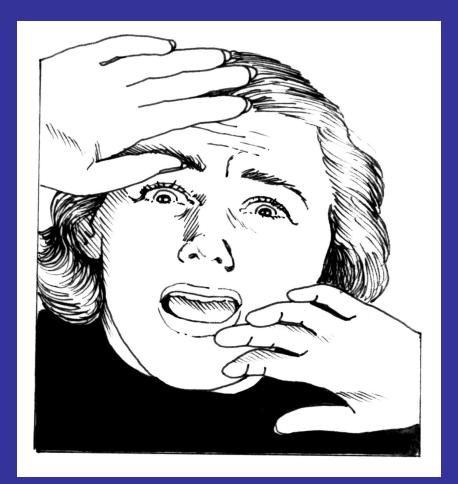
# The Opioid Pandemic – An Update

Kevin Wadalavage, M.A., LMHC, CASAC, MAC, NCACII Outreach <u>kevinwadalavage@opiny.org</u> (no conflict\$ to declare)

# Oh no, statistics!

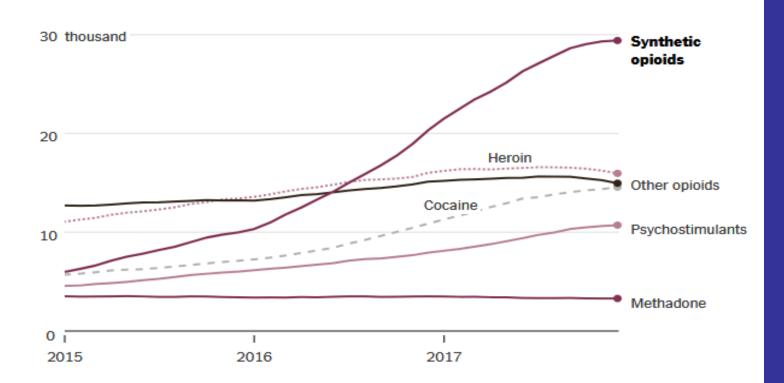


### Illicit Drug Deaths Continue to Rise

- Led by opioids
- Fentanyl variations and other synthetics/analogs are more often involved in fatalities
- Many overdoses involve combining various drugs in hazardous manners
- But were not even sure of these numbers

### Synthetic Opioids Are Driving Up the Overdose Rate

#### Overdose deaths in thousands in preceding 12 months



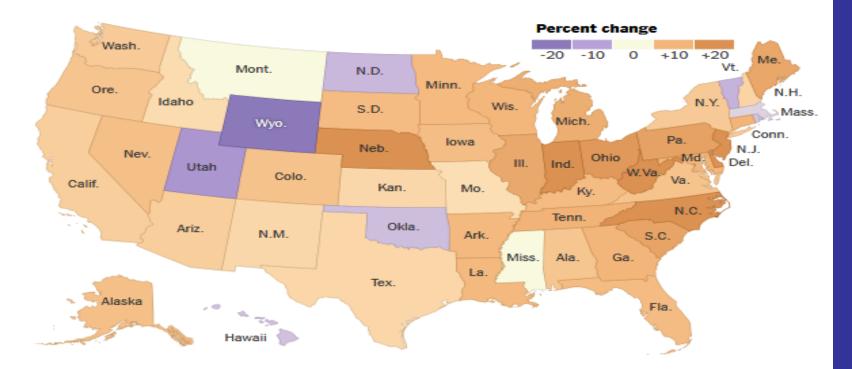
Note: These numbers are adjusted to account for some death investigations that are not completed. Some deaths involve more than one drug.

By The New York Times | Source: The Centers for Disease Control and Prevention

Source: NCHS Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts

### Change in Overdose Deaths Last Year

Reductions in New England give some cause for hope, while the situation in the Midwest and Mid-Atlantic remains bleak.



Note: These numbers are adjusted to account for some death investigations that are not completed. They may change slightly before they become final. Estimates for less populous states are highly variable.

Source: Centers for Disease Control and Prevention



🗰 🏹 🧭 Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™

Rising Numbers of Deaths Involving Fentanyl and Fentanyl Analogs, Including Carfentanil, and Increased Usage and Mixing with Non-opioids



Distributed via the CDC Health Alert Network July 11, 2018, 1300 ET (1:00 PM ET) CDCHAN-00413

#### Summary

This Health Alert Network (HAN) Update is to alert public health departments, health care professionals, first responders, and medical examiners and coroners to important new developments in the evolving opioid overdose epidemic, which increasingly involves illicitly manufactured fentanyl and an array of potent fentanyl analogs (i.e., compounds that are chemically related to fentanyl). It is the second update to the original health advisory, HAN 384 (https://emergency.cdc.gov/han/han00384.asp), issued October 26, 2015, which alerted the public to the increase in unintentional overdose fatalities involving fentanyl in multiple states, primarily driven by illicitly manufactured fentanyl. The first update to this health advisory was released on August 25, 2016 (HAN 395 (https://emergency.cdc.gov/han/han00395.asp)), describing the sharp increase in the availability of counterfeit pills containing varying amounts of fentanyl and fentanyl analogs, the continued increase of overdose deaths involving fentanyl across a growing number of states, and the widening array of fentanyl analogs being mixed with heroin or sold as heroin.

"...preliminary counts from the National Center for Health Statistics (NCHS) indicate that more than 55% of opioid overdose deaths occurring nationally in the 12-months ending November 2017 involved synthetic opioids, accounting for more than 27,000 overdose deaths."



### NDEWS National Drug Early Warning System

Funded at the Center for Substance Abuse Research by the National Institute on Drug Abuse

About Us Drugs

Project Publications

Sentinel Sites Re

Resources

### Drug Outbreak Testing Service (DOTS)

The Drug Outbreak Testing Service (DOTS) pilot study supports local experts and public health agencies experiencing a drug outbreak to identify the drug(s) behind the outbreak by providing free urinalyses of specimens already obtained from affected persons.

Up to 20 de-identified urine specimens may be submitted to DOTS and will be sent to an independent laboratory for testing for approximately 240 licit and illicit drugs, including synthetic opioids and other new psychoactive substances. Results will be provided for epidemiologic purposes only. Results are not for clinical use or legal proceedings.

Send inquiries regarding participation to DOTS at: ndewsdots@umd.edu

Overview, methodology, and detailed list of individual studies

### Drug Outbreak Testing Service (DOTS)



Drugs or Drug Metabolites Detected by DOTS Laboratory Urinalyses (N = 10 opiate-positive urine specimens submitted to DOTS by Charlie's Place Recovery Center, Corpus Christi, Texas)

|                    | с               | ommo       | n Drug          | ļs                        |          | Non      | fentan                    | yl Opl        | olds      |          |                 |               | maceu<br>pioid (               |                   |                  |            | otr              | ner Dru          | ıgs              |                           |
|--------------------|-----------------|------------|-----------------|---------------------------|----------|----------|---------------------------|---------------|-----------|----------|-----------------|---------------|--------------------------------|-------------------|------------------|------------|------------------|------------------|------------------|---------------------------|
|                    |                 |            |                 |                           |          |          |                           |               |           |          | Ar<br>histar    | nti-<br>mines | Ber<br>diaze                   |                   |                  |            | Ca               | Synt<br>annabin  | hetic<br>oids (S | C)                        |
| Specimen           | Methamphetamine | Amphetamhe | THC (marijuana) | Benzoy Bogonine (pocaine) | Morphine | Codeline | 6-Acetylmorphine (heroin) | Hydromorphone | Noscapine | Tramadol | Dipherhydramine | Promethazine  | Alprazciam/o-Hydroxyalprazciam | 7-Aminocionazepam | Destromethorphan | Bufotenine | 5F-ADB (metab 7) | SF-AMB (metab 7) | FUB-PB-223CI     | MDMB-FUBINA CA (metab MI) |
| 1                  | •               |            | ~               | ~                         | ~        | 1        |                           | ~             |           |          |                 |               |                                |                   |                  |            | ~                | ~                | ~                | ~                         |
| 2                  | •               | ~          | ~               | ~                         | ~        | ~        | ~                         | ~             |           |          | 1               |               | 1                              |                   |                  |            |                  |                  |                  |                           |
| 3                  | •               | ~          | ~               |                           | ~        | ~        | 1                         |               | ~         |          |                 |               | 1                              |                   |                  |            |                  |                  |                  |                           |
| 4                  | •               |            |                 |                           | ~        | ~        |                           | ~             | ~         |          |                 | 1             |                                |                   | ~                | 1          |                  |                  |                  |                           |
| 5                  | •               | ~          | ~               |                           | ~        | ~        |                           | ~             |           |          |                 |               |                                |                   |                  | 1          |                  |                  |                  |                           |
| 6                  | •               |            |                 | ~                         | ~        | ~        | ~                         | ~             | ~         |          |                 |               |                                |                   |                  |            |                  |                  |                  |                           |
| 7                  | •               |            |                 |                           | ~        | ~        |                           | ~             | ~         | ~        |                 |               |                                |                   |                  |            |                  |                  |                  |                           |
| 8                  | •               | ~          | ~               | ~                         | ~        |          |                           | ~             |           |          |                 |               |                                |                   |                  |            |                  |                  |                  |                           |
| 9                  | •               | ~          |                 |                           | ~        | *        |                           | ~             |           |          |                 |               |                                | ~                 |                  |            |                  |                  |                  |                           |
| 10                 | •               |            |                 |                           | ~        | ~        |                           | ~             | ~         |          |                 |               |                                |                   |                  |            |                  |                  |                  |                           |
| Total<br>Positive: | •               | 5          | 5               | 4                         | 10       | 9        | 3                         | 9             | 5         | 1        | 1               | 1             | 2                              | 1                 | 1                | 2          | 1                | 1                | 1                | 1                         |

