria, hallucinations, and changes in mood.

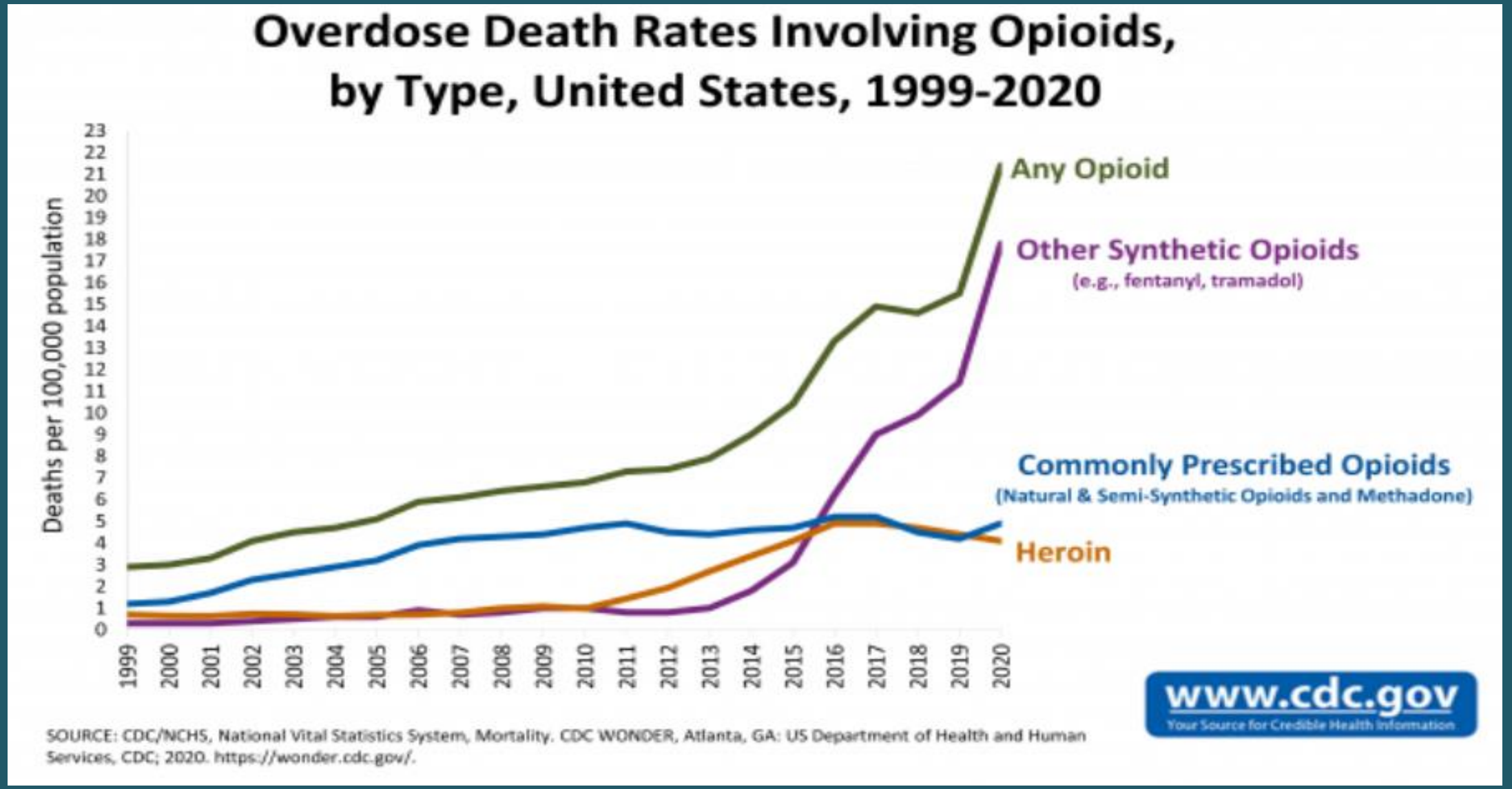
HHS Scheduling Recommendations to DEA

- From evaluation of data under the eight factors, HHS will make these three findings necessary for the overall scheduling recommendation to DEA
  1. The degree to which the drug has abuse potential
  2. Whether there is a currently accepted medical use of the drug or substance in the U.S.
  3. Safe use under medical supervision, or degree of dependence liability
- DEA will carry out the scheduling action through notice and comment rulemaking, published in the Federal Register
- The Secretary's recommendation to DEA is binding with respect to scientific and medical findings, and DEA "shall not" control a drug for which HHS has concluded does not have abuse potential to warrant control

