

Law: When a Crisis Meets a Crisis: Has the Pandemic Affected Drug Overdose Deaths?

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1

Disclosure statement:
"Dr Gianutos has no actual or potential conflict of interest associated with this presentation, nor does Dr Gianutos have any relevant financial interests."

2

What Will We Discuss?

- The drug overdose crisis continued in 2020
- There was a Coronavirus pandemic
- What effect, if any, has the pandemic had on the pattern of drug overdoses?

3

Pharmacist and Technician Learning Objectives

- At the completion of this activity, the participant will be able to:
 - Describe the current drug overdose crisis
 - Evaluate how COVID-19 has affected substance use disorders
 - Discuss regulatory and public health activities that could mitigate the problem

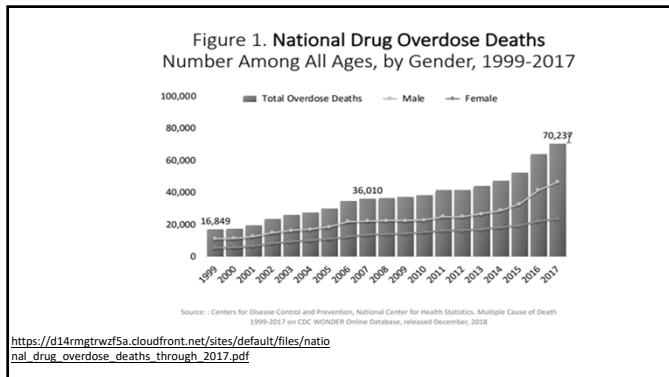
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2020

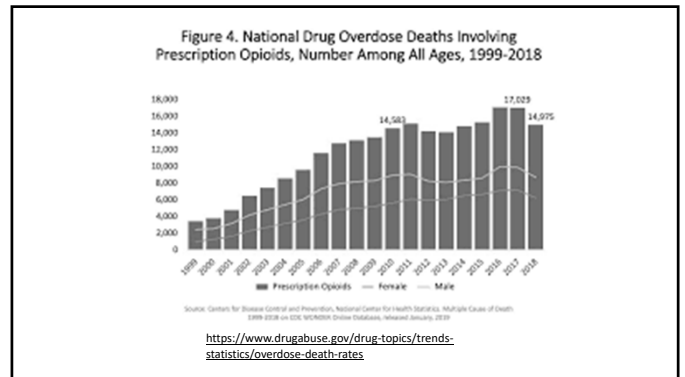
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First Crisis: Drug Overdose Deaths

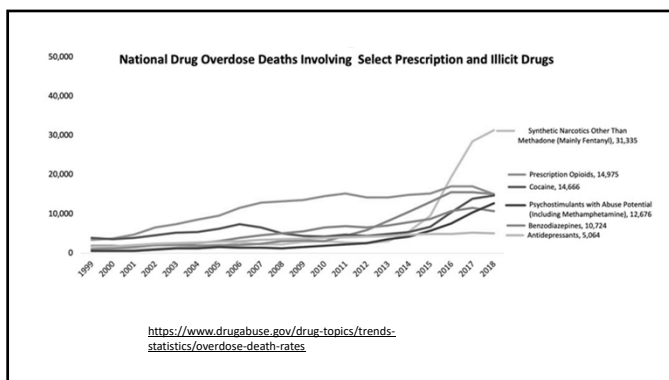
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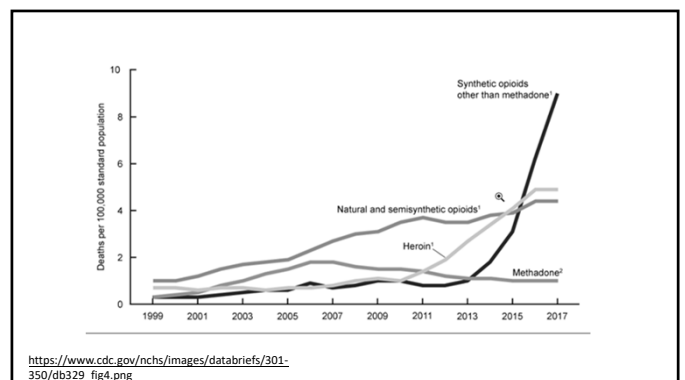
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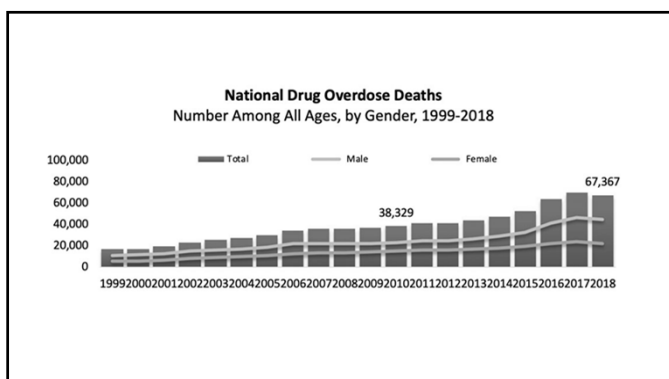
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A New Trend?