### **Drugs or Drug Metabolites Detected by DOTS Laboratory Urinalyses** (N = 20 urine specimens submitted to DOTS by Aspenti Health, Burlington, Vermont)

|                    | Com                   | mon D                     | rugs            | Fent-<br>anyl       |          | I       | lonfen        | tanyl (     | Opioid   | s                               |                |                 |               |           |                                     | Phar        | maceu      | utical I  | Vonop      | ioid Dı    | ugs           |          |         |            |                  | Otł   | ner Dru    | ıgs                               |                   |
|--------------------|-----------------------|---------------------------|-----------------|---------------------|----------|---------|---------------|-------------|----------|---------------------------------|----------------|-----------------|---------------|-----------|-------------------------------------|-------------|------------|-----------|------------|------------|---------------|----------|---------|------------|------------------|-------|------------|-----------------------------------|-------------------|
|                    |                       |                           |                 |                     |          |         |               |             |          |                                 |                | Ai<br>hista     | nti-<br>mines | Benzot    |                                     |             | Anti       | depress   | sants      |            |               |          |         |            |                  |       |            |                                   |                   |
| Specimen           | THC (marijuana)       | Benzoylecgonine (cocaine) | Methamphetamine | Fentany/Morfentanyl | Morphine | Codeine | Hydromorphone | Oxymorphone | Tramadol | Bupren orphine/Norbuprenorphine | Methadone/EDDP | Diphenhydramine | Cetitzine     | Lorazepam | Desvenlataxine/Desmethylvenlafaxine | Venlataxine | Sertraline | Bupropion | Trazodone* | Citalopram | Nortriptyline | Naloxone | Quinine | Gabapentin | Dextromethorphan | mCPP* | Bufotenine | Mitragynine/7-Hydroxy-Mitragynine | Total<br>Detected |
| 1                  | ✓                     |                           | ✓               | ✓                   | 1        | ~       |               |             |          | 1                               |                | 1               |               |           | ✓                                   | 1           |            |           |            |            |               |          | ✓       |            |                  |       |            |                                   | 10                |
| 2                  | ✓                     | ~                         |                 | ~                   | 1        |         | 1             | ~           |          | ~                               |                | 1               |               |           |                                     |             |            |           |            |            |               | ~        |         |            |                  |       |            |                                   | 9                 |
| 3                  | ✓                     | ~                         |                 | ✓                   | 1        |         | 1             |             |          | ✓                               |                |                 | 1             |           |                                     |             |            | ~         |            |            |               |          |         |            |                  |       |            |                                   | 8                 |
| 4                  | <ul> <li>✓</li> </ul> | ~                         |                 | ✓                   | 1        |         | 1             |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               | ~        |         |            |                  |       |            |                                   | 7                 |
| 5                  |                       |                           |                 |                     |          |         |               |             |          | ~                               |                | 1               |               |           |                                     |             | ~          |           | ✓          |            |               | ~        |         |            |                  | ~     |            |                                   | 6                 |
| 6                  |                       |                           |                 |                     |          |         |               |             |          | ✓                               |                | 1               |               |           | ✓                                   | 1           |            |           |            |            | ✓             | ~        |         |            |                  |       |            |                                   | 6                 |
| 7                  |                       |                           |                 | ✓                   | 1        | ~       | 1             |             | ~        | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               |          |         |            |                  |       |            |                                   | 6                 |
| 8                  | ×                     |                           |                 | ~                   |          |         |               |             |          | ~                               |                |                 |               |           | ✓                                   | 1           |            |           |            |            |               |          |         |            |                  |       |            |                                   | 5                 |
| 9                  | ×                     |                           |                 |                     |          |         |               |             |          | ~                               |                | 1               |               |           |                                     |             |            |           |            |            |               | ~        |         |            | ~                |       |            |                                   | 5                 |
| 10                 |                       |                           |                 |                     |          |         |               |             |          | ✓                               |                |                 |               |           | ✓                                   |             | ~          |           |            |            |               | ~        |         |            |                  |       | ~          |                                   | 5                 |
| 11                 |                       |                           |                 |                     |          |         |               |             |          | ✓                               |                |                 |               |           |                                     |             |            | 1         |            |            |               | ~        | ✓       |            |                  |       |            | ~                                 | 5                 |
| 12                 |                       |                           |                 | ✓                   | 1        |         | 1             |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            | ✓          |               |          |         |            |                  |       |            |                                   | 5                 |
| 13                 | ✓                     |                           |                 | ✓                   |          |         |               |             |          | 1                               |                |                 |               |           |                                     |             |            |           |            |            |               |          |         | ✓          |                  |       |            |                                   | 4                 |
| 14                 | ✓                     |                           |                 | ✓                   | 1        |         |               |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               |          |         |            |                  |       |            |                                   | 4                 |
| 15                 |                       |                           |                 | ~                   |          |         | 1             |             |          |                                 | ~              |                 |               | 1         |                                     |             |            |           |            |            |               |          |         |            |                  |       |            |                                   | 4                 |
| 16                 |                       |                           |                 | ~                   | 1        |         |               |             |          | ~                               |                |                 |               |           |                                     |             |            |           |            |            |               |          |         |            |                  |       |            |                                   | 3                 |
| 17                 |                       |                           |                 | ✓                   |          |         |               |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               |          |         |            |                  |       |            |                                   | 2                 |
| 18                 |                       |                           |                 |                     |          |         |               |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               | ✓        |         |            |                  |       |            |                                   | 2                 |
| 19                 |                       |                           |                 |                     |          |         |               |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               | ✓        |         |            |                  |       |            |                                   | 2                 |
| 20                 |                       |                           |                 |                     |          |         |               |             |          | ✓                               |                |                 |               |           |                                     |             |            |           |            |            |               | ✓        |         |            |                  |       |            |                                   | 2                 |
| Total<br>Positive: | 8                     | 3                         | 1               | 12                  | 8        | 2       | 6             | 1           | 1        | 19                              | 1              | 5               | 1             | 1         | 4                                   | 3           | 2          | 2         | 1          | 1          | 1             | 10       | 2       | 1          | 1                | 1     | 1          | 1                                 |                   |

### Table 1: Drugs or Drug Metabolites Detected by DOTS/NDEWS Collaborating Laboratory Urinalyses

(N = 8 Urine specimens submitted to DOTS by the University of Maryland Medical Center, Midtown Campus Emergency Department)

|                    | Со                        | mmo             | n Dru           | igs         |                 |              |            |             |                                | P                | harma     | aceut       | tical I  | Nono      | pioid      | Druę      | js            |               |            |          |         |            |          | No                        | nfent   | anyl     | Opio      | ids            |                                |                      | Fenta                                 | anyls                       |                        |       | her<br>≥Sª       |                   |
|--------------------|---------------------------|-----------------|-----------------|-------------|-----------------|--------------|------------|-------------|--------------------------------|------------------|-----------|-------------|----------|-----------|------------|-----------|---------------|---------------|------------|----------|---------|------------|----------|---------------------------|---------|----------|-----------|----------------|--------------------------------|----------------------|---------------------------------------|-----------------------------|------------------------|-------|------------------|-------------------|
|                    |                           |                 |                 |             | ļ               | Antihis      | tamine     | es          |                                | Be               | nzodia    | azepin      | ies      |           |            | Antid     | epres         | sants         |            |          |         |            |          |                           |         |          |           |                |                                |                      |                                       |                             |                        |       | SC⊳              |                   |
| Specimen           | Benzoylecgonine (cocaine) | THC (marijuana) | Methamphetamine | Amphetamine | Diphenhydramine | Promethazine | Cetirizine | Hydroxyzine | Alprazolam/a-Hydroxyalprazolam | 7-Aminodonazepam | Demoxepam | Nordiazepam | Oxazepam | Temazepam | Citalopram | Bupropion | Nortriptyline | Amitriptyline | Trazodonec | Naloxone | Quinine | Gabapentin | Morphine | 6-Acetylmorphine (heroin) | Codeine | Tramadol | Noscapine | Methadone/EDDP | Buprenorphine/Norbuprenorphine | Fentanyl/Norfentanyl | FIBF (para-fluoroisobutyryl fentanyl) | para-Fluorobutyryl Fentanyl | Furanyltentanyl (Fu-F) | mCPP° | 5F-ADB (metab 7) | Total<br>Detected |
| 1                  |                           | ✓               |                 |             | 1               | 1            |            |             |                                |                  |           | 1           | ✓        | ✓         | 1          |           |               |               |            | ~        | ✓       |            | 1        | ✓                         | ✓       | 1        |           |                | ~                              | ✓                    | ✓                                     | 1                           |                        |       |                  | 17                |
| 2                  |                           |                 | ~               | 1           | 1               |              |            |             | 1                              |                  |           |             |          |           |            |           |               |               |            | ~        | ✓       |            | 1        |                           |         | √        | 1         | 1              |                                | ✓                    | 4                                     | 1                           | 1                      |       | 1                | 15                |
| 3                  |                           |                 |                 |             | 1               | ✓            | 1          | 1           | ✓                              | ✓                | ✓         |             |          |           |            |           |               | 4             | ✓          |          |         | ✓          |          |                           |         |          |           | ✓              |                                |                      |                                       |                             |                        | 1     |                  | 12                |
| 4                  | ✓                         | ·               |                 |             | 1               |              | 1          |             |                                |                  |           |             |          |           |            |           | ✓             |               |            |          | ✓       |            | ~        |                           |         |          | ✓         |                |                                | ✓                    | ✓                                     | ✓                           |                        |       |                  | 10                |
| 5                  | ✓                         |                 |                 |             |                 | ✓            |            |             | ✓                              |                  |           |             |          |           |            |           |               |               |            | ~        |         |            | 1        |                           |         | ✓        |           |                | ~                              | ✓                    |                                       |                             |                        |       | •                | 8                 |
| 6                  |                           |                 |                 |             |                 |              |            |             |                                |                  |           |             |          |           |            |           |               |               |            | 1        |         |            |          |                           |         | ✓        |           | ✓              | ~                              |                      |                                       |                             |                        |       |                  | 4                 |
| 7                  |                           | ·               |                 |             | 1               |              | 1          | 1           |                                |                  |           |             |          |           |            | ✓         |               |               |            |          |         |            |          |                           |         |          |           |                |                                |                      |                                       |                             |                        |       |                  | 4                 |
| 8                  | •                         |                 |                 | •           | •               | •            | •          | •           | •                              | •                | •         | •           | •        | •         | •          | •         | •             | •             |            |          | •       | •          | •        | •                         | •       | •        |           | •              |                                |                      |                                       |                             |                        |       | •                | 0                 |
| Total<br>Positive: | 2                         | 1               | 1               | 1           | 5               | 3            | 3          | 2           | 3                              | 1                | 1         | 1           | 1        | 1         | 1          | 1         | 1             | 1             | 1          | 4        | 3       | 1          | 4        | 1                         | 1       | 4        | 2         | 3              | 3                              | 4                    | 3                                     | 3                           | 1                      | 1     | 1                |                   |

### Heroin Use - Past Year

#### **HEROIN DEATHS:** 1M Heroin users doubled 948,000 Heroin deaths 7.7 times higher 886,000 828,000 15,594 800K 13,219 13,101 600K 404,000 400K 200K 2,013 est. 0.2% 0.3% 0.3% 0 2002 2015 2016 2017 2002 2015 2016 2017 .....

See table 7.2 in the 2017 NSDUH detailed tables for additional information and the 2017 CDC Mortality Data.



PAST YEAR, 2002 AND 2015- 2017, 12+

### Health Care Crisis: OPIOIDS

### One in four patients concurrently use opioids, benzodiazepines

McClure FL, et al. *J Addict Med.* 2017;doi:10.1097/ADM.00000000000354. October 9, 2017

ADD TOPIC TO EMAIL ALERTS



Research published in the *Journal of Addiction Medicine* indicated concurrent use of opioids and benzodiazepines among approximately 25% of patients who were prescribed at least one drug and tested for both.

