



A Legal Analysis for Safe Supply in the US

PRESENTED BY:
Dari Pogach and Erin Russell



Land Acknowledgement

We stand on the lands of the Chehalis, Chinook, Colville, Cowlitz, Duwamish, Hoh, Jamestown S’Klallam, Kalispel, Lower Elwha Klallam, Lummi, Makah, Muckleshoot, Nisqually, Nooksack, Port Gamble S’Klallam, Puyallup, Quileute, Quinault, Samish, Sauk-Suiattle, Shoalwater Bay, Skokomish, Snoqualmie, Spokane, Squaxin Island, Stillaguamish, Suquamish, Swinomish, Tulalip, Upper Skagit, Wanapum, and Yakama tribes.





AGENDA

- » Land Acknowledgement
- » Agenda Review
- » Introductions
- » Public Comment
- » Personal Stories from the Field
- » Introduction to Recording the Presentations
- » Presentation: Dari Pogach
- » Next Steps

MEMBER INTRODUCTIONS

- Name
- Pronouns (*optional*)
- Affiliation



HMA TEAM



Charles Robbins, MBA

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PUBLIC COMMENT

- » The workgroup meetings of the Safe Supply Work Group are not subject to the WA Open Public Meetings Act
- » Members have requested the ability for non-members to participate, but in listen mode only
- » We would like to offer 5 minutes for public comment at this time. Please be respectful and brief in your remarks.
- » Please know that future meetings may be closed at the discretion of membership
- » Members may request a link to view recordings of missed meetings. Presentation PDFs will be shared with members after the meeting.

PERSONAL STORIES FROM THE FIELD

>> Speaker: Chelsea

RECORDING

The presentation will
be recorded at this
time



PRESENTER



Dari Pogach

(she/her)

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HMA

Dari Pogach has more than 15 years of experience working with clients, communities, nonprofit organizations, policy makers, and state and national government leaders.

As an attorney, Dari advocated for individual clients and worked on local and national reform efforts to improve access to self-directed, high-quality supports and services.

Dari began her career as a legal services attorney and represented clients as they navigated complex and bureaucratic social services systems to access crucial services and supports. She approaches her work with the passion of an advocate and a commitment to achieve the best possible outcomes for her clients and the populations they serve.

LEARNING OBJECTIVES

1

Identify the federal laws, regulations, and rules that prohibit substances from being used as safe supply

2

Examine the laws and regulations for opportunities to advocate for safe supply legality

3

Understand the agencies responsible at the federal and state level for overseeing laws and regulations that restrict safe supply

BIG PICTURE

SAFE SUPPLY MODALITIES

Prescription injectable opioid agonist treatment (not currently available in the US):

1. Injectable hydromorphone
2. Injectable diacetylmorphine

Prescription opioids (available in the US but not for OUD treatment):

1. Hydromorphone tablets (Dilaudid)
2. Fentanyl patches
3. Slow release oral morphine

Prescription full agonist opioids available for OUD treatment in US but limited access:

1. Oral methadone

BIG PICTURE VIEW

1. The DEA regulates controlled substances into one of five schedules.
2. The FDA may approve a drug on Schedules II to V for medical purposes.

Currently, injectable hydromorphone and injectable diacetylmorphine are Schedule I drugs that could not be approved in any circumstances.

Hydromorphone tablets (Dilaudid), fentanyl patches, and slow release oral morphine are on Schedule II and are not approved for OUD treatment. (Oral methadone is on Schedule II and is approved for OUD treatment.)

HISTORICAL CONTEXT - ENSHRINED ATTITUDES – 1979 INTRO TO CSA

- Substance abuse is at the core of other problems, such as rising violent teenage and violent gang crime, increasing health care costs, HIV infections, teenage pregnancy, high school dropouts, and lower economic productivity.
- Increases in substance abuse among youth are due in large part to an erosion of understanding by youth of the high risks associated with substance abuse, and to the softening of peer norms against use.
- Substance abuse is a preventable behavior and a treatable disease