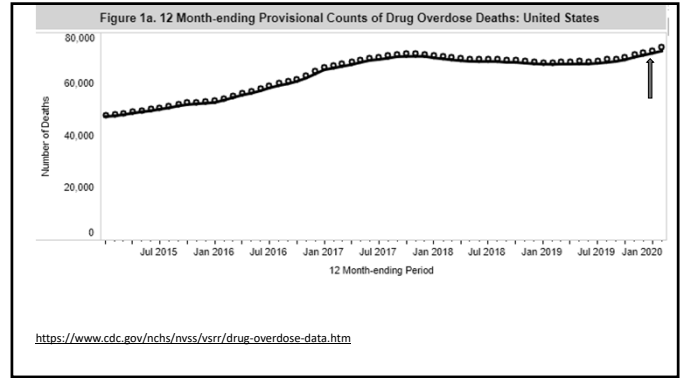
- 2017 – 70,237
- 2018 - 67,367
 - First drop in 28 years!
- “Tremendous”
- Prescription opioids?

12

Why the Drop?

- Opioid prescriptions decreased 37% between 2014 and 2019
 - 244M to 153M
- 64% increase in use of PDMP in 2018
- Increased funding to states to expand access to treatment and support near real-time data on the drug overdose crisis

13



14

- The drug(s) which are most responsible for overdose deaths in the U.S. are:
 - A. Cocaine
 - B. Heroin
 - C. Synthetic opioids like fentanyl
 - D. Prescription opioids

15

2020
Will Numbers Increase or Decrease?

16

INCREASE!

17

Could it Have Decreased?

- Disruption of supply lines
 - Border lockdown
 - Reduced social interaction
- Lockdowns kept users away from drug-using peers
- “Many patients described a kind of peacefulness without the constant hubbub of modern life and the constant triggers they’re exposed to,”
- Relaxing rules for prescribing methadone and buprenorphine

18

Factors

- According to the UN, border and other restrictions linked to the pandemic have caused drug shortages on the street, leading to price hikes.
 - Especially affecting synthetic drugs which are more often trafficked by air
- Reducing traffic in precursor and other needed supplies for processing
 - <https://news.un.org/en/story/2020/06/1066992> (Office on Drugs and Crime Report, June 20, 2020)

19

What do the (Interim) Data Say?

20

Data

- Surveillance (ODMAP)
 - 62% of participating counties reported increased overdoses in first part of 2020.
 - Since the first reported case of COVID-19, suspected overdose submissions display an average increase of 20% when compared to the same time-period during the previous year.
 - Suspected overdoses nationally — not all of them fatal — increased 18% in March compared with last year, 29% in April and 42% in May

21

Data

- More than 40 states have reported increases in opioid-related mortality.
 - In March alone, York County in Pennsylvania recorded three times more overdose deaths than normal
 - In Arkansas, the use of Narcan, an overdose-reversing drug, has tripled.
 - Jacksonville, Fla., has seen a 40% increase in overdose-related calls.
 - <https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf>

22

Data

- Kentucky reported its first decline in overdose deaths in early 2020, after five years of crisis.
- By early summer, many towns experienced an abrupt reversal in the numbers.

23

Data

- Shelby County, TN Health Department reported 391 suspected overdoses from April 7, 2020 to May 7, 2020, 58 of which were fatal, the most in a 30-day period.
- Franklin County, OH Coroner, reported 50% more deaths in the first four months of 2020 than in the same period of 2019.
- Milwaukee, WI Emergency Medical Services Division reported a 54% increase in drug overdose calls in March and April 2020 compared with the same time period of 2019.

24

Data

- In the first three months of 2020, emergency workers in Brattleboro, VT responded to 10 overdose calls, none of them fatal. But by August they had responded to a total of 53 overdoses, including seven that were fatal.

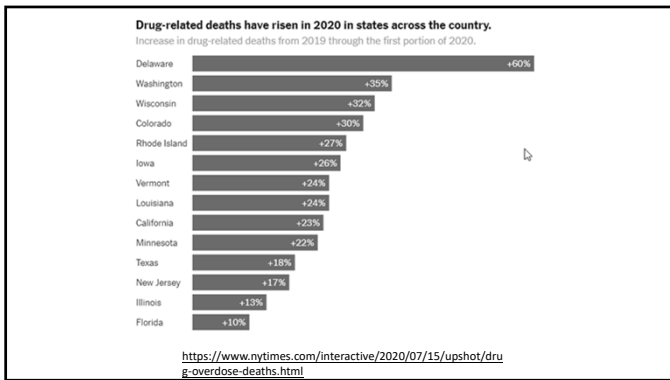
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Reports

- Last year (2019), after aggressive efforts to expand access to treatment, Vermont saw its first decrease in opioid-related deaths since 2014; that year, then-Gov. Peter Shumlin devoted his entire State of the State Message to what he called “a full-blown heroin crisis” gripping Vermont.
- But Vermont saw 82 opioid overdoses through July of this year, up from 60 during the same period last year.