Harvey W. Kaufman

According to an accompanying press release, concurrent use of these drugs can lead to respiratory suppression, cardiac distress and death.

"<u>Concurrent use of opioids and benzodiazepines</u> has been on clinicians' radar screens for a few years, based on the increase in opioid prescriptions, the increase in prescription overdoses and opioid-related deaths, and the concern that both opioids and benzodiazepines depress the central nervous system and respiration," **Harvey W. Kaufman**, **MD**, study researcher and senior medical director for Quest Diagnostics, Madison, N.J., told *Healio Family Medicine*. "But we haven't fully understood the breadth of concurrent use."

"...researchers culled prescription and urine drug testing data from a drugmonitoring database. Overall, 231,228 samples from 144,535 patients prescribed at least one drug and tested for both benzodiazepines and opioids were analyzed. According to results, 25.8% of patients were using benzodiazepines and opioids at the same time. In 52% of these patients, only one of the drugs was prescribed.

### Fentanyl (Actiq®, Duragesic®, Sublimaze®)



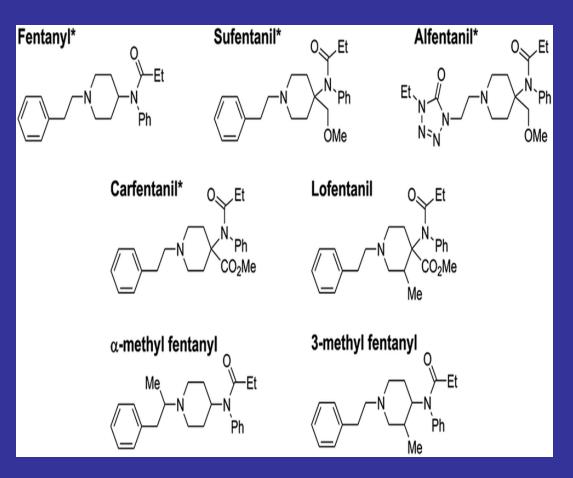






# **Analog Drugs**

Change some of the atoms in a molecule while leaving it's core structure intact.



# The Result

### Properties:

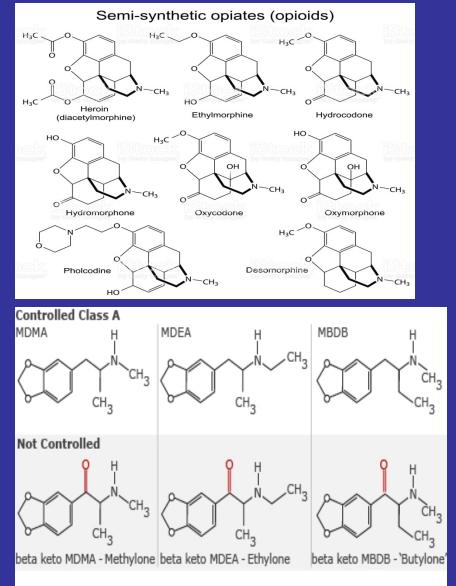
- Potentially shifted in minor or major ways: change in strength of effect, longer or shorter lasting, easier to break down in body or certain organs, etc.

- Shift in chemical structure makes it harder or impossible to detect in standard drug testing (which targets specific chemical structures).

### Legal:

- For pharmaceutical companies: potential for new patents

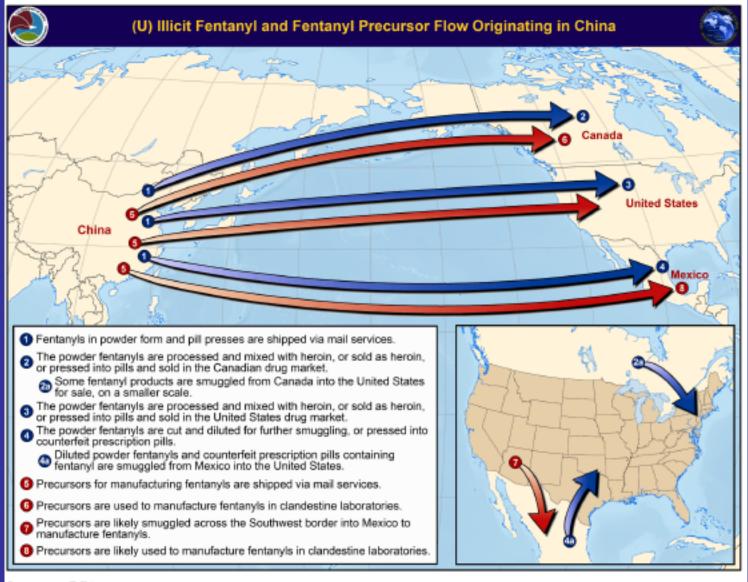
- For makers of illicit drugs: Potential to no longer be considered a "controlled" substance



# Fentanyl & other opioid analogs are now being used...

- To "boost" heroin
- As a heroin substitute
- As counterfeits (oxycodone, Xanax®, Norco®, etc.),
  - including
     cocaine(!)





#### Source: DEA

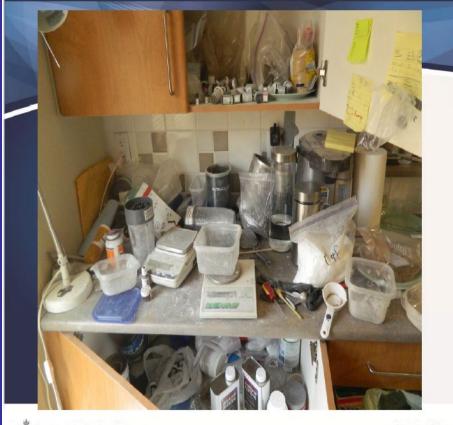
\* A second and a set of a second sec second sec

Figure 11: Synthetic Drug Factory in China.



Figure 12: Synthetic Drug Factory in China.





Royal Canadian Gendarmerie royale Mounted Police du Canada

Canada

Source: DEA

### Lethal Dose Comparison



### **Commercial Tableting Machines**



Cost: \$6000 - \$10,000 US

### Origin: China

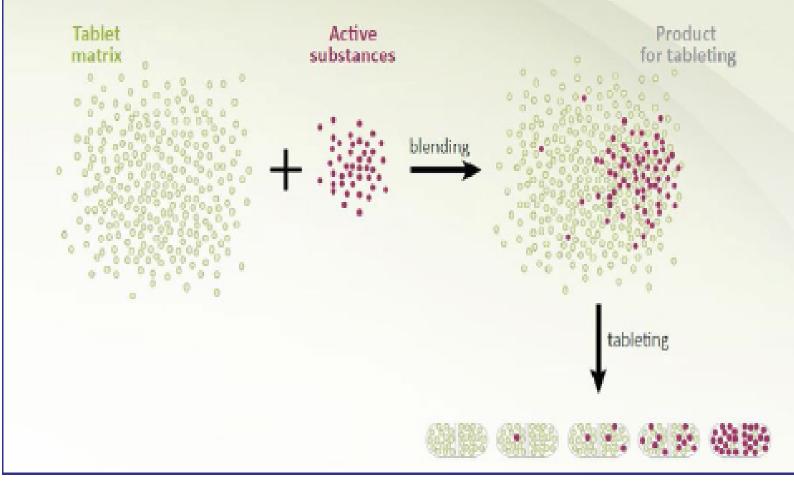
Production Capacity: 10,000 – 18,000 tablets per hour

Non-regulated in Canada, controlled item by the DEA in the United States





### Figure 53. Variable Dose of Active Substance in Clandestinely Manufactured Pills.



Source: United Nations Office on Drugs and Crime

### Why Fentanyl?

- Easy to obtain (overseas labs)
- More predictable, secure & manageable than opium poppy growing (no crop concerns, less people in chain, transport, etc.)
- More profitable (next slide  $\rightarrow$ )
  - Small quantities can lead to high profits
  - More potent but shorter high than heroin, leading to potentially more return business

|  | Figure 54. Pote                                 | ential Fentanyl Prof  | itability.                   |                            |
|--|---|---|------------------------------|----------------------------|
|  | Cost Per 1 Kg                                   | Approximate<br>Number of<br>Kgs Produced<br>from Original<br>Drug | Wholesale Price<br>per Kg in | Revenue to<br>DTO from     |
| Drug                                   | to DTO  | Procurement   | Massachusetts                | 1 Kg                       |
| Heroin                                 | \$5,000 - 7,000<br>(Purchased from<br>Colombia) | 1 kg  | \$80,000                     | \$80,000                   |
| Pu <del>r</del> e<br>Fentanyl<br>(99%) | \$3,300 -5,000<br>(Purchased from<br>China)     | 16-24 kgs   | \$80,000                     | \$1,280,000 -<br>1,920,000 |
| Source: DEA                            |   |   |                              |                            |

### Police Seize Enough Fentanyl To Kill 26 Million People

By Bryan Le (/bio/bryan-le) 05/29/18

The record-breaking seizure was one of the biggest fentanyl busts in US history.

Nebraska State Patrol managed to seize 118 pounds of fentanyl (https://www.cnn.com/2018/05 /25/health/nebraska-fentanylbust/index.html) during a routine traffic stop.

According to estimates by the U.S. Drug Enforcement Administration, this was enough fentanyl to kill 26 million people. This estimate is based on the fact, according



photo via Nebraska State Patrol

to the DEA, that just two milligrams (https://www.dea.gov/druginfo/fentanyl-faq.shtml) of the drug is enough to kill a person.

### WEEKLY DRUG ENVIRONMENT REPORT

10 September 2018 ~ ROIC201809-12024D Office of the Regional Operations and Intelligence Center (ROIC) Office of Drug Monitoring & Analysis (ODMA) NJ ROIC SIN: NJ CRM-0100 (Geographic)/DHS SIN: HSEC 10 (Illicit Operations

The Office of the New Jersey Regional Operations & Intelligence Center (ROIC) monitors New Jersey's drug environment through the Office of Drug Monitoring & Analysis (ODMA). This information is derived from drug evidence that has been analyzed and reported during the past week by forensic crime labs throughout the state.

#### HEROIN AND ADULTERANTS

The following information pertains to the forensic identification of suspected heroin seized throughout the state. Stamp names by themselves do not constitute reliable connections between incidents such as overdoses and arrests. However, stamp names in combination with other variables such as stamp colors and adulterants, provide potential investigative leads. Moreover, stamps having these similarities, and located within regional proximity and time, provide stronger indicators of potential connectivity.