Summarizing the Inter-Agency Administrative Drug Scheduling Process



The Opioid Abuse and Overdose Epidemic

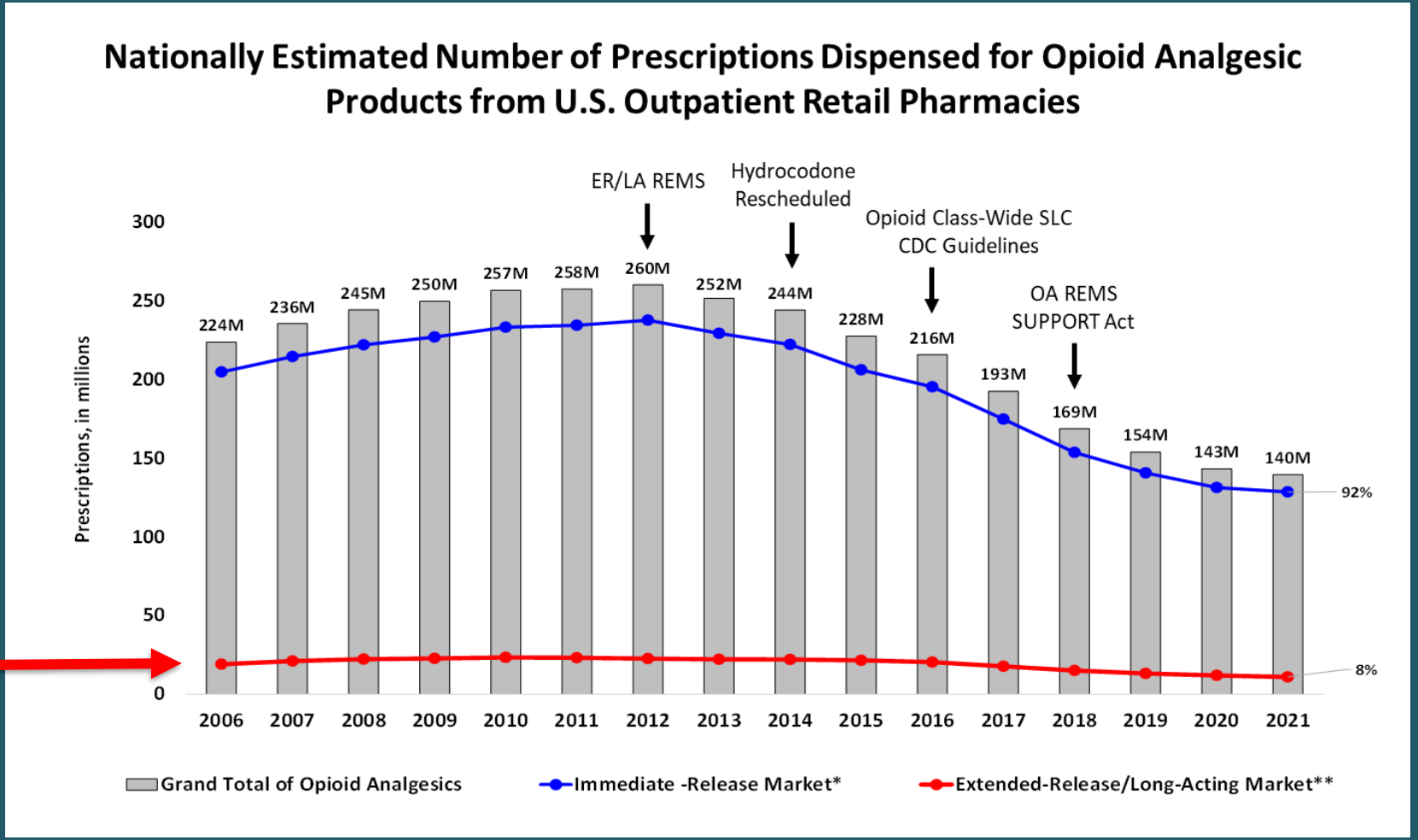


Snapshot of Opioid Prescribing

Dispensing of opioid analgesics peaked in 2012

Since 2012, steady decline in number of opioid prescriptions

ER/LA opioid analgesics (incl. OxyContin) account for a small fraction of total opioid analgesic prescriptions dispensed



IQVIA, National Prescription Audit (NPA). January 2006-December 2021. Includes opioid analgesics only, excluding injectable formulations as well as opioid-containing cough-cold products and opioid-containing products for opioid use disorder (OUD).

HHS Overdose Prevention Strategy

Prevention **Harm Reduction** **Treatment** **Recovery**

Primary Prevention

Preventing substance use disorder is the first step towards addressing overdoses. Learn about effective prevention programs and safe prescribing practices.

Harm Reduction

Harm reduction is critical to keeping people who use drugs alive and as healthy as possible. Read the research and reduce stigma.

Evidence-Based Treatment

When a person is ready, high-quality treatment must be available without delay. Help improve access to treatment.

Recovery Support

Recovery support services can lead to better long-term outcomes, especially when available in communities where they are needed. Explore different types of recovery services.