<https://www.nytimes.com/2020/09/29/health/coronavirus-overdose-opeioids-addi.html?action=click&module=News&pgtype=Homepage>

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27

Connecticut

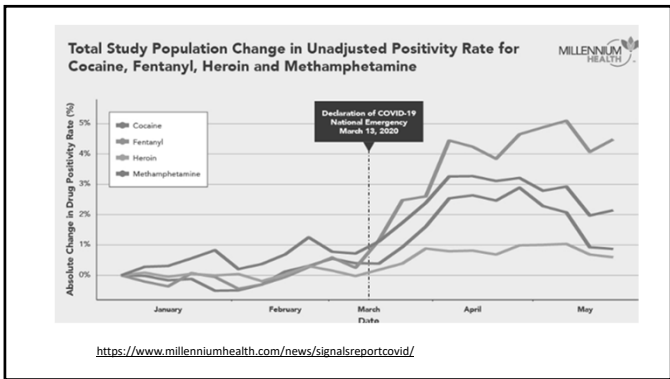
- 18% increase in drug overdoses compared with last year
- 650 people in Connecticut died of unintentional drug overdoses from January to June.
- Overdose deaths are on track to surpass last year's total of 1,200.
- Nearly 87% of all overdose deaths this year have been associated with fentanyl.

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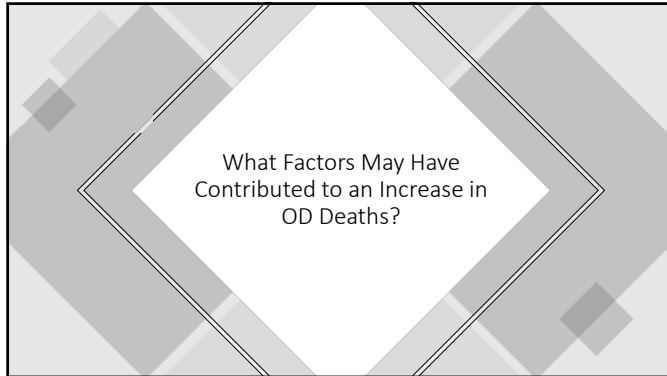
Which Drugs?