NOTE: Stamps with adulterants are listed first. Stamps found at scenes of overdoses are denoted with \* (fatal) or \*\* (non-fatal). FIBF is para-Fluoroisobutyryl fentanyl. 6-MAM is 6-Monoacetylmorphine.

| Drug                            | <u>Color</u> | <u>Stamp</u>                                 | Agency         | <u>Date</u> | <u>County</u> |
|---------------------------------|--------------|--|----------------|-------------|---------------|
| Heroin/Fentanyl/4-ANPP          | Multi        | *Hipsters Paradise & Skull w/Glasses (Image) | Atlantic City  | 8/11/18     | ATL           |
| Heroin/Fentanyl                 | Green        | Patron                                       | Ramsey         | 5/21/18     | BER           |
| Fentanyl                        | Multi        | **Nose Bleed & Nose (Image)                  | Garfield       | 7/25/18     | BER           |
| Fentanyl                        | Red          | Superbad                                     | NJSP Red Lion  | 2/17/18     | BUR           |
| Fentanyl/Acetyl Fentanyl        | Black        | Jumanji & Monkey (Image)                     | Camden Co PD   | 2/19/18     | CAM           |
| Heroin/Acetyl Fentanyl/Fentanyl | Black        | Witchcraft                                   | Camden Co PD   | 2/21/18     | CAM           |
| Heroin/Acetyl Fentanyl/Fentanyl | Red          | Telephone inside Circle (Image)              | Gloucester Twp | 2/21/18     | CAM           |
| FIBF                            | Black        | Hipsters Paradise                            | Berlin         | 4/27/18     | CAM           |
| Heroin/Fentanyl                 | Red          | Rolex  | Camden Co SO   | 7/22/18     | CAM           |
| Acetyl Fentanyl/Fentanyl        | Black        | Steph Curry                                  | Camden Co PD   | 8/7/18      | CAM           |
| FIBF/Furanyl Fentanyl           | Red          | Rolex & Sword (Image)                        | Camden Co PD   | 8/8/18      | CAM           |
| Heroin/Fentanyl/4-ANPP          | Black        | Witchcraft & Star In Circle (Image)          | Camden Co PD   | 8/9/18      | CAM           |
| Fentanyl/Acetyl Fentanyl        | N/A          | Unmarked                                     | Pine Hill      | 8/16/18     | CAM           |
| Heroin/Fentanyl                 | Black        | King Kong & Ape (Image)                      | Camden Co PD   | 8/17/18     | CAM           |
| Heroin/Fentanyl                 | Black        | King Kong & Gorilla (Image)                  | NJSP           | 8/21/18     | CAM           |
| Heroin/Fentanyl                 | Red          | Power  | Newark         | 5/8/18      | ESS           |

#### Acetyl Fentanyl/Fentanyl Heroin/Fentanvl Heroin/Fentanyl Red Acetyl Fentanyl/Fentanyl Heroin/Fentanyl Heroin/Fentanyl Red Heroin/Fentanyl Bue Fentanyl Heroin/Fentanyl/Acetyl Fentanyl Red Acetyl Fentanyl/Fentanyl Red Heroin/Fentanyl/Acetyl Fentanyl Fentanyl Fentanvl Red Acetyl Fentanyl/Fentanyl Red Fentanyl Heroin/Fentanyl Red Heroin/Fentanyl Red Heroin/FIBF/Fentanyl Heroin/FIBF Heroin/Fentanyl Red Fentanyl Red Heroin/Fentanyl/FIBF/alpha-PiHP Heroin/FIBF Heroin/FIBF Heroin/Fent/Acetyl Fent/Tramadol Heroin/Fentanyl Heroin/FIBF Heroin/Fentanyl Heroin/Fentanyl Fentanyl Red Heroin/FIBF/Fentanyl Heroin/Acetyl Fentanyl/Fentanyl Drug Heroin

Heroin

Heroin

#### UNCLASSIFIED//LAW ENFORCEMENT SENSITIVE

Raw & Hand w/Serrated Object (Image) Purple Black Frank Mathews King of Death & Skull w/Crown (Image) Black Steph Curry Dice (Image) Black Moneybag & Mask (Image) Holy Ghost & Car (Image) Black Slam Dunk 007 \*\*Game Over Sonic the Hedgehog (Image) Blue Blue Feeling Good & Dragon (Image) Ice Berg Kiss Me Lyft & Balloon & Car (Image) Purple \*\*Midnight AK47 Baseball Green \*Dirty Sprite & Bottle (Image) Purple Red Monkey Tom Brady \*Avatar & 2 Avatar Characters (Image) Purple Patron & Bottle (Image) Green Blue Big Fish & Fish (Image) Blue Great Adventures King Kong Black Wall Street Purple Blue Dorney Park Blue Ghost Chi-Raq Stranger Danger Multi \*Empire & Pyramid (Image) Black Stamp Stamp Green Apple Apple & Apple (Image) Green EBT Purple

| Belleville       | 6/15/18     | ESS           |
|------------------|-------------|---------------|
| NJ Transit PD    | 6/16/18     | ESS           |
| NJSP             | 6/28/18     | ESS           |
| Gloucester Co SO | 8/13/18     | GLO           |
| Deptford         | 8/18/18     | GLO           |
| Bayonne          | 7/31/18     | HUD           |
| Bayonne          | 8/2/18      | HUD           |
| NJSP Hamilton    | 2/19/18     | MER           |
| Trenton          | 2/20/18     | MER           |
| Ewing            | 2/26/18     | MER           |
| Trenton          | 5/28/18     | MER           |
| Trenton          | 6/13/18     | MER           |
| Ewing            | 8/19/18     | MER           |
| Sayreville       | 1/30/18     | MID           |
| NJSP Bloomfield  | 7/3/18      | MID           |
| Freehold Boro    | 4/12/18     | MON           |
| Monmouth Co PO   | 4/13/18     | MON           |
| Wall             | 4/15/18     | MON           |
| NJSP Hamilton    | 7/17/18     | MON           |
| Neptune Twp      | 7/25/18     | MON           |
| Denville         | 7/4/18      | MOR           |
| Rockaway         | 7/23/18     | MOR           |
| Passaic Co PO    | 6/11/18     | PAS           |
| Passaic Co PO    | 6/12/18     | PAS           |
| Passaic Co PO    | 6/12/18     | PAS           |
| Wayne            | 6/17/18     | PAS           |
| NJSP Somerville  | 3/9/18      | SOM           |
| Stanhope         | 5/6/18      | SUS           |
| Union Co PO      | 6/12/18     | UNN           |
| Warren Co PO     | 2/2/18      | WAR           |
| Phillipsburg     | 2/11/18     | WAR           |
| Mansfield        | 8/8/18      | WAR           |
| <u>Agency</u>    | <u>Date</u> | <u>County</u> |
| Atlantic City    | 5/23/18     | ATL           |
| Atlantic City    | 7/8/18      | ATL           |
| Ramsey           | 5/21/18     | BER           |
|                  |             |               |



### Three Stamps Involved in Multiple Fatalities



### **Key Findings:**

5/6/2018 Neptune Twp., Monmouth

Three associated stamps, "Below 11", "Tom Brady", and "Unforgiven," have caused multiple suspected fatal and non-fatal overdoses since May 1, 2018.

| "Below   | 11" stamp, black ink,  | "Tot   | nill<br>m Br                                    | and the second sec | "Unfor   | given" stamp, red ink,  |
|--|--|--|---|--|--|---|
|  | white glassine   |  |   | white glassine   |  | white glassine  |
| Suspe  | cted Fatal Overdoses   | Su   | ispe  | cted Fatal Overdoses   | Susp   | ected Fatal Overdoses   |
| 5/13/2018  | Spotswood, Middlesex   | 6 12 120   | 10  | Maturahan Middleson  |  |   |
| 5/15/2010  | spotswood, Middlesex   | 6/2/20   | 18  | Metuchen, Middlesex  | 5/25/2018  | Union, Union  |
|  | Elizabeth, Union   | 6/1/20   | 18  | Hazlet, Monmouth   |  | Union, Union<br>Linden, Union   |
| 5/13/2018  |  | 6/1/20<br>6/1/20   | 18<br>18  | Hazlet, Monmouth<br>Washington, Warren   | 5/21/2018  |   |
| 5/13/2018<br>5/11/2018   | Elizabeth, Union   | 6/1/20<br>6/1/20<br>5/26/2                                       | 18<br>18<br>018                                 | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic  | 5/21/2018  | Linden, Union<br>Elizabeth, Union   |
| 5/13/2018<br>5/11/2018<br>Suspecto<br>5/22/2018  | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth   | 6/1/20<br>6/1/20<br>5/26/2<br>Susp                               | 18<br>18<br>018<br>018                          | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br>d Non-Fatal Overdoses   | 5/21/2018<br>5/10/2018<br>5/7/2018   | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris   |
| 5/13/2018<br>5/11/2018<br>Suspecto<br>5/22/2018  | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses  | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20                     | 18<br>18<br>018<br>018<br>0ecte                 | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br>d Non-Fatal Overdoses<br>Brielle, Monmouth  | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect  | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>ed Non-Fatal Overdoses   |
| 5/13/2018<br>5/11/2018<br>Suspecto<br>5/22/2018<br>5/16/2018   | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth   | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20<br>5/7/20           | 18<br>018<br>018<br>0ecte<br>18<br>18           | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br><b>d Non-Fatal Overdoses</b><br>Brielle, Monmouth<br>Keansburg, Monmouth  | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect<br>5/25/2018                                       | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>e <b>d Non-Fatal Overdoses</b><br>Kenilworth, Union  |
| 5/13/2018<br>5/11/2018<br>Suspecto<br>5/22/2018<br>5/16/2018<br>5/11/2018                                      | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth<br>Roselle Park, Union  | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20<br>5/7/20<br>5/1/20 | 18<br>018<br>018<br>0ecte<br>18<br>18<br>18     | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br>d Non-Fatal Overdoses<br>Brielle, Monmouth<br>Keansburg, Monmouth<br>Newark, Essex  | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect<br>5/25/2018<br>5/12/2018                          | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>ed Non-Fatal Overdoses<br>Kenilworth, Union<br>Edison, Middlesex                           |
| 5/13/2018<br>5/11/2018<br>Suspecto<br>5/22/2018<br>5/16/2018<br>5/11/2018                                      | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth<br>Roselle Park, Union<br>Middletown, Monmouth  | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20<br>5/7/20           | 18<br>018<br>018<br>0ecte<br>18<br>18<br>18     | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br><b>d Non-Fatal Overdoses</b><br>Brielle, Monmouth<br>Keansburg, Monmouth  | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect<br>5/25/2018<br>5/12/2018                          | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>e <b>d Non-Fatal Overdoses</b><br>Kenilworth, Union  |
| 5/13/2018<br>5/11/2018<br>Suspecto<br>5/22/2018<br>5/16/2018<br>5/11/2018<br>5/10/2018                         | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth<br>Roselle Park, Union<br>Middletown, Monmouth<br>Cranford, Union   | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20<br>5/7/20<br>5/1/20 | 18<br>018<br>018<br>0ecte<br>18<br>18<br>18     | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br>d Non-Fatal Overdoses<br>Brielle, Monmouth<br>Keansburg, Monmouth<br>Newark, Essex  | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect<br>5/25/2018<br>5/12/2018                          | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>ed Non-Fatal Overdoses<br>Kenilworth, Union<br>Edison, Middlesex                           |
| 5/13/2018<br>5/11/2018<br>5/22/2018<br>5/16/2018<br>5/16/2018<br>5/10/2018<br>5/9/2018<br>5/8/2018<br>5/8/2018 | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth<br>Roselle Park, Union<br>Middletown, Monmouth<br>Cranford, Union<br>Elizabeth, Union<br>Asbury Park, Monmouth<br>Bridgewater, Somerset | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20<br>5/7/20<br>5/1/20 | 18<br>018<br>018<br>0ecte<br>18<br>18<br>18     | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br>d Non-Fatal Overdoses<br>Brielle, Monmouth<br>Keansburg, Monmouth<br>Newark, Essex<br>Keansburg, Monmouth   | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect<br>5/25/2018<br>5/12/2018<br>5/8/2018              | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>ed Non-Fatal Overdoses<br>Kenilworth, Union<br>Edison, Middlesex<br>Perth Amboy, Middlesex |
| 5/13/2018<br>5/11/2018<br>5/22/2018<br>5/16/2018<br>5/11/2018<br>5/10/2018<br>5/9/2018<br>5/8/2018             | Elizabeth, Union<br>Eatontown, Monmouth<br>ed Non-Fatal Overdoses<br>Ocean, Monmouth<br>Roselle Park, Union<br>Middletown, Monmouth<br>Cranford, Union<br>Elizabeth, Union<br>Asbury Park, Monmouth                          | 6/1/20<br>6/1/20<br>5/26/2<br>Susp<br>6/4/20<br>5/7/20<br>5/1/20 | 18<br>018<br>018<br>018<br>18<br>18<br>18<br>18 | Hazlet, Monmouth<br>Washington, Warren<br>Little Falls, Passaic<br>d Non-Fatal Overdoses<br>Brielle, Monmouth<br>Keansburg, Monmouth<br>Newark, Essex  | 5/21/2018<br>5/10/2018<br>5/7/2018<br>Suspect<br>5/25/2018<br>5/12/2018<br>5/8/2018<br>tamps (Lo | Linden, Union<br>Elizabeth, Union<br>Rockaway, Morris<br>ed Non-Fatal Overdoses<br>Kenilworth, Union<br>Edison, Middlesex<br>Perth Amboy, Middlesex |