FDA's Current Focus in Combatting Opioid-Related Harms

Changing prescriber behavior for opioids

Considering ways to expand access to opioid overdose reversal agents

Implement SUPPORT Act Sec. 3032 on disposal and packaging solutions

Considering new authorities for opioid approvals and alternatives

Work with federal partners, such as DEA, to reduce illicit opioid supply

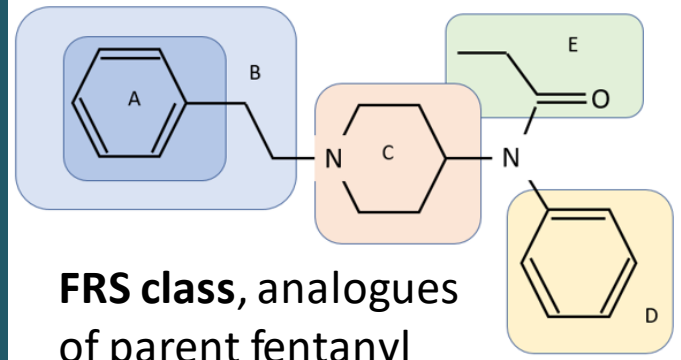
Synthetic Illicit Opioids' Contribution to Overdose Numbers

Rise in opioid-involved overdoses and deaths appear to be linked to fentanyl, fentanyl analogues, and other synthetic opioids, e.g., 2-benzylbenzimdazole class

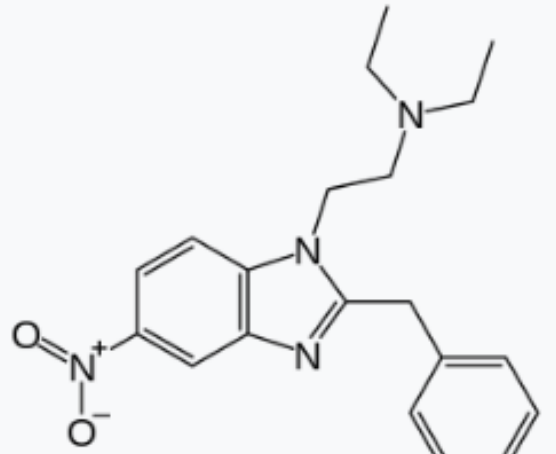
DEA's 2018 temporary order to control "fentanyl-related substances" (FRS) as a class in schedule I is still in effect.

Congress has extended the schedule I status of the FRS class through 2022

FDA's role in drug scheduling conducting 8FAs has assisted DEA in placing dozens of synthetic opioids, mainly FRS, in schedule I Evaluations of new emergent substances are ongoing.



FRS class, analogues of parent fentanyl



Etonitazene, an example of the 2-benzyl benzimidazole class

Abuse Potential Assessment in the Context of Drug Development and NDA Submissions

- Sponsors of INDs are advised when and how to collect necessary data characterizing abuse potential and dependence as elements of a drug's safety profile
- Under 21 CFR § 314.50 (d) (5) (vii), if potential for abuse exists, the NDA submission must include:
  - All data and information relevant to the abuse potential of the drug
  - A proposal for scheduling under the CSA
  - Data related to drug overdose
- These requirements apply equally to…
  - CNS-active new molecular entities
  - Reformulated products or new indications of a controlled substance
  - A schedule I substance in drug development, would need rescheduling to a schedule reflecting medical use
- For new drug approvals, appropriate scheduling and labeling must be determined prior to marketing