- Cocaine
- Fentanyl
- Heroin
- Methamphetamine

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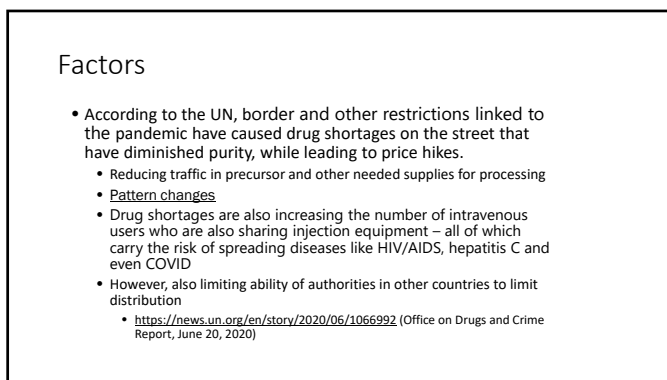
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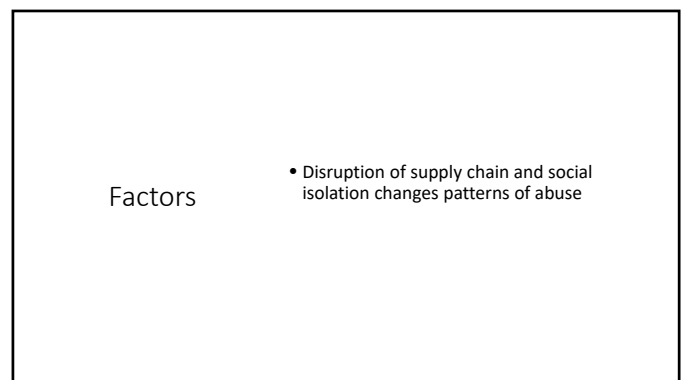
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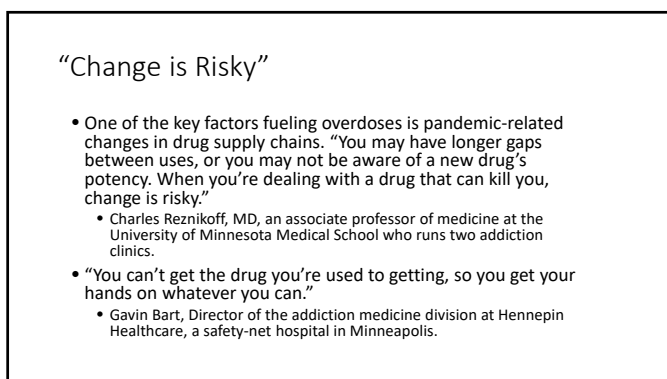
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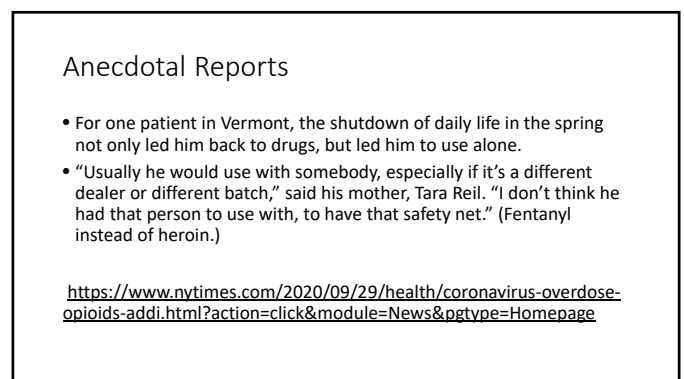
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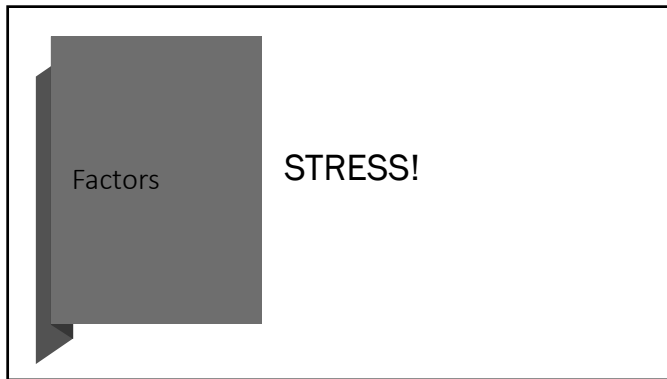
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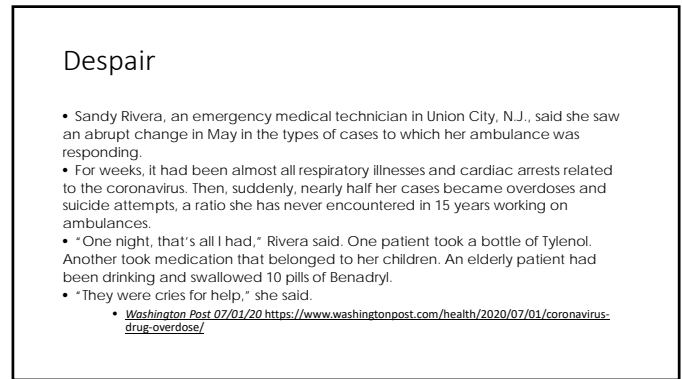
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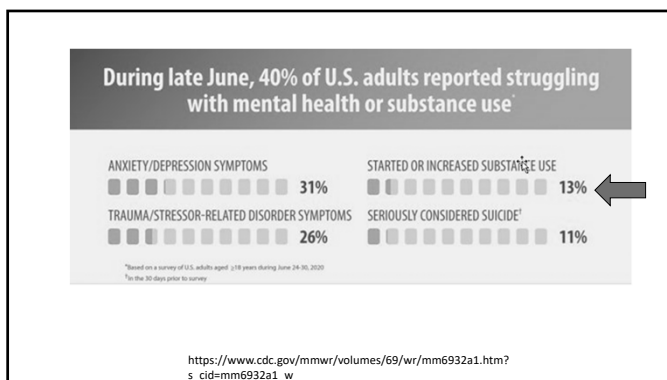
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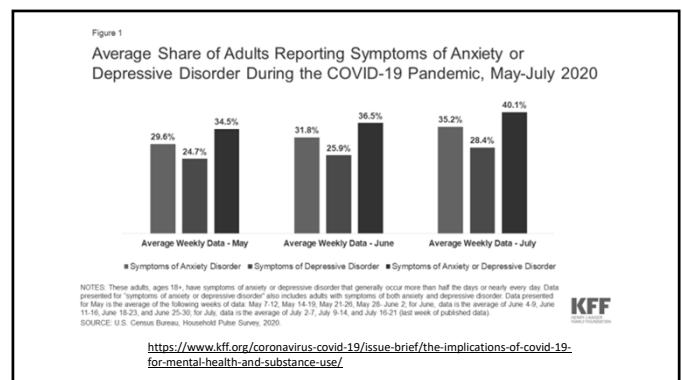
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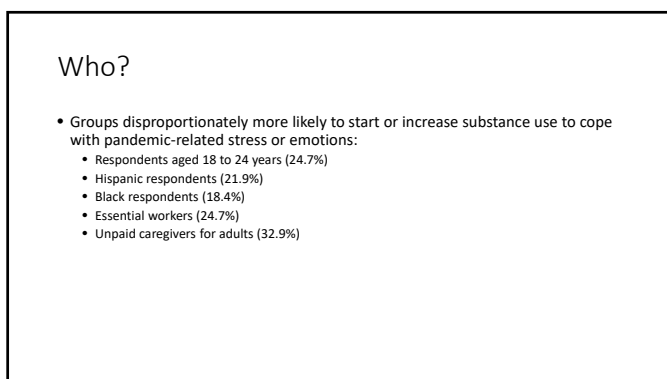
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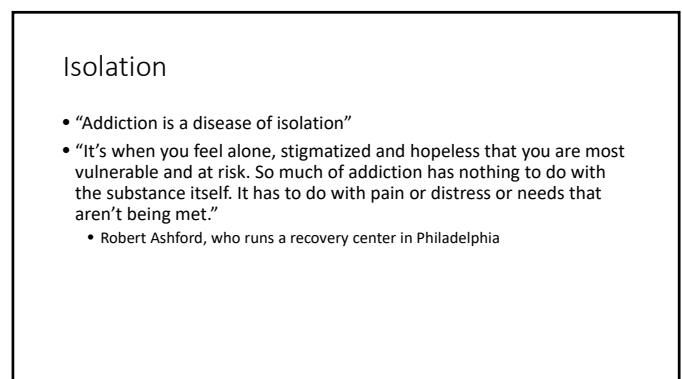
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41