|           | Associated Stamps (Loc | ations)            |
|-----------|------------------------|--------------------|
| 5/28/2018 | Unforgiven & Below 11  | Neptune, Monmouth  |
| 5/21/2018 | Unforgiven & Tom Brady | Essex County       |
| 5/16/2018 | Unforgiven & Below 11  | Newark, Essex      |
| 4/23/2018 | Tom Brady & Below 11   | Trenton. Mercer    |
| 4/17/2018 | Tom Brady & Below 11   | East Orange, Essex |

# Fentanyl tends to be shorter acting but more potent. As a result...

- Some users will like the explosive first "rush" in spite of the shorter duration.
- Some will dislike this because withdrawal will set in quicker
- Some might use it to overcome the tolerance or blockade they had developed to either heroin or other medications (e.g. Suboxone®, Vivitrol®)
- Some might seek a heroin/fentanyl mix for the intense rush of fentanyl with the longer duration of heroin.

# Legal Response: Ban

### **In New York State:**

### On Federal Level (Feb. 2018):

#### HEADQUARTERS NEWS

February 07, 2018 Contact: DEA Public Affairs (202) 307-7977

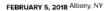
#### U.S. Drug Enforcement Administration emergency schedules all illicit fentanyls in an effort to reduce overdose deaths

**WASHINGTON** – The U.S. Drug Enforcement Administration this week placed all illicit fentanyl analogues not already regulated by the Controlled Substances Act into Schedule I—the category for substances with no currently accepted medical use—for two years, with the possibility of a one-year extension. This action is expected to reduce these substances' flow into the country and slow the alarming increase in overdose deaths linked to synthetic opioids.

"DEA is committed to using all of its tools to aggressively fight and address the opioid crisis and growing fentanyl problem plaguing the United States," said DEA Acting Administrator Robert W. Patterson. "By proactively scheduling the whole class of illicit fentanyl substances simultaneously, federal agents and prosecutors can take swift and necessary action against those bringing this poison into our communities."

A fentanyl analogue is a substance intended for human consumption that is substantially similar in its chemical makeup and effects to fentanyls already listed in Schedule I. Fentanyl is often mixed with heroin and other substances (such as cocaine and methamphetamine) or used in counterfeit pharmaceutical prescription drugs. As a consequence, users who buy these substances on the illicit market are often unaware of the specific substance they are actually consuming and the associated risk.

Anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue will be subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. This will make it easier for federal prosecutors and agents to prosecute traffickers of all forms of fentanyl-related substances.



### Governor Cuomo Announces 30-Day Budget Amendment to Help Combat the Fentanyl Crisis in New York State

Legislation Will Add 11 Types of Fentanyl to the State's Controlled Substances Schedule

Governor Andrew M. Cuomo today announced a 30-day budget amendment will be advanced to add 11 fentanyl analogs to the state controlled substances schedule and provide the New York State Health Commissioner the authority to add any new drugs that have been added to the federal schedule, to the state controlled substances schedule. These actions will support law enforcement in their efforts to stop the spread of lethal drugs in New York State.

# Fentanyl Derivatives and Other Synthetic Opioids

### **Fentanyl Derivatives**

- Acetyl fentanyl
- Butyryl fentanyl
- β-Hydroxythiofentanyl
- p-Fluoro fentanyl
- Acryl fentanyl
- Furanyl fentanyl
- Valeryl fentanyl

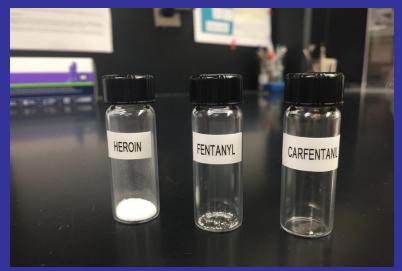
### **Synthetic Opioids**

- MT-45
- AH-7921
- U-47700
- W-15
- W-18

# Carfentanil

• A synthetic opioid approximately at least hundreds of times more potent than morphine and 50 - 100 times more potent than some fentanyl compounds.





### U-47700



| Best-Fee        | .com®               |                     |   | Welcome Join Free   | e or Sign In       | Currency:USD 📒 | Langua |
|-----------------|---------------------|---------------------|---|---------------------|--------------------|----------------|--------|
| Home Specials   | News                | Service Payment&Shi | pment Contact Us N                      | fy Account          | Track              |                | -      |
| U-47700         |                     |                     | Product 4/4                             | )                   |                    |                |        |
|                 |                     |                     | U-47700                                 |                     |                    |                |        |
|                 |                     |                     | Price: <del>\$162.</del><br>Save: 76% c | off<br>Weight: 1lbs |                    |                |        |
|                 | ♪₩<br>}             |                     | Add<br>(                                | Add to cart +       |                    |                |        |
|                 |                     |                     | WcAfee<br>SECURE                        | \$100,000 Ide       | ntity Protecti     | on             |        |
|                 |                     | QTY                 | DISCOUNTS NEW PRICE                     |                     |                    |                |        |
|                 | 5-9g                | 10-19g              | 20-49                                   |                     | 50-99g             | 10             | 0-199g |
| 1-4g            |                     |                     |   |                     |                    |                |        |
| 1-4g<br>\$39.20 | \$35.50             | \$25.50             | \$22.80                                 |                     | \$16.98            | \$             | 9.88   |
|                 | \$35.50<br>500-999g | \$25.50             |   |                     | \$16.98<br>5,000+g |                | ;9.88  |

### Figure 5: Counterfeit Oxycodone Pills Containing U-47700.



Source: Lorain County, Ohio, Sheriff's Office



#### eDarkTrends update: New synthetic opioids, MPF-47,700, U-4TDP, U-48,800, U-49,900, and U-50,488 identified on two cryptomarkets.

New synthetic opioids emerge periodically circumventing existing administrative bans and fueling the opiate/opioid crisis with unknown substances. In an effort to inform public health practitioners on new emerging substances in a timely manner, the **eDarkTrends** project aims to collect and analyze synthetic opioids-related data from Darknet cryptomarkets. Recently notified through the NDEWS network, new substances (U-48,800, ortho-Methylmethoxyacetylfentanyl, Despropionyl ortho-Methylfentanyl) were identified by the Organized Crime Drug Enforcement Task Force (OCDETF). Based on these recent developments, we would like to share some preliminary results from the eDarkTrends project.

The "Fentanyl/Synthetic opioids" and "RC's" sections of three cryptomarkets (DreamMarket, Point / T•chka Free Market, and Wall St Market) were monitored over a two-weeks period (03/20/2018-04/03/2018). Five new non-fentanyl-type synthetic opioids appeared on two cryptomarkets (DreamMarket and Wall St Market):



- MPF-47,700 is sold by only one seller located in China and shipping worldwide; advertised as "a synthetic opioid substance of the benzamide chemical class that produces analgesic, relaxing, sedating and euphoric effects when administered. MPF is a new U47700 analogue." Quantity advertised varies from 2g (US\$50) to 1kg (US\$6,500).
- <u>U-4TDP</u> is sold by only one seller located in China and shipping worldwide; advertised as "a synthetic opioid substance of the benzamide chemical class that produces analgesic, relaxing, sedating and euphoric effects when administered. U-4TDP is similar to U-51754." Quantity advertised varies from 10g (USS210) to 1kg (USS6.500).
- <u>U-48,800</u> is sold by three sellers, two located in China/Hong-Kong and shipping worldwide (no information on the geographical location of the third seller). U-48,800 is advertised as "an opioid analgesic drug analogue of originally U-47700, just added one methylene on the benzene ring, at the same time, 2,4-dichlorophenyl replaced the 3,4-dichlorophenyl. U-48800 is selective for the μ-opioid receptor, having around 7.5 x the potency of morph in animal models. Research results shows that U-48800 has the same potency level as originally U-47700." Quantity advertised varies from 5g (US\$150) to 1kg (US\$6,500).

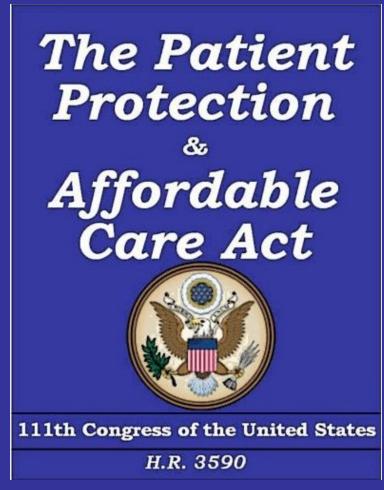
<u>U-49,990</u> is sold by two sellers located in China and shipping worldwide; advertised as "a new product similar to U-47700, with high quality." Quantity advertised varies from 1g (US\$50) to 1kg (US\$6500).