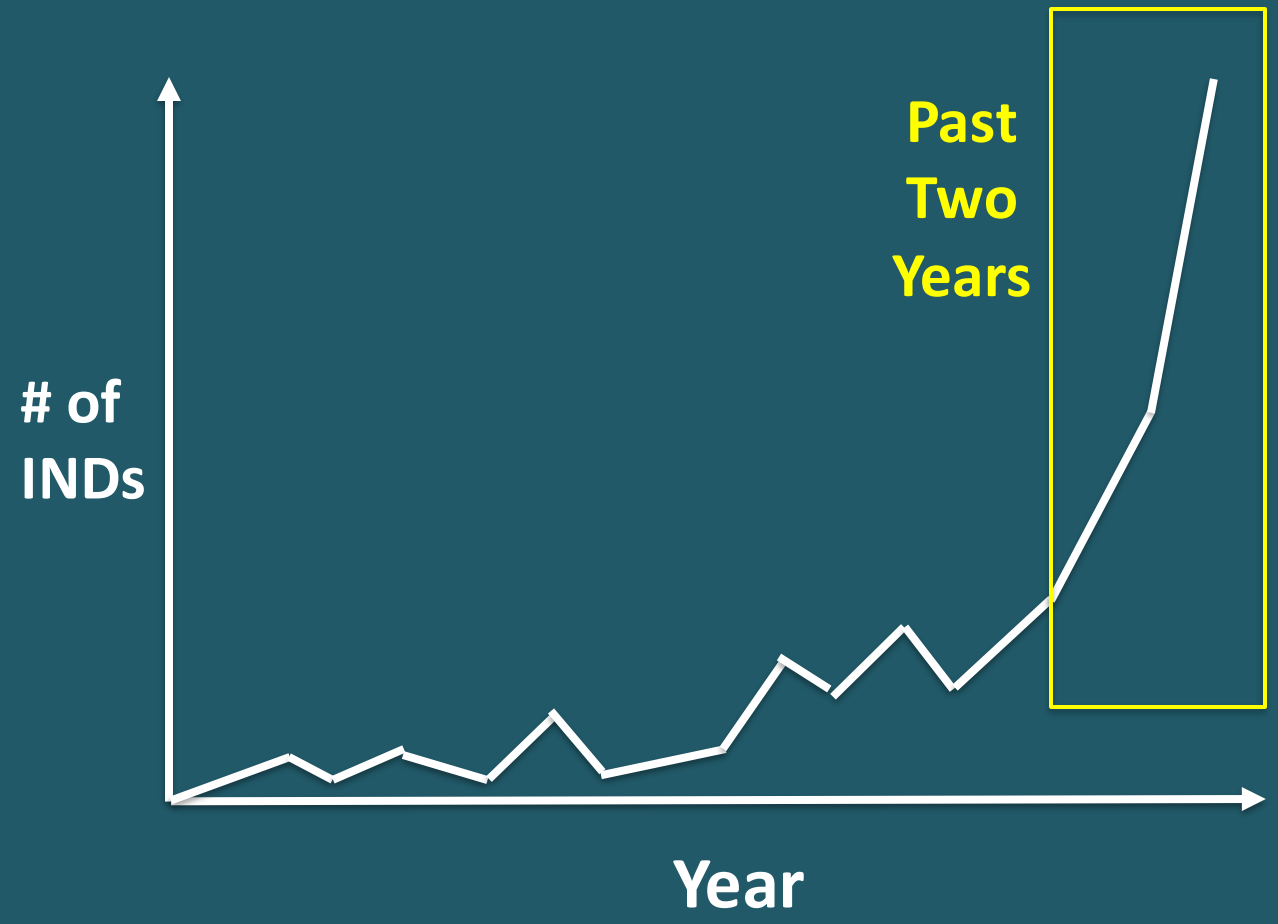
IRTNMTA Legislation (2015) Ensures Drug Scheduling Is Complete Soon After NDA Approval

Improving Regulatory Transparency for New Medical Therapies Act

- Applies for new drug approvals for which a drug scheduling action by DEA is needed prior to drug marketing [New sections 505(x) of FD&C Act, and 201(j) of the CSA [21 U.S.C. 355(x) & 811(j)]
- Provides that DEA shall have not more than 90 days to issue an (interim) final rule describing its scheduling action, counting from the latter of:
  - The date on which HHS transmitted scheduling recommendations to DEA for the drug
  - The date on which FDA notified DEA that it has approved the NDA
- The date of DEA's rulemaking in the Federal Register establishes the "effective" date of approval
- After the interim final rule, the NDA applicant must update product labeling reflecting control status, then can market
  - Done via supplementary NDA submission, as CBE-0 supplement (not "prior approval")

A Timely Example: Psychedelics in Drug Development

In recent years, classic hallucinogens and entactogens have been of increasing interest for drug development, reflected in dramatic increase of Investigational New Drug (IND) applications submitted to FDA. See also ClinicalTrials.gov



These psychedelic drugs include mainly **psilocybin, LSD, MDMA**, and several others, all of which are currently **schedule I controlled substances**

Indicated uses being studied are mainly psychiatric conditions

Example indications include:

- Depression-related (e.g., MDD, TRD)
- PTSD
- Anxiety disorder

Some Reports of Preliminary Study Findings are Positive

Two drugs receiving the most public attention in recent years are **psilocybin**, a classic hallucinogen and 5-HT_{2A} receptor partial agonist, and the entactogen, **MDMA**

- Discussion of some clinical trial findings in a well-regarded publication in 2019, titled:

"Psychedelics and Psychedelic-Assisted Psychotherapy"

Reiff, C. M., et al. (2019) American Journal of Psychiatry, 177(5), 391-410.