42

Social Isolation

- Isolation increases stress.
- "It's when you feel alone, stigmatized and hopeless that you are most vulnerable and at risk. So much of addiction has nothing to do with the substance itself. It has to do with pain or distress or needs that aren't being met."
 - Robert Ashford, who runs a recovery center in Philadelphia
- Taking drugs alone increases risks.
 - As the pandemic increases fear, uncertainty, anxiety and depression into people's lives, it has cut off the human connections that help ease those burdens.
 - Safety net

43

Lockdown

- Fewer visits for health care
- More reliance on tele-medicine

44

Factors

- Social-isolation limitations complicated treatment for people who struggle with addiction and for the organizations that provide services to them.
 - In-person support services like group meetings weren't gathering in person due to stay-at-home orders.
 - Video less appealing
 - Lack of resources

45

Factors

- Reliance on Telemedicine
- "Telehealth is not the magic solution,"
 - Caleb Banta-Green, PhD, a principal research scientist at the University of Washington Alcohol and Drug Abuse Institute
- "Telehealth is great for people who are already engaged in care," but that is not the case for the majority of people with opioid addiction.
 - Some adults struggling with opioid use are also homeless or lack technical resources or have other mental health disorders.
- Patients often struggle with the TeleHealth interface, or don't have a private space from where to conduct a confidential visit."
 - Veronika Mesheriakova, M.D., assistant professor of clinical pediatrics, UCSF
 - <https://abcnews.go.com/Health/opioid-overdoses-rise-covid-19-pandemic-telemedicine-care/story?id=72442735>

46

Loss of Support Services

- Many treatment centers, drug courts and recovery programs have been forced to close or significantly scale back during shutdowns.
- With loss of revenue for services and little financial relief from the government, some may be on the brink of financial collapse.
- Even before the pandemic, experts note, the nation's infrastructure for helping people with substance use disorders was underfunded and inadequate. Without government intervention, local officials and drug policy experts warn, overdoses and deaths will continue to climb during the pandemic and the existing system will be inundated.

47

Loss of Support Services

- **Fear of attending treatment**
Many people are apprehensive to attend medical settings of any type during COVID-19, unless in the event of an extreme emergency. Unfortunately, this means that substance use disorders now have more time to grow without early intervention, which raises the overdose risk.
- **Suspension of outreach, health campaigns and opioid-related projects**
From naloxone availability to physician prescribing patterns, many initiatives in the public and private sector have been disrupted due to the pressing urgency of responding to the pandemic and slow to restart.
- **Cuts to programming due to financial strains**
The progression of most substance use disorders may eventually include the loss of employment, which often corresponds with the loss of commercial health insurance and other wellbeing benefits. Prior to COVID-19, there were already huge shortages in public aid treatment providers for addiction despite the demand, and the financial strain of COVID-19 has only exacerbated this problem, with many states slashing their treatment budgets.

48

Economic Factors

- Experts say factors that usually fuel substance use are heightened by the pandemic. Researchers have noted that drug use often increases during economic downturns.
 - Loss of income and insurance

49

Factors

- "If there's no way to make money, your use goes down and your tolerance goes down. But if the economy opens a bit and you get some resources, maybe a stimulus check, you might try to use the amount you used to. And you don't have the tolerance to handle it."
 - Dr. Josiah Rich, a professor of medicine and epidemiology at Brown

50

Anecdotal Evidence

- Madison County (KY) Coroner Jimmy Cornelison, said since the first virus case, he's seen more frequent overdose deaths including a man in a rented bedroom, needles beside him and what appeared to be a cashed stimulus check.
- "I found eleven- \$100 dollar bills. Brand new, just came out of a bank. The 12th one was folded up in a square with fentanyl or heroin in it," he said.