<u>U-50,488</u> is sold by two sellers located in China and shipping worldwide; advertised as "a highly selective κ-opioid agonist, but without any μ-opioid antagonist effects. It has analgesic, diuretic and antitussive effects, and reverses the memory impairment produced by anticholinergic drugs." Quantity advertised varies from 1g (US\$40) to 1kg (US\$6,500).

NB: prices vary daily accordingly to Bitcoin-US\$ exchange rate.

Principal Investigators: Francois Lamy, Ph.D. (Lecturer, HSSIP, Mahidol University); Raminta Daniulaityte, Ph.D. (Associate Professor/Associate Director, CITAR, WSU); Amit Sheth, Ph.D. (Professor and Director, Kno.e.sis, WSU); Co-Investigators: Robert Carlson, Ph.D. (Professor and Director, CITAR, WSU), Ramzi Nahhas, Ph.D. (Associate Professor, DPPHS, WSU), Monica Barratt, Ph.D. (Research Fellow, NDARC, UNSW); Ph.D. Student: Usha Lokala, M.S. (Kno.e.sis, WSU). Contact: Francois Lamy (francois.lam@mahidol.edu) This study was supported by the NIDA Grant No. 1R21DA044518-01. The funding source had no further role in the study design, in the collection, analysis and interpretation of the data.

### Increased Access to Health Insurance to Cover Addiction Treatment ...which is evolving



Mental Health Parity and Addiction Equity Act of 2008

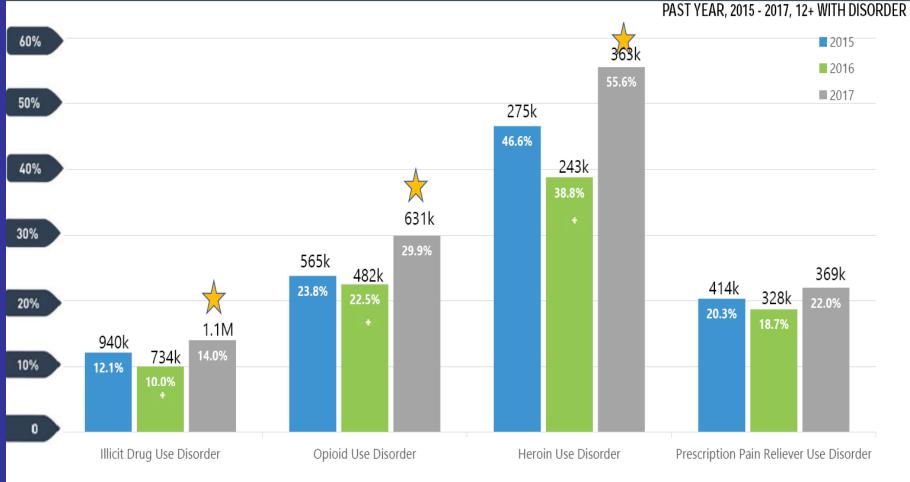


It's gotta go. Repeal and replace with something terrific.

# As a result...

- Increased access for more people into healthcare, including addiction treatment.
- Addiction treatment becoming an attraction to the private sector. Implications for privatization of treatment, pharmaceutical development

### Receipt of Opioid Use Disorder Treatment at Specialty Facilities or Private Doctor Offices



+ Difference between this estimate and the 2017 estimate is statistically significant at the .05 level.



Special analysis of the 2017 NSDUH.

# The Market for Addiction Treatment is \$35 Billion



# Investing in Addiction Treatment and Recovery

Jobs

My Network

Messaging

Notifications

Me▼

Work -

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Published on July 8, 2018

Behavioral Healthcare 190 articles



Gina Meyer + Follow Senior Program Manager at Institute for the Advancement of

Home

stitute for the Advancement of

The fourth annual Treatment Center Investment & Valuation Retreat brings together owners and senior executives from the addiction treatment and recovery community to meet with key members of the investment and financial community for an exclusive three-day educational, business, and networking event.

- Little-to-no federal or (in some states) local oversight for treatment credentials or pricing
- Advertised high success rates with no valid evidence.
- Real-estate investing for lightly regulated "Sober Homes".
- "Finders fees" & for hotlines, referral lines, interventionists, etc. who bring referrals (patient brokering).
- "Creaming" of self-pay and private insurance coverage away from public and non-profits.

# Patient Brokering

### What is Patient Brokering and how does it work?

Rehab Facilities will hire people to recruit drug addicts or alcoholics into their programs.

Patient Sign-up



# In New York State

 OASAS has issued guidance specifically prohibiting it's authorized providers from engaging in dual relationships, "steer clients", accept certain kinds of remuneration, etc.



• Mental Hygiene L. § 32.06 prohibits any individual, addiction professional, credentialed professional, health care provider, health care facility or substance abuse program from giving or receiving a commission, bonus, rebate, or kickback, directly or indirectly, to induce the referral of a potential service recipient in connection with the performance of substance abuse services. This section establishes any violation of this section will constitute a misdemeanor.



日本語

#### **Addiction Treatment Certification**

Let search engines know that you operate safely and legally with LegitScript Certification for providers of drug and alcohol addiction treatment

Addiction Treatment Certification is an important service from LegitScript for providers of drug and alcohol addiction treatment.

LegitScript provides the only certification service for drug and alcohol addiction treatment providers that is relied on by Google and Facebook to vet advertisers for eligibility. Reduce costly interruptions to your Google Ads and Facebook Ads by getting LegitScript-certified.

#### Who Addiction Treatment Certification applies to:

- In-Person Addiction Treatment (Google and Facebook): Any website, application, or merchant that provides information about in-person drug or alcohol addiction treatment, or facilitates in-person or online drug or alcohol treatment, other than at a private residence or non-clinical setting. Currently, recovery residences, which do not provide clinical services or addiction treatment, provide or purport to provide a cooperative living environment in a non-commercial location (a private residence or similar setting), and are not part of a larger treatment program offered by an addiction treatment provider, are not eligible for certification.
- Mutual Support Groups (Google): Any website, application, online forum, or merchant that does not offer treatment for drugs or alcohol, but that facilitates interactions between non-professional members engaged in recovery.
- Crisis Hotlines (Google): Any website, application, call center, chat feature, or telephone number that provides or purports to provide remote assistance or information to individuals who are in recovery or who are seeking information about addiction or addiction treatment, or to any person associated with such individuals, that does not identify particular treatment facilities on the site itself.

Facebook is now requiring addiction treatment centers to obtain certification from a monitoring service

#### Network Open.

#### Original Investigation | Substance Use and Addiction

#### Changes in Buprenorphine-Naloxone and Opioid Pain Reliever Prescriptions After the Affordable Care Act Medicaid Expansion

Brendan Saloner, PhD; Jonathan Levin, MPH; Hsien-Yen Chang, PhD; Christopher Jones, PharmD, MPH; G. Caleb Alexander, MD, MS

#### Abstract

IMPORTANCE Expanding Medicaid eligibility could affect prescriptions of buprenorphine with naloxone, an established treatment for opioid use disorder, and opioid pain relievers (OPRs).

OBJECTIVE To examine changes in prescriptions of buprenorphine with naloxone and OPRs after the US Affordable Care Act Medicaid expansion.

DESIGN, SETTING, AND PARTICIPANTS In this cohort study, longitudinal, patient-level, retail pharmacy claims were extracted from IQVIA real-world data from an anonymized, longitudinal, prescription database. The sample included 11.9 million individuals who filled 2 or more prescriptions for a prescription opoid during at least 1 year between January 1, 2010, and December 31, 2015, from California, Maryland, and Washington (expansion states) and Florida and Georgia (nonexpansion states). Data analysis was conducted from August 1, 2017, to May 31, 2018. Data were aggregated to county-year observations (N = 2082) and linked to county-level covariates. For each outcome, a difference-in-differences regression model was estimated comparing changes before and after expansion in expansion vs nonexpansion counties, Models were adjusted for county demographics, uninsured rate, and overdose mortality in the baseline year (2010).

EXPOSURES Presence of Medicaid expansion in the year.

MAIN OUTCOMES AND MEASURES For buprenorphine with naloxone and OPRs, rates per 100 000 county residents were calculated separately for any prescriptions overall and by different payment sources. Mean days of medication per county among people filling prescriptions for these agents were also determined.

RESULTS The study sample included 11.9 million individuals (expansion states: 40.9% mer; mean [SD] age, 44.1 [13.8] years; nonexpansion states: 41.0% mer; mean [SD] age, 43.7 [13.7] years). In expansion counties, 68.8 individuals per 100 000 county residents filled buprenorphine with nakoone and 5298.3 filled OPR prescriptions in 2010. After expansion, buprenorphine with nakoone fills per 100 000 county residents increased significantly in expansion relative to nonexpansion counties (8.7; 95% CI, 17 to 15.7). Opioid pain reliever fills per 100 000 county residents did not significantly drage in expansion counties relative to onexpansion counties (327.4; 95% CI, 20.25 to 857.4). The rate of OPRs per 100 000 county residents paid for by Medicaid significantly increased (374.0; 95% CI, 25.83 to 489.7). There were no significant dranges in days per 100 000 county residents on filter expansion.

CONCLUSIONS AND RELEVANCE Medicaid expansion significantly increased buprenorphine with naloxone prescriptions per 100 000 county residents in expansion counties, suggesting that expansion improved access to opioid use disorder treatment. Expansion did not significantly increase

#### Key Points

Question Did Medicaid expansion under the US Affordable Care Act change prescription fills for buprenorphine with naloxone, a treatment for opicid use disorder, and opicid pain relievers?

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Findings In this cohort study using difference-in-differences analysis of all-payer prescription fill data from 5 states, Medicaid expansion was associated with a significant overall increase in people filling prescriptions for bupenorphine with naloxone. Expansion was not associated with changes in fills per 100 000 county residents of opioid pain relievers overall, but significantly more people filled prescriptions for opioid pain relievers paidfor specifically by Medicaid.

Meaning Medicaid expansion may increase the role of states in providing opioid use disorder treatment and in paying for opioid pain relievers for pain management.

🕂 Supplemental content

Author affiliations and article information are listed at the end of this article.

"Medicaid expansion was associated with a significant overall increase in people filling prescriptions for buprenorphine with naloxone."

## Addiction Medications

- Insurers cannot require prior approval for emergency supplies of drug treatment medications. Similar provisions that apply to managed care providers treating Medicaid recipients who seek access to buprenorphine and injectable naltrexone took effect in June 2016
- Insurance companies must cover the costs of naloxone when prescribed to a person who is addicted to opioids and to his/her family member/s on the same insurance plan.
- Trained professionals can now administer naloxone in emergency situations without risk to their professional license.