MDMA for PTSD

- In two double-blind, controlled trials (n=23 and n=26) MDMA demonstrated significant reduction in severity of symptoms of PTSD

Psilocybin for cancer-related anxiety and depression

- In three clinical trials (n = 12, 51, and 29), sustained benefits were observed, including at 6 months out from treatment.
- For example: reductions in anxiety, depression, existential distress; improved quality of life and attitudes toward death

Psychedelics Involve Some Unique Considerations

Clinical trial design and conditions of investigational use of psychedelics have some particular challenges and considerations for safety:

- Not well-understood dose-response relationship
  - Applies to both efficacy and safety
- Need to understand durability of response to inform timeframe for repeat dosing, and the effectiveness of subsequent doses relative to initial doses
- Need for monitoring during drug treatment session, with well-qualified lead monitor and assistant monitor. Additionally, a licensed physician must be on call and able to reach the clinical site within 15 minutes in the event of a physiological or psychiatric emergency.
- Need to conduct trials that will help determine appropriate treatment conditions postmarketing, with a REMS if necessary to address identified safety concerns

Risk Evaluation Mitigation Strategies (REMS)

- FDA can require a REMS for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks
- Focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of the event
- REMS are *not* intended to assure effectiveness

Risk Evaluation Mitigation Strategies (REMS)

- Product specific
- Most include a communication component about the specific safety risk or risks that the REMS is intended to mitigate
- Some include additional requirements such as clinical activities that the health care providers may need to perform prior to prescribing or dispensing a medication to the patient
- **Must not be "unduly burdensome** on patient access to the drug" and, to the extent practicable, must "**minimize the burden** on the health care delivery system"

REMS Considerations

- What are the drug product's risks to patients?
- Does the current system support safe use given those risks?
- What are the care gaps?
- For what setting will this product be prescribed?
- How does the drug's intended use fit in the current system of care?

Care Gaps Associated with Psychedelics

- Clinical use of psychedelics may represent a new treatment paradigm
    - Limited knowledge of how to use psychedelics safely
    - Limited knowledge of specific training for psychotherapy
    - Limited resources, guidelines, policies and procedures in place in post marketing setting for either psychedelics or psychotherapy

Abuse Potential Assessment and Drug Scheduling Considerations For Psychedelics

As described in the 2017 FDA guidance for industry: *Assessment of Abuse Potential of Drugs*, the data that are evaluated to determine abuse potential include:

- Chemistry
- Receptor binding and functional studies
- Animal drug discrimination and self-administration behavioral studies
- Animal and human physical dependence studies
- Human adverse events in clinical trials
- Human abuse potential (HAP) study
- Epidemiological data (when available)

Generally, Three Key Dedicated Studies for the Abuse Potential Assessment

- **Animal drug discrimination study**

  Determines whether an animal, trained to recognize the effects of a known drug, signals (through pattern of lever pressing) that the investigational drug causes similar effects

- **Animal self-administration study**

  Demonstrates (through pattern of lever pressing) whether the drug induces rewarding effects such that the animal wants to self-administer the drug

- **Human abuse potential (HAP) study**

  Conducted in recreational drug users. Compares investigational drug to appropriate positive comparators (known drugs of abuse), and to placebo, to determine the "likeability" and other subjective effects of the drug indicative of its relative potential for abuse

Results from these studies are usually highly influential to scheduling recommendations and would be described under Factor 2

Abuse Potential Assessment and Drug Scheduling Considerations For Psychedelics

For drugs like psilocybin and MDMA:

- There is already extensive scientific literature from preclinical research on chemistry, receptor binding/functionality, and animal drug discrimination
- There is likely not a need for commercial sponsors to replicate these preclinical abuse-related studies
- It is also unlikely that a HAP study will be required for psilocybin, MDMA, and other schedule I psychedelics known to be abused
- Adverse events, other measures of hallucinogenic effects, and analyses of epidemiological data will be important for the abuse potential assessment data package in an NDA submission

Abuse Potential Assessment and Drug Scheduling Considerations For Psychedelics

- New molecular entities not as well-studied as classic psychedelics would require more comprehensive data collection, consistent with the Guidance
- Only following a new drug approval can a schedule I drug be rescheduled to reflect an accepted medical use, i.e., placed in schedule II, III, IV, or V
- All studies conducted with schedule I substances have DEA registration requirements for investigators, including for "Research Protocols" under 21 CFR 1301.18 and 1301.32
    - We have been down this same path before for other drug development... FDA approval of EPIDIOLEX (cannabidiol (CBD) oral solution) in 2018, was controlled in schedule I prior to its approval

An Update on FDA's Regulation of Cannabis-Derived Products (CDPs)

Important policy elements:

- Protecting the public from fraudulent products with unproven disease claims (which could result in patients foregoing proven treatments)
- Protecting the public from harmful products
- Protecting the integrity of the food supply
- Incentivizing rigorous scientific research to support beneficial therapies (through requiring NDAs)
  - Fast Track or Breakthrough Therapy designations, and "priority" NDA reviews

Continuing Impact of the Agriculture Improvement Act of 2018 (a.k.a, the Farm Bill)