<https://capitololutions.net/why-the-coronavirus-pandemic-is-fueling-drug-overdoses-in-kentucky/>

51

Change in Focus

- Pandemic crisis has shifted attention away from SUD.
 - "If it weren't for Covid, these opioid deaths are all we'd be talking about right now."
 - Natalia Derevyanny, spokesperson for the medical examiner's office in Cook County, IL.

52

1. Patients on OAT are particularly vulnerable to disruptions caused by a pandemic. Co-occurring health conditions and daily dosing in large clinics may crowd many patients in close proximity on a daily or near-daily basis increasing their susceptibility to COVID-19 infections. Opiate agonist treatment dosing and community pharmacy staff have increased infection risks providing these services.
2. Given the above vulnerabilities, without proactive measures, patients attending treatment services may be more susceptible to develop COVID-19 infections, may be less likely to be tested for SARS-CoV2, have increased difficulty complying with home isolation and may be in living situations where the infection may spread rapidly.

- MORE

53

Direct Risks

- At least 2 million persons in the United States have OUD, and more than 10 million misuse opioids; these individuals may be at increased risk for the most adverse consequences of COVID-19.
 - Compromised lung function from COVID-19 and chronic respiratory disease increases risk for fatal overdose in those who use opioids.
 - Slowed breathing due to opioids causes hypoxemia which can aggravate COVID-19 outcomes.
 - Methamphetamine and cocaine produce cardiovascular effects, use increases risk for adverse COVID-19 outcomes.

54

Another Interaction

- The use of drugs by smoking or vaping (e.g., heroin, crack cocaine, marijuana) can make lung conditions worse.

55

Direct Effect

- Patients with recent diagnosis of SUD had significantly higher prevalence of asthma, chronic kidney disease, chronic obstructive pulmonary disease, diabetes, cancer, HIV, chronic liver disease, cardiovascular diseases including hypertension, and obesity as compared to patients without recent diagnosis of SUD.
- Patients with recent SUD diagnosis had significantly higher risk of developing COVID-19 compared to patients without recent SUD diagnosis, after adjusting for age, gender, race, and insurance types. AOR=8.7.
- Especially African Americans
 - Wang QQ et al. *Molec Psychiat*. 2020.

56



Perfect Storm

<https://medium.com/the-transformation-games-in-english/ol-a-perfect-storm-df68f2006ff>

57

Dilemma

- While most businesses in the county closed in March, the Brattleboro (VT) Retreat, a psychiatric and addiction treatment hospital, remained open. It was able to stockpile hand sanitizer and protective gear, and even created a 22-bed, negative-pressure unit so it could accommodate coronavirus patients in the event of an outbreak.
- But in order to be admitted, patients have to test negative for Covid-19 — a potentially deadly setback for some who are unable or unwilling to wait several days for results.

58

Pain

- The COVID-19 pandemic has made access to crucial healthcare services a challenge for many patients, especially those with chronic pain.
 - Chronic pain is one of the most common reasons adults seek medical care. In the United States, an estimated 20.4% (50 million) of adults had chronic pain according to 2016 National Health Interview Survey data.
 - Chronic pain patients are increasingly isolated many of them are at a higher risk for opioid addiction or overdose.
 - Severe pain are associated with more severe levels of depression in 50% and suicidal thinking in 34.6% ??

59

Not Just Illicit Drugs

- There has been a 250% increase in online alcohol sales.
- The increase in episodes of binge drinking is estimated to be 25%.
- It is estimated that there has been a 40% increase in the use of medications for non-medical reasons.

60

- Drug overdose deaths have increased during the pandemic due to the following factors EXCEPT:
 - A. Many controlled substances produce respiratory depression which is exacerbated by the pulmonary effects of COVID-19.
 - B. Many controlled substances produce cardiovascular effects which are exacerbated by the cardiac effects of COVID-19.
 - C. The stress associated with isolation/lockdown increases the risk of abuse of controlled drugs.
 - D. Many of the controlled substances produce a dangerous interaction with therapy for COVID-19.

61

What to Do?

62

What to Do?

- AMA
 - Continue to provide increased flexibility for prescribing methadone and buprenorphine
 - Flexibility for Rx's
 - Removing arbitrary dose, quantity and refill restrictions on controlled substances
 - Complete removal of prior authorization, step therapy and other administrative barriers for medications used to treat opioid use disorder
 - Telemedicine

63

What to Do?