# The current thinking on the best treatment for opioid abuse:

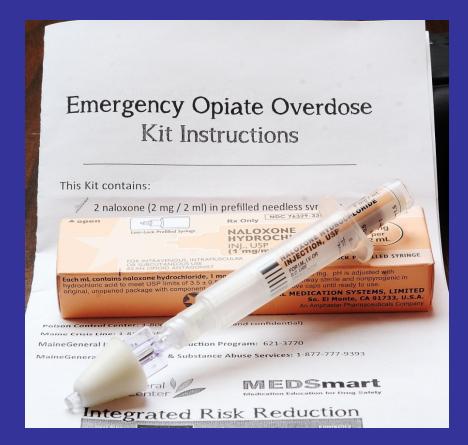
- "MAT (medication assisted treatment) is the use of medications (i.e. buprenorphine, methadone, extended-release injectable naltrexone), in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders, including opioid use disorders."
- "Studies have shown that the most effective treatments for opioid use disorders are those that include a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual."
- "Although MAT has significant evidence to support it as an effective treatment, it remains highly underutilized..."
  - Source: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. Dept. Of Health & Human Services Office of the Asst. Secr'y for Planning & Evaluation. March 26, 2015.

Medications Currently Available for the Treatment of Opioid Dependency

- Methadone
- Naltrexone (including Vivitrol ® & Narcan ®)
- Buprenorphine

# Naloxone (Narcan ®)

- Opioid antagonist which reverses opioid overdoses
- Flushes other opioids off the receptors & prevents them from being activated for 30-90 minutes



## New York State Law...

• Allows patient-specific or non-patient specific prescribing, dispensing or distributing an opioid antagonist to a person at risk of experiencing an opioid-related overdose, or a family member, friend or other person in a position to assist a person experiencing or at risk of experiencing an opioidrelated overdose.



# Buprenorphine originally came in two forms:





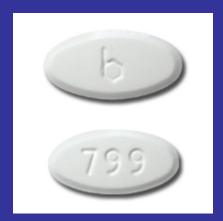




## "The Film"



### Now Available: Generic buprenorphine, and other buprenorphine-based products





BUNAVAIL 2.1/0.3 mg (buprenorphine/naloxone)

UNAVAIL 4.2/0.7 mg puprenorphine/naloxone) 3UNAVAIL 6.3/1 mg buprenorphine/naloxone}





#### FDA News Release

# FDA approves first generic versions of Suboxone sublingual film, which may increase access to treatment for opioid dependence

Agency is taking additional steps to advance the development of new FDA-approved treatments for opioid dependence and encourage their more widespread use

| For Immediate Release | June 14, 2018  |
|-----------------------|--|
| Release               | The U.S. Food and Drug Administration today approved the first generic versions of Suboxone (buprenorphine and naloxone) sublingual film (applied under the tongue) for the treatment of opioid dependence.  |
|                       | "The FDA is taking new steps to advance the development of improved treatments for opioid use disorder, and to make sure<br>these medicines are accessible to the patients who need them. That includes promoting the development of better drugs, and<br>also facilitating market entry of generic versions of approved drugs to help ensure broader access," said FDA Commissioner<br>Scott Gottlieb, M.D. "The FDA is also taking new steps to address the unfortunate stigma that's sometimes associated with<br>the use of opioid replacement therapy as a means to successfully treat addiction. Patients addicted to opioids who are<br>eventually treated for that addiction, and successfully transition onto medicines like buprenorphine, aren't swapping one<br>addiction for another, as is sometimes unfortunately said. They're able to regain control of their lives and end all of the<br>destructive outcomes that come with being addicted to opioids. When coupled with other social, medical and psychological<br>services, medication-assisted treatments are often the most effective approach for opioid dependence. |
|                       | Medication-assisted treatment (MAT) (/Drugs/DrugSafety/InformationbyDrugClass/ucm600092.htm) is a<br>comprehensive approach that combines FDA-approved medications (currently methadone, buprenorphine, or naltrexone) with  |

# Treatment Magazine

#### HOME DIRECTORY SPECIAL REPORTS PUBLISHER'S NOTE UPFRONT FEATURES NEW

#### Newswires

#### Purdue Pharma Scion Granted Opioid Addiction Therapy Patent

09/07/2018 -ATIN- A scion of the family that controls Oxycontin maker Purdue Pharma, Dr. Richard Sackler, has been granted a U.S. patent on a new opioid addiction therapy. The patent was granted for a new drug, a variation on the blockbuster compound buprenorphine.

The Sackler family of Connecticut has long controlled Purdue, which has come under intense fire for allegedly kicking off the opiate addiction epidemic through unscrupulous and misleading advertising and marketing of OxyContin. Dr. Richard Sackler was at one time the CEO of Purdue, a time when OxyContin sales were soaring, driving immense profits at Purdue.

Purdue is now facing over 1,000 lawsuits, many brought by state attorneys general seeking redress and compensation for the medical and economic damages caused by alleged improper and misleading marketing of OxyContin, which the suits claim was a major cause of the unprecedented opiate addiction epidemic. The latest CDC number put OD deaths in 2017 at 72K+, up from \$62K+ in 2016. That makes opiate ODs one of the leading causes of premature death.

#### SAMHSA Gives No Information on How Many Patients Are on **Buprenorphine or How Well They Are Doing – Addiction** Treatment Forum



#### By Alison Knopf

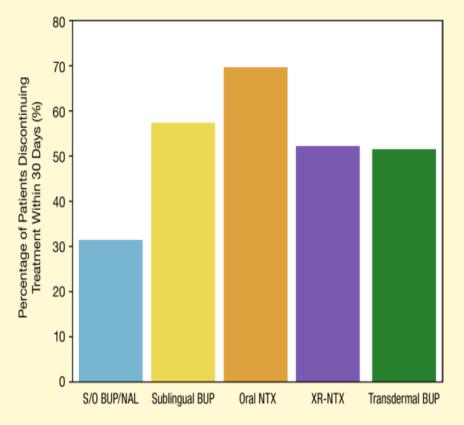
Opioid treatment programs (OTPs) must submit a plethora of information on their services to the Substance Abuse and Mental Health Services Administration (SAMHSA). Office-based outpatient treatment (OBOT) providers who prescribe buprenorphine must submit exactly nothing, it appears.

On May 20, we asked SAMHSA, "How is office-based treatment with buprenorphine working, since the patient cap was increased from 100 to 275 in July of 2016? How many patients are getting treatment? What kind of treatment are they getting? Are doctors reporting anything?"

On May 23, SAMHSA responded: "The only MAT data we have would be from N-SSATS, and that doesn't include private practitioners." (N-SSATS is the National Survey of Substance Abuse Treatment Services.)

SAMHSA then provided this statement: "SAMHSA promotes access to medication-assisted treatment for opioid use disorder through training of providers (e.g., physicians, nurse practitioners, and physician assistants). For example, the 4,151 buprenorphine prescribers who have increased their patient limit from 100 to 275 represent the potential to treat up to 726,425 additional people with opioid use disorder. Starting with the 2019 National Survey on Drug Use and Health [NSDUH], SAMHSA is planning to include questions on the use of medication-assisted treatment among Americans for the treatment of opioid and alcohol use disorders."

#### Patients Are More Likely To Stop Taking Certain Medications



Adapted from Morgan et al. 2017; permission for use of data provided by Dr. J.R. Morgan

Many patients who received MOUD prescriptions stopped taking the medication within the first 30 days. Patients were least likely to stop taking S/O BUP/NAL (31 percent) and most likely to stop taking oral NTX (70 percent).

Dr. Morgan cites several reasons why patients might be more likely to discontinue some medications than others:

- Patients who stop taking NTX do not experience withdrawal symptoms, making it easier to discontinue that medication. In contrast, stopping opioid agonists, such as BUP, leads to withdrawal symptoms.
- Opioid agonists, such as BUP, may have greater rewarding effects.
- The logistics of treatment (e.g., frequency of administration, oral administration vs. injection) may influence medication compliance.



# Who Can Prescribe?

- For "qualifying" licensed physicians...
  - Board certified in Addiction Psychiatry
  - ASAM or AOA certified
  - Bupernorphine Clinical Trial Investigator
  - 8 hours of specific training
  - have other training/clinical experience that is considered comparable
- Has a DEA Identifier Number
- Only up to 30 patients initially, can apply for up to 275 after 1 year and either: 1) possess subspecialty board certification in addiction medicine or addiction psychiatry or 2) practice in a "qualified" practice setting

The 2016 Comprehensive Addiction and Recovery Act authorizes Nurse Practitioners and Physician Assistants with 24 hours of training to also prescribe.



#### U.S. Department of Justice

United States Attorney Southern District of New York

86 Chambers Street New York, New York 10:

October 3, 2017

By First Class Mail New York State Office of the Attorney General One Civic Center Plaza, Suite 401 Poughkeepsie, NY 12601

#### Re: Medication-Assisted Treatment and the ADA

Dear New York State Office of the Attorney General:

It has come to our attention that the Family Court and Surrogate's Court in Sullivan County, New York, as well as the stakeholders involved with those courts, may benefit from further information about the ADA's application to individuals receiving medication-assisted treatment ("MAT"), such as treatment with methadone or buprenorphine, for substance use disorders.

Title II of the Americans with Disabilities Act ("ADA"), 42 U.S.C. §§ 12131-34, protects qualified individuals with a disability from discrimination by public entities—including state and local courts—on the basis of their disability. As explained below, a MAT participant will often be a "qualified individual with a disability" under the ADA, either because the person has a current or past history of an opioid use disorder that substantially limits a major life activity, or because the person is regarded as having a disabling impairment by reason of her participation in MAT. If a MAT participant is a qualified individual with a disability, then the ADA prohibits the Sullivan Family Court and Sullivan Surrogate's Court from (1) denying the MAT participant the benefits of their services, programs, or activities; (2) excluding the MAT participant from their services, programs, or activities; or (3) otherwise subjecting the MAT participant to discrimination, by reason of her disability. See 28 C.F.R. § 35.130. For example, a court generally could not deny a parent visitation with her child by reason of the parent's past history of opioid use disorder or current use of MAT. Nor could a court impose a blanket rule requiring parents to stop participating in MAT in order to gain custody of their children.

We recognize that safety concerns are paramount when courts make decisions about the care and custody of children and other vulnerable individuals. Under the ADA, a public entity is not required to allow someone to participate in or benefit from its services or programs if the person poses a "direct threat to the health or safety of others." 28 C.F.R. § 35.139. Thus, in the above example, a court could deny a MAT participant custody or visitation rights if the parent posed a direct threat to her child. Crucially, the ADA requires a public entity to base its assessment of "direct threat" on an individualized evaluation that is grounded in current medical knowledge and the best available objective evidence. *Id.* A court may not conclude that a MAT participant poses a "direct threat" based on generalizations or scientifically unsupported assumptions about MAT or persons who receive MAT for opioid use disorders.