The Farm Bill…

- **Removed hemp from the definition of marijuana** in the Controlled Substances Act (CSA)
  - Hemp: defined as cannabis (*Cannabis sativa* L.), and derivatives of cannabis, with not more than 0.3 percent on a dry weight basis of delta-9 tetrahydrocannabinol (delta-9-THC)
- Cannabis and derivatives not excluded from CSA's definition of "Marihuana" (e.g., as "hemp") are still regulated by DEA under Schedule I of the CSA
- CDPs proliferate in the marketplace, including CBD products, most of which are unlawful if introduced into interstate commerce

FDA Drug Authorities Applied to CDPs

Under the FD&C Act:

- Any product, **including a cannabis product (hemp or otherwise)**, that is marketed **with a claim of therapeutic benefit, or with any other disease claim, is considered to be a drug if…**

  "…intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or is an "article (other than food) intended to affect the structure or any function of the body of man or other animals." Refer to section 201(g) of the Federal Food Drug and Cosmetic Act

- **A new drug must be approved by the FDA for its intended** use before it may be introduced into interstate commerce

Food and dietary supplement authorities: Δ9-THC (dronabinol) and CBD are active ingredients in approved drugs

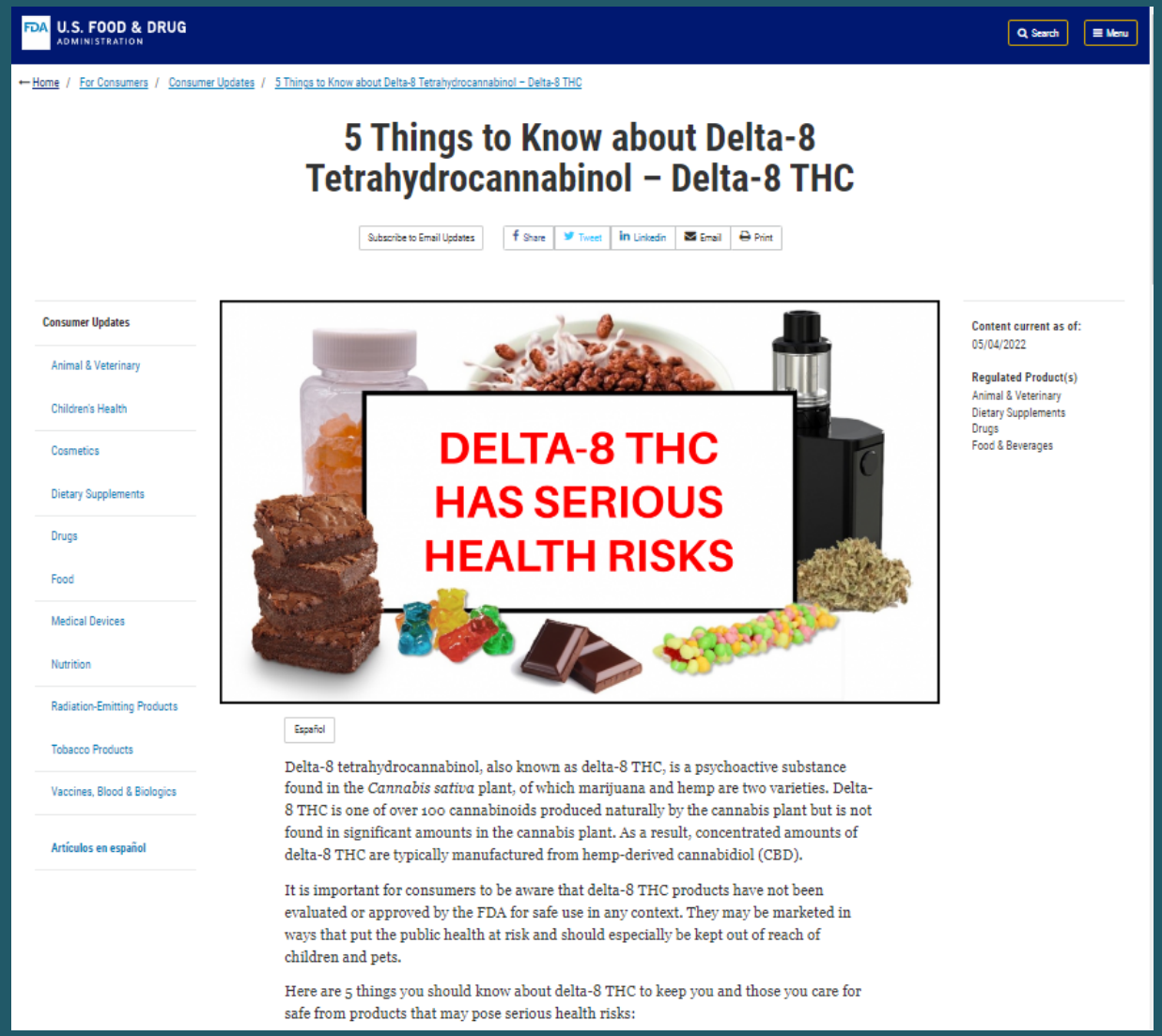
- Sec. 301(ll) of the FD&C Act (21 U.S.C. § 331)- paraphrased
  - It is **prohibited** to introduce into interstate commerce any food that contains an active ingredient (such as **Δ9-THC or CBD**) in an approved drug product or in a potential drug for which substantial clinical investigations have been instituted and made public.
- CBD and Δ9-THC **cannot** be added to foods under the FD&C Act
  - This prohibition applies regardless of whether the substances are hemp-derived
- CBD and Δ9-THC products **are also excluded** from the definition of dietary supplements under FD&C Act Section 201(ff)(3)(B)(i) and (ii)
- Enforcement actions taken as necessary against violative CBD products or other CDPs, particularly those that present serious human or animal health risks