- Designate medications to treat addiction (buprenorphine, methadone, naltrexone) and medications to reverse opioid-related overdose (naloxone) as "essential services" to reduce barriers to access during "shelter-in-place" orders
- Implement and support harm reduction strategies, including removing barriers to sterile needle and syringe services programs
- Correctional and justice settings should temporarily waive strict requirements for submitting drug tests, in-person counseling and "check-ins" and similar requirements; suspend consequences for failure to meet strict reporting, counseling and testing requirements, including removal from public housing, loss of public benefits, and return to jail or prison
- Strongly urges legislators, regulators, governors and policymakers to remove additional barriers to pain treatment to help ensure that patients with pain have access to the treatments prescribed

64

Pharmacists

- Expand naloxone programs

65

CDC

- Screen patients for drug use and drinking patterns
- DATA waiver for buprenorphine
 - "DATA-waived practitioners should feel free to prescribe buprenorphine to new patients with OUD for maintenance treatment or detoxification treatment following an evaluation via telephone voice calls, without first performing an in-person or telemedicine evaluation."
 - <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>

66

SAMSA Guidelines (Methadone)

- Historically the dispensing of methadone has been tightly regulated, requiring many patients to receive no more than 1 directly observed daily dose at a time.
- Substance Abuse and Mental Health Services Administration (SAMHSA) recently released new guidance increasing the ability of opioid treatment programs to transfer as many patients as possible to take-home methadone maintenance protocols.
- With naloxone

67

DEA

- Federal regulation* requires that, following the issuance of an oral emergency schedule II prescription from a prescriber to a pharmacist, the prescriber is required to follow up with an original prescription (hardcopy or electronic) to the pharmacy within 7 days.
 - EXEMPTION:** *During the emergency period, DEA is allowing prescribers 15 days to provide the follow-up prescription to the pharmacy.*
- The federal regulation also requires the follow up prescription be in hard copy format or electronically transmitted.
 - EXEMPTION:** *During the emergency period, DEA is allowing prescribers to send the follow-up prescription to the pharmacy via facsimile, or to take a photograph or scan of the follow-up prescription and send the photograph or scan to the pharmacy in place of the paper prescription.*
 - * Section 21 CFR 1306.11(d)(4)

68

Audio – Only Telehealth

- New DEA Guidelines (3/31/20) “to provide flexibility in the prescribing and dispensing of controlled substances to ensure necessary patient therapies remain accessible.”
 - [https://www.deadiversion.usdoj.gov/GDP/DEA-DC-022/\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf?mc_cid=8dffbf637&mc_eid=d4494a732e](https://www.deadiversion.usdoj.gov/GDP/DEA-DC-022/(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf?mc_cid=8dffbf637&mc_eid=d4494a732e)
- Authorized practitioners may to prescribe buprenorphine to new and existing patients with OUD via telephone without requiring them to first conduct an examination of the patient in person or via telemedicine during the nationwide public health emergency.
- RI - Rhode Island Buprenorphine Hotline (telephone)

69

Pharmacy-Related Changes During Pandemic (States)

- Waiving in-person (prescriber) visit for prescribing controlled substances (mostly C-III – CV)
 - (CT)
- Modified Counseling Methods
- Many states have relaxed emergency refills for controlled and NON-controlled substances (90 days)
- Technician ratios
- “Work from home”
- HCQ restrictions

70

Minnesota

- Board will allow counseling on new prescriptions to be completed in other than a face-to-face manner.
 - Phone, written materials, and advise pt that they may call with any questions
 - Suspending the requirement that refusals for counseling be documented on a log
- May provide (certain) services at Satellite locations not currently licensed as pharmacies
- Will permit exceeding technician-to-pharmacist ratio

71

Minnesota

- Board will allow pharmacists and technicians to work from home to the extent that they can
 - May have some staff work remotely to verify prescriptions, complete data entry of prescriptions, certify the accuracy of data entry, conduct profile reviews and prospective drug utilization reviews;
 - Must have adequate safeguards to protect privacy
- May have a technician working in one pharmacy to do remote data entry for another pharmacy and pharmacist may certify accurate data entry of Rx at another pharmacy
- May use mail or curbside pickup without store opening
- Can fill an Rx from another pharmacy which is closed due to Covid-19 without obtaining transfer information IF there is adequate information to accurately fill the Rx (e.g., label)
 - Can include controlled substances IF a failure to dispense the drug to the patient would result in harm to the health of the patient in pharmacist's judgment

72

Minnesota

- Removed 30-day time limits for filling prescriptions for opiate analgesics
- Prescriptions for Schedule II drugs can be issued for a 12-month quantity at one time (Pharmacist is to use professional judgement before filling)
- Waiving requirement for ID for picking up controlled substances prescriptions and PSE if the purchaser is known to the pharmacist
- Will allow pharmacists to rely on an expired driver's license, state ID card, or other form of identification to meet the requirement

73

Minnesota

- Pharmacists whose CPR certification expires during the duration of the emergency declaration may continue to administer vaccinations.