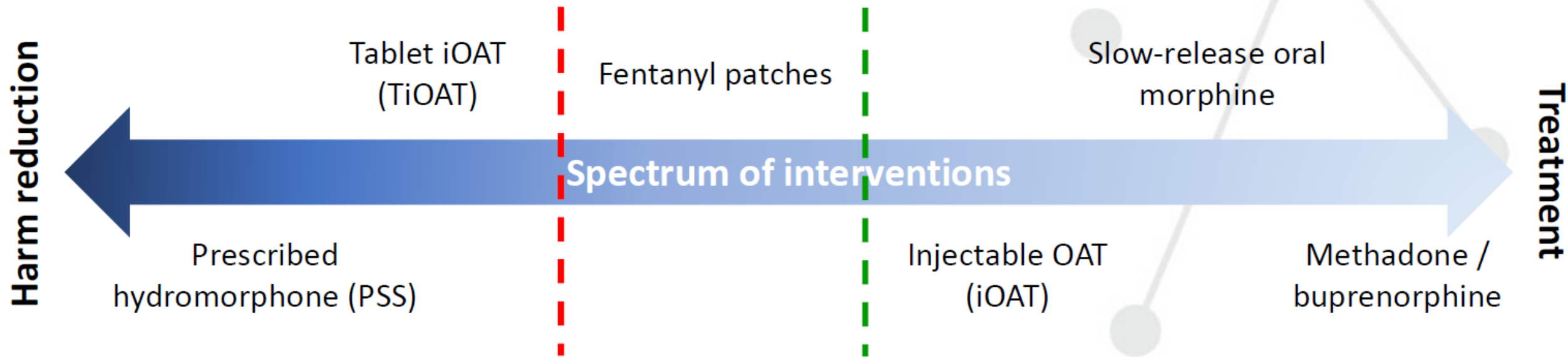
HISTORICAL CONTEXT - ENSHRINED ATTITUDES – 1979 INTRO TO CSA

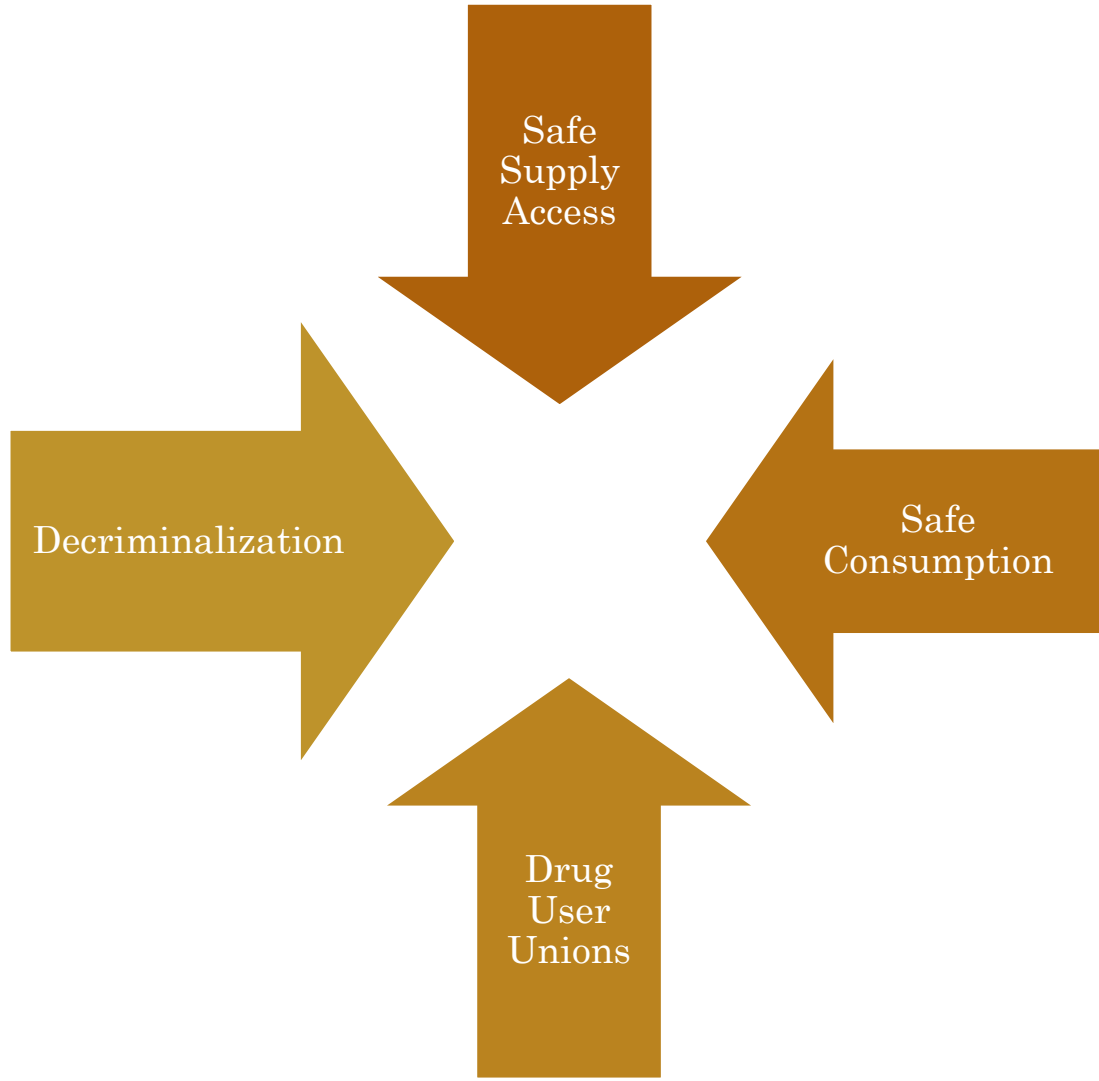
- During the 13-year period beginning with 1979, monthly use of illegal drugs among youth 12 to 17 years of age declined by over 70 percent; and
- Data suggests that if parents would simply talk to their children regularly about the dangers of substance abuse, use among youth could be expected to decline by as much as 30 percent.
- Community anti-drug coalitions throughout the United States are successfully developing and implementing comprehensive, long-term strategies to reduce substance abuse among youth on a sustained basis.