Unknown safety of other plant-derived cannabinoids

There are many **minor cannabinoids in hemp cannabis**, of relatively low abundance, e.g., **Δ8-THC,** *but manufacturing methods can lead to greatly enhance levels*

- Products are now in the marketplace with **unnaturally high concentrations of some cannabis constituents**
- There is a **lack of prior experience or demonstrated safety** for human exposure to extremely **enhanced concentrations** of minor cannabinoids
- There are a substantial number of reports of adverse events, some attributed to **intoxicating psychoactive effects (often unexpected)** , such as with Δ8-THC

Enforcement and Safety Alerts on Δ8-THC, Other CDPs



Consumer Update, March 2022

Five things to know about Δ8-THC….

1. Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put the public health at risk.
2. The FDA has received adverse event reports involving delta-8 THC-containing products.
3. Delta-8 THC has psychoactive and intoxicating effects.
4. Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.
5. Delta-8 THC products should be kept out of the reach of children and pets.

Enforcement and Safety Alerts on Δ8-THC, Other CDPs

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FDA NEWS RELEASE

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products

Violations Include Marketing Unapproved New Drugs, Misbranding, Adding Delta-8 THC to Food Products

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More Press Announcements

For Immediate Release: May 04, 2022

Content current as of: 05/04/2022

Español

Today, the U.S. Food and Drug Administration issued warning letters to five companies for selling products labeled as containing delta-8 tetrahydrocannabinol (delta-8 THC) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). This action is the first time the FDA has issued warning letters for products containing delta-8 THC. Delta-8 THC has psychoactive and intoxicating effects and may be dangerous to consumers. The FDA has received reports of adverse events experienced by patients who have consumed these products.

There are no FDA-approved drugs containing delta-8 THC. Any delta-8 THC product claiming to diagnose, cure, mitigate, treat, or prevent diseases is considered an unapproved new drug. The FDA has not evaluated whether these unapproved drug