74

Idaho

- Permitting temporary licensing (30 days) of pharmacy personnel while application is being processed
- Permitting remote data entry

75

Kansas - Remote

- Any supervision of technicians, including those working remotely, must be conducted by a pharmacist physically located at the pharmacy. A pharmacist working remotely may not supervise a technician.
- Technicians may only work remotely during the pharmacy's regular business hours.
- Technicians may perform the following tasks when working remotely:
 - o Data Entry
 - o Order Entry (hospital pharmacies)
 - o Refill queue processing
 - o Sending refill requests to prescribers by automated methods
 - o Insurance Processing or Billing
 - o Contacting patients for clarification of personal data and insurance processing information (i.e., date of birth, insurance information, etc.)
- Please note: Patients may be unwilling to provide personal information to a person calling from a phone number unrelated to the pharmacy. Please do not be forceful with patients in these situations and have the technician contact the pharmacy to call the patient directly.
- While working remotely, technicians may not:
 - o Directly contact prescribers or prescriber offices for clarifications or refills
 - o Directly contact patients for issues related to medication therapy.
- This list is not exhaustive.
- Any technician working remotely must maintain direct communication capabilities with the supervising pharmacist (located at the pharmacy) at all times. A video component is not required.

76

Kansas - Remote

- Interns
 - Interns may work remotely to perform technician functions and are expected to follow the guidelines for technicians. Any hours spent working remotely to perform technician duties shall not count towards the intern hours required by the Board.

77

New Jersey

- Pharmacies may be open less than 40 hrs/week (with notice to pts).
- Will not require the pharmacist, at the time of dispensing, to obtain the signature of the patient or caregiver that counseling was provided or refused.

78

Indiana

- Each pharmacist may now supervise 8 pharmacy technicians instead of 6. Additionally, pharmacy technicians may work remotely for non-dispensing job functions such as data entry, insurance processing or other roles that do not require the physical presence.

79

Iowa

- When a prescriber issues an oral emergency schedule II prescription, the quantity is generally limited to the quantity sufficient to meet the needs of the patient during the emergency period. During this public health emergency, "sufficient quantity" may be that which provides an adequate supply of medication to the patient until the prescriber can again access prescribing capabilities under the normal regulatory structure.
- A prescription for a schedule II controlled substance is not required to be on an official prescription blank of the prescriber, so long as the prescription contains all the required elements.

80

West Virginia

- The Governor waived the requirement that for chronic pain patients there must be an in-person physical examination every 90 days prior to prescribing a refill for a Schedule II opioid medication to an existing patient for chronic pain treatment (provided that the provider utilizes other appropriate tools to evaluate the patient at these intervals, and assesses whether continuing the course of treatment would be safe and effective for the patient).
- In the case of an emergency situation, a practitioner may communicate a prescription for a Schedule II controlled substance orally or by way of electronic transmission other than electronic prescribing, provided that :
 - if the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call-back to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his or her identity.

81

WV - 2

- (Current) WV law restricts early refills on controlled substances to no more than 3 days early per. (Schedule III or IV)
- New guidance for refilling Schedule III or IV: Pharmacist may dispense the refill early using his or her professional judgement and shall document the reason for the early refill.

82

NH

- A pharmacist may refill a prescription drug order, including controlled substances listed in Schedules III, IV and V, without the authorization of the prescribing practitioner, provided that: the quantity of prescription drug dispensed does not exceed a 90 day supply for maintenance medications. (Unless federal law states otherwise)

83

Other Community-Based Changes

- A harm reduction organization in Ohio will provide naloxone to community groups and others.
- A Wisconsin and a Seattle opioid treatment program are using telehealth to check-in with patients.
- The Seattle clinic is also using a mobile methadone unit.
- The Indiana Division of Mental Health and Addiction will provide opioid treatment programs with lockboxes for take home methadone and naloxone kits for patients who are stable in their treatment of opioid use disorder, in order to reduce their number of trips and time spent at a facility to receive their daily dose of methadone.
- RI : Community – based organizations are supplying naloxone, needle exchange, fentanyl test strip kits. In some cases, statewide, free delivery.

84

- In response to the pandemic, regulations for remote work have been enacted by states:
 - A. For technicians
 - B. For pharmacists
 - C. For both technicians and pharmacists
 - D. No state currently permits "work from home" for any pharmacy personnel involved in direct patient contact

85

Final Comments

- Overdose deaths have increased during the Coronavirus pandemic.
- Stress associated with social isolation/lockdown increases risk of substance use as a self-treatment for anxiety, depression.
- Adverse consequences of COVID-19 infection increase susceptibility to overdose.
- Use of drugs like opioids and CNS stimulants may increase risk associated with COVID infection.
- COVID has produced changes in medical and pharmacy practice on SUD and controlled substances.
- Natalia Derevyanny, spokesperson for the medical examiner's office in Cook County, Ill: "One epidemic began, but the other one never stopped."

86

Parting Thought

- Should any of the changes brought about by the pandemic be made permanent?

87

Thank You!

88