SAMHSA – TREND TOWARD LESS RESTRICTION

- Substance Abuse and Mental Health Services Administration (SAMSHA) is a branch of the U.S. Dept of Health and Human Services.
- March 2020: SAMSHA published guidance regarding flexibilities that could be leveraged in the provision of unsupervised doses of methadone ...
 - First substantial change to OTP treatment and medication delivery standards in more than 20 years.
- April 2024: SAMSHA developed Final Rule: modification of federal regulations to update OTP accreditation and certification standards, and treatment standards for provision of MOUD as dispensed by OTPs.

Health Canada: Safer supply is defined as “providing prescribed medications as a safer alternative to the toxic illegal drug supply to people who are at high risk of overdose”.





CONTEXT OF SAFE SUPPLY

OTHER SUPPORTIVE WA STATE POLICIES

- 1. Access to drug administration supplies:** Sale of drug paraphernalia is prohibited, however distribution or use of public health supplies, including syringe equipment ... through public health programs, community based HIV prevention programs, outreach, shelter, and housing programs and pharmacies, is not prohibited.
- 2. Drug Checking Technologies:** Public health and syringe service program staff taking samples of substances and using drug testing equipment for the purpose of analyzing the composition of the substances or detecting the presence of certain substances are acting legally and are exempt from arrest and prosecution under RCW 69.50.4011(1) (b) or (c), 69.50.4013, 69.50.4014, or 69.41.030(2) (b) or (c). Public health and syringe service program staff are allowed to perform drug checking services and when doing so are exempt from most controlled substances possession and use offenses. Wash. Rev. Code Ann. § 69.50.4121(3).
- 3. Safe Consumption:** not currently sanctioned in Washington State
- 4. Drug Decriminalization:** gross misdemeanor to knowingly possess controlled substances or knowingly use prohibited substances in a public place.

FEDERAL CONTROLLED SUBSTANCES ACT

CONTROLLED SUBSTANCES ACT

- Controlled Substances Act (CSA), 21 U.S.C. § 801 et al. Regulates certain drugs into one of five schedules.
 - **Washington regs will schedule substances according to federal regs. Wash. Rev. Code. Ann. § 69.50.201.**
- Federal drug statutes, prohibit manufacture, distribution, importation, exportation of controlled substances, unless authorized by statute.
- Any drug that is a controlled substance listed in any schedule under the CSA or implementing regulations must be **dispensed by prescription only** in accordance with federal regulations.

"ILLEGAL DRUG" DEFINED

- An “illegal drug” is a controlled substance but does not include a controlled substance that is legally possessed or used under the supervision of a licensed health-care professional or that is legally possessed or used under any other statutory authority.
- A substance that meets the definition of a controlled substance analogue and is intended for human consumption may be treated under the CSA as if it were a controlled substance in Schedule I. [21 U.S.C. § 802(32), 21 U.S.C. § 813].