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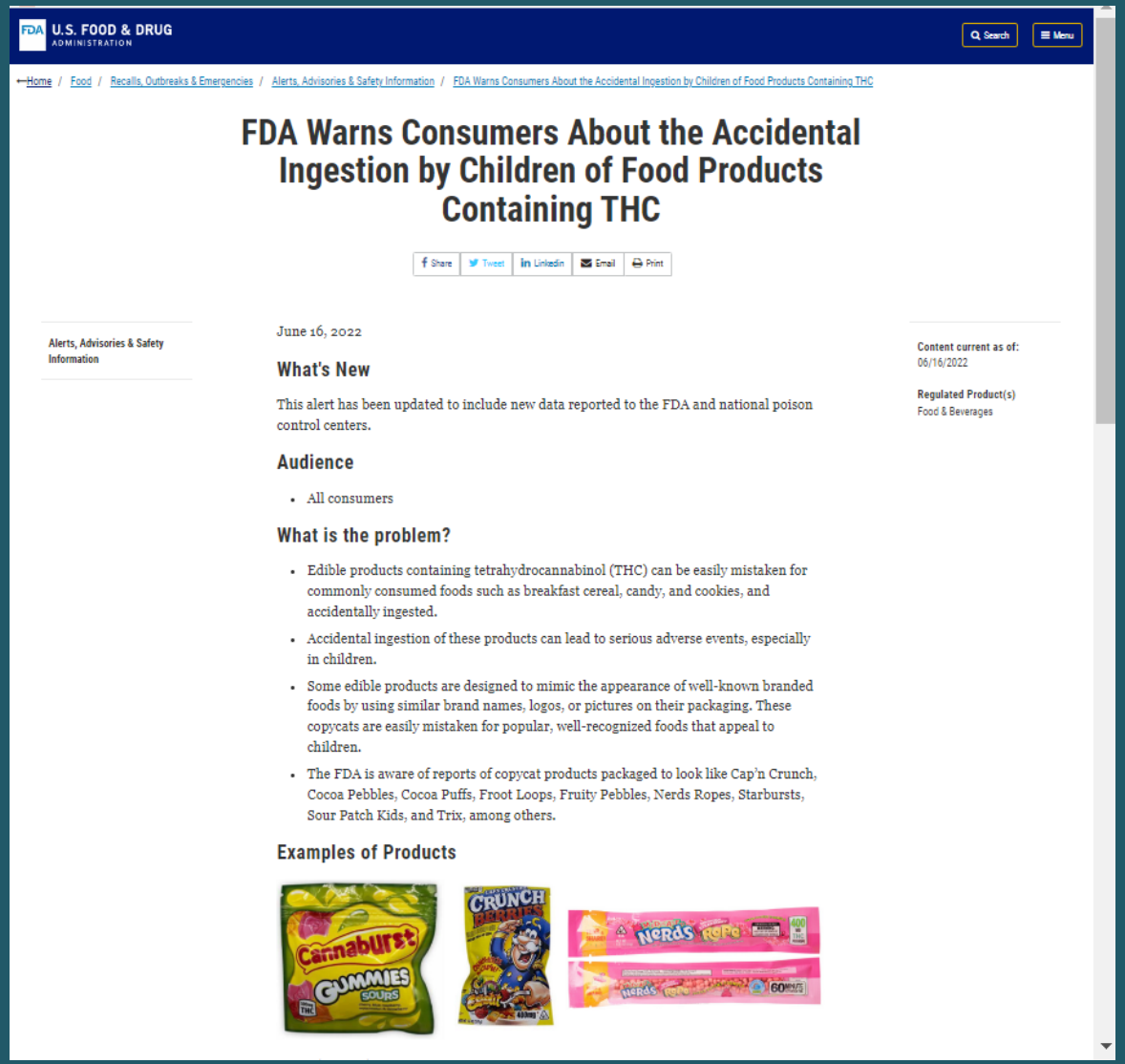
Warning Letters issued May 4, 2022, on Δ8-THC Products

"The FDA is very concerned about the growing popularity of delta-8 THC products being sold online and in stores nationwide. These products often include claims that they treat or alleviate the side effects related to a wide variety of diseases or medical disorders, such as cancer, multiple sclerosis, chronic pain, nausea and anxiety," said FDA Principal Deputy Commissioner Janet Woodcock, M.D. "It is extremely troubling that some of the food products are packaged and labeled in ways that may appeal to children. We will continue to safeguard Americans' health and safety by monitoring the marketplace and taking action when companies illegally sell products that pose a risk to public health."

Enforcement and Safety Alerts on Δ8-THC, Other CDPs



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FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC

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Alerts, Advisories & Safety Information

June 16, 2022

Content current as of: 06/16/2022

Regulated Product(s): Food & Beverages

What's New

This alert has been updated to include new data reported to the FDA and national poison control centers.

Audience

- All consumers

What is the problem?

- Edible products containing tetrahydrocannabinol (THC) can be easily mistaken for commonly consumed foods such as breakfast cereal, candy, and cookies, and accidentally ingested.
- Accidental ingestion of these products can lead to serious adverse events, especially in children.
- Some edible products are designed to mimic the appearance of well-known branded foods by using similar brand names, logos, or pictures on their packaging. These copycats are easily mistaken for popular, well-recognized foods that appeal to children.
- The FDA is aware of reports of copycat products packaged to look like Cap'n Crunch, Cocoa Pebbles, Cocoa Puffs, Froot Loops, Fruity Pebbles, Nerds Ropes, Starbursts, Sour Patch Kids, and Trix, among others.

Examples of Products

Safety Alert on June 16, 2022

THC-containing edibles as "copycat" products of well-known food brands

"The FDA is aware of multiple media reports describing children and adults who accidentally consumed copycat edible products containing THC and experienced adverse events…"

"In addition, national poison control centers received 10,448 single substance exposure cases involving only edible products containing THC between January 1, 2021, and May 31, 2022. Of these cases, 77% involved patients 19 years of age or younger. Of the total cases, 65% involved unintentional exposure to edible products containing THC and 91% of these unintentional exposures affected pediatric patients…"

In Conclusion…

- Controlled substances pose serious challenges in mitigating risks of abuse, misuse, addition, physical dependence and withdrawal-related adverse effects
- FDA is committed to protect and promote the public health with respect to CDPs, controlled substances, or other products possessing similar drug effects
- We will continue to use our authorities and regulatory programs under the FD& C Act to promote better and safer new medicines and manage risks of approved products to ensure that benefits to patients outweigh drug risks
- We will exercise our roles under the CSA to help mitigate drug abuse and diversion risks

Thank you for your attention

Questions?