HOW DRUGS ARE CLASSIFIED IN THE US

SCHEDULE	DESCRIPTION	EXAMPLES
Schedule 1	Drugs with no currently accepted medical use and a high potential for abuse. They are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence.	<ul style="list-style-type: none"> - Heroin - Lysergic acid diethylamide (LSD) - Marijuana (Cannabis) - Methylenedioxymethamphetamine (Ecstasy) - Methaqualone - Peyote
Schedule 2	Drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.	<ul style="list-style-type: none"> - Combination products with less than 15mg of hydrocodone per dosage unit (Vicodin) - Cocaine - methamphetamine - Methadone - Hydromorphone (Dilaudid) - Meperidine (Demerol) - Oxycodone (OxyContin) - Fentanyl - Dexedrine - Adderall - Ritalin
Schedule 3	Drugs with a moderate to low potential for physical and psychological dependence. Schedule 3 drugs abuse potential is less than Schedule 1 and Schedule 2 drugs but more than Schedule 4.	<ul style="list-style-type: none"> - Products containing less than 90mg of codeine per dosage unit (Tylenol and codeine) - Ketamine - Anabolic steroids - Testosterone
Schedule 4	Drugs with a low potential for abuse and low risk of dependence.	<ul style="list-style-type: none"> - Xanax - Soma - Darvon - Darvocet - Valium - Ativan - Talwin - Ambien - Tramadol
Schedule 5	Drugs with lower potential for abuse than Schedule 4 and consist of preparations containing limited quantities of certain narcotics. Schedule 5 drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.	<ul style="list-style-type: none"> - Cough preparations with less than 200mg of codeine per 100ml (Robitussin AC) - Lomotil - Motofen - Lyrica - Parepectolin

SOURCE: Drug Enforcement Administration

BUSINESS INSIDER

SAFE SUPPLY SCHEDULES

Schedule I

Injectable
hydromorphone

Injectable
diacetylmorphine
or diamorphine

Schedule II

Hydromorphone
tablets
(Dilaudid)

Fentanyl

Morphine

Methadone

SCHEDULING

FDA APPROVAL

- FDA approval is required for legal use for medical purposes.
21 CFR § 290.1
- Moving a substance from a Schedule I to a less harsh schedule does not mean the substance is legal for medical use.

OPIOID TREATMENT PROGRAMS

- FDA Approved Opioid Agonist Treatment Medications for use in treatment of OUD, 42 CFR § 8.12(h)(2)
 - Methadone in oral form only
 - Levomethadyl acetate (LAAM);
 - Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid use disorder.

- Closed system of distribution for controlled substances. All authorized distributors must register with DEA. Required to maintain complete and accurate inventories, records of all transactions involving controlled substances, security for storage.

OPPORTUNITY

» OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer **a drug that has been authorized by the FDA under an investigational new drug application**

RESCHEDULING

SCHEDULE DETERMINATION UNDER THE CSA

Determining Factors:

- » Its actual or relative potential for abuse.
- » Scientific evidence of its pharmacological effect, if known.
- » The state of current scientific knowledge regarding the drug or other substance.
- » Its history and current pattern of abuse.
- » The scope, duration, and significance of abuse.
- » What, if any, risk there is to the public health.
- » Its psychic or physiological dependence liability.
- » Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

LEGAL PATHWAYS TO RESCHEDULING

- Interested parties, including state or local government agency, can petition to decontrol substances.
- Congress or President can change status
- DEA can change status

MARIJUANA EXAMPLE

- Currently, marijuana is a Schedule I drug.
- Advocates for decriminalization of marijuana want to de-schedule the drug altogether.
- Rescheduling Schedule I heroin to a less harsh Schedule is a different goal that may present fewer barriers.

MARIJUANA EXAMPLE

- May 2024: DEA announces proposal to reschedule marijuana on the CSA from Schedule 1 to 3. Currently in 60 day comment period.
- Moving marijuana to a lesser schedule would officially acknowledge medical benefits, but medical and adult use in legal state would still be illegal under federal law.
- Continued existence of penalties for personal use and selling marijuana with and without a license. However, since 2014 DOJ ceased federal prosecution of conduct in compliance with state medical marijuana laws.
- Mandatory minimum sentences.
- Noncitizens could be deported for working in the marijuana industry, even in legal states.

RESEARCH OPTIONS

- Clinical trial for schedule II drugs – adding treatment as a purpose for prescription
 - Tablet hydromorphone
- Every researcher who intends to conduct research with schedule I controlled substances or schedule II-V controlled substances must be registered with DEA

DISCUSSION

REFERENCES

- » Controlled Substances - alphabetical order (pp. 1–21). (24 C.E.).
https://www.dea diversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf
- » Medications for the treatment of opioid use disorder. (2024, February 2). Federal Register. <https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder>
- » MRSC - New Law on Drug Possession, use takes effect July 1, 2023. (n.d.).
<https://mrsc.org/stay-informed/mrsc-insight/may-2023/new-law-on-drug-possession-use>

NEXT STEPS

- » Next meeting date:
 - » Thursday, July 11, 2024
8:30AM – 10:00AM (PST)