# M.A.T. in Nursing Homes

#### STAT

Nursing homes routinely refuse people on addiction treatment - which some experts say is illegal

#### By Allison Bood

April 17, 2018



A cap is filled with a dose of methadome. Law a Mergos for STAT

#### 🎯 United States Department of Justice

#### THE UNITED STATES ATTORNEY'S OFFICE

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#### FOR IMMEDIATE RELEASE

Thursday, May 10, 2018

#### U.S. Attorney's Office Settles Disability Discrimination Allegations at Skilled Nursing Facility

BOSTON – The U.S. Attorney's Office reached a settlement agreement today with Charlwell House, a skilled nursing facility in Norwood, to resolve allegations that the facility violated Title III of the Americans with Disabilities Act (ADA) by refusing to accept a patient because they were being treated for Opioid Use Disorder (OUD).

Charlwell House is a 124-bed health and rehabilitation center that provides skilled nursing services and rehabilitation programs. According to a complaint filed with the United States Attorney's Office, an individual seeking admission for treatment at Charlwell House was denied because they were being treated with Suboxone, a medication used to treat OUD. Individuals receiving treatment for OUD are generally considered disabled under the ADA, which among other things prohibits private healthcare providers from discriminating on the basis of disability.

"Our office is committed to protecting the rights of people with disabilities, which includes those in treatment for an Opioid Use Disorder," said United States Attorney Andrew E. Lelling. "The number one enforcement priority of my office is addressing Massachusetts' opioid crisis. Overdoses killed more than 2,000 individuals in Massachusetts last year alone. As Massachusetts faces this overdose epidemic, now more than ever, individuals in recovery must not face discriminatory barriers to treatment. We appreciate the cooperation that Charlwell House has offered throughout our investigation."

Under the terms of the agreement, Charlwell House will, among other things, adopt a non-discrimination policy, provide training on the ADA and OUD to admissions personnel, and pay a civil penalty of \$5,000 to the United States.

This matter was handled by Special Assistant U.S. Attorney Gregory Dorchak of Lelling's Civil Rights Unit.

The Civil Rights Unit of the U.S. Attorney's Office was established in 2015 with the mission of enhancing federal civil rights enforcement. For more information on the Office's civil rights efforts, please visit www.justice.gov/usao-ma/civil-rights.

# Lucemyra <sup>®</sup> (lofexidine)

- "the first and only non-opioid medication indicated for mitigation of opioid withdrawal symptoms"
- "LUCEMYRA is not a treatment for opioid • use disorder. Patients who complete opioid discontinuation are likely to have a reduced tolerance to opioids and are at increased risk of fatal overdose should they resume opioid use. Use LUCEMYRA in patients with opioid use disorder only in conjunction with a comprehensive management program for the treatment of opioid use disorder and inform patients and caregivers of this increased risk of overdose."
  - *Source*: Manufacturer website



# Kratom







Figure 2. Images of kratom products purchased at a "smoke shop" in suburban Chicago. The images show chopped leaves (A), which are typically brewed into "kratom tea", capsules containing finely chopped leaves (B), and compressed tablets containing leaves or resin (C).

- Grows from 15 50 feet tall; native to Southeast Asia.
- While legal under federal law, it has been banned in several states.
- Advertised and sold online as
  - "cheaper alternative" to traditional opioid replacement therapies (as it binds to opiate receptors, but quite differently from morphine, etc., )
  - a detox drug
  - a treatment for chronic pain
  - an anti-anxiety remedy

- Varied reports of overall effects: kratom leaves have been chewed for stimulant, sedative, and euphoric effects. They can also be smoked, brewed as a tea, or made into an extract.
- The primary active chemicals are mitragynine & 7-hydroxymitragynine.
   Different versions of the plant might have significantly different levels of these chemicals.



### STAT

#### Salmonella outbreak in 20 states linked to kratom consumption

By Helen Branswell @HelenBranswell

February 20, 2018



Apopular herbal supplement that some people use in lieu of powerful opioid drugs has been linked to an outbreak of salmonella, the Centers for Disease Control and Prevention reported Tuesday.

#### **August 2016**

#### February 2018



This document is scheduled to be published in the Federal Register on 08/31/2016 and available online at http://tederalregister.gov/a/2016-20803, and on FDsys.gov

Billing Code 4410-09-P

#### DEPARTMENT OF JUSTICE

**Drug Enforcement Administration** 

21 CFR Part 1308

[Docket No. DEA-442]

Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-

Hydroxymitragynine into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice

ACTION: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule the opioids mitragynine and 7-

hydroxymitragynine, which are the main active constituents of the plant kratom, into

schedule I pursuant to the temporary scheduling provisions of the Controlled Substances

Act. This action is based on a finding by the Administrator that the placement of these

#### FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse

Additional adverse events associated with kratom use identified

#### For Immediate Release

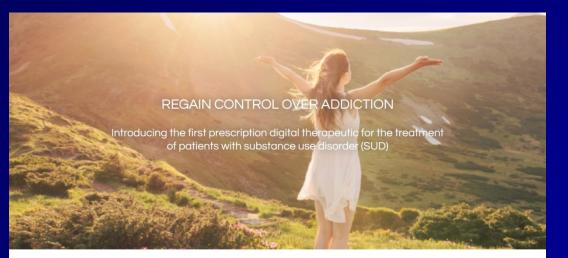
February 6, 2018

#### Summary

FDA releases adverse events and scientific analysis providing even stronger evidence of kratom compounds' opioid properties.

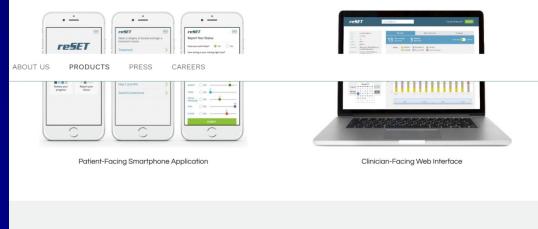
#### Approved September 2017 by the FDA

"The first mobile medical application to help treat substance use disorders (SUD). ..The ReSet<sup>®</sup> device is indicated as a prescription-only adjunct treatment for patients with SUD who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or whose primary substance of abuse is not opioids."



#### reSET® for Substance Use Disorder

Pear Therapeutics has developed reSET®, a prescription digital therapeutic to be used in conjunction with standard outpatient treatment for substance use disorder (SUD)



reSET® as a Prescription Digital Therapeutic for Treating Substance Use Disorder

### **Approved November 2017 by the FDA**

"The NSS-2 Bridge<sup>®</sup> device is a small electrical nerve stimulator placed behind the patient's ear. It contains a battery-powered chip that emits electrical pulses to stimulate branches of certain cranial nerves. Such stimulations may provide relief from opioid withdrawal symptoms. Patients can use the device for up to five days during the acute physical withdrawal phase."



# The FDA Approval Process

Are innovations being too "fast-tracked" in response to the opioid pandemic?



#### 21<sup>st</sup> Century Cures Act Speeds Up FDA Approval Process, But For Better or For Worse?

Arguments For and Against 21st Century Cures Act Changes to the FDA Approval Process

#### Section 2062 on Evidence Standards for Drugs and Medical Devices: "Evoluate the potential use of evidence from clinical experience"

Key Takeaway: The FDA would be able to consider evidence from clinical case studies when evaluating efficacy, rather than more rigorous randomized controlled trials

Section 2121 on Expedited Antibiotic Drug Development: "Approval of certain drugs for use in a limited population"

Key Takeaway: New antibiotics would be approved to enter the market for a limited population of patients with antibiotic-resistant infections after "limited" testing

#### SUPPORTERS SAY

Waiting for results of large clinical trials slows down the approval process, keeping potentially lifesaving drugs and medical devices from patients for years.

#### CRITICS SAY

This would allow drugs to be approved based on anecdotal evidence, which may not accurately represent actual efficacy of the drug or medical device.

#### SUPPORTERS SAY

Speeding up the approval process for new antibiotics will help combat the antibiotic-resistant infections crisis and save lives of affected patients.

#### CRITICS SAY

This would allow for the results of animal studies alone to be used as evidence of efficacy, which may not translate to efficacy or safety for humans.

#### Analysis

The bipartisan 21<sup>st</sup> Century Cures Act (H.R. 6) passed 344 – 77 in the House on July 10<sup>th</sup>, 2015. It would expedite the FDA approval process for drugs and medical devices by providing alternative regulatory pathways under certain circumstances.
 Supporters say changes in the regulatory process would increase the number of new lifesaving drugs entering the market, while critics believe that the bill would lead to the approval of ineffective and potentially unsafe drugs.

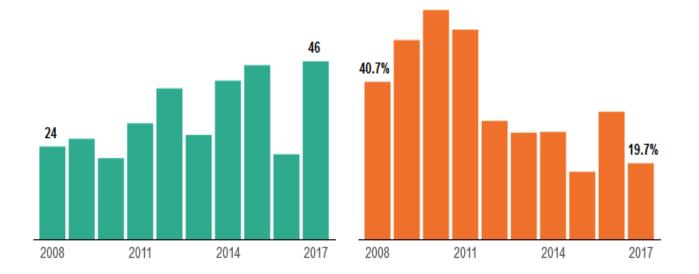
#### FDA Is Approving More New Drugs and Rejecting Fewer Overall

#### FDA Approvals of "Novel" Drugs

The number of "novel" drugs – those with new chemical structures – approved by the FDA nearly doubled over the last 10 years.

#### FDA Rejections of All Applications

The FDA's Center for Drug Evaluation and Research is denying a smaller percentage of all drug applications.



Sources: Center for Drug Evaluation and Research; Credit: Riley Wong

The FDA's assessment of depot naltrexone's efficacy was primarily based on a single trial in Russia, in which 250 eligible patients were randomly assigned to receive depot naltrexone or placebo

- Of the patients...
  - 41% were HIV positive
  - 91% were Hep C positive
- 54% of patients did not complete the protocol and just over half of those on naltrexone received the full treatment course
- It was not a true "double-blind" study in that any opiate use would indicate if a subject was on naltrexone or placebo
- Inclusion criterion included patients having someone available to supervise attendance, the provision of individual counseling, and the promise of active XR-NTX treatment for all patients after 6 months in the subsequent open-label extension safety study.

The Bridge<sup>®</sup> was not approved by the FDA based on any standard clinical trial (e.g. double blind or vs. placebo study, informed consent, measure of dropout or relapse rate, etc.).

Data was based on "retrospective assessment" which looked at patient records and reports of withdrawal symptoms, including by an author who had a potential conflict of interest.



## Proposed changes for meeting "effectiveness" criteria

Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment Guidance for Industry

#### DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Silvana Borges at 301-796-0963.

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER)

> August 2018 Clinical/Medical

 Reduction in drug-taking (standard "endpoint")

- Mortality (overall or overdoses)
- Need for emergency interventions
- Hepatitis C conversion
- Patient reports on how they feel or function
- Intensity of urge to use

Healthy intranasal users of heroin (men and women, age 21-45yrs) needed for 9-10 week inpatient study of medication effects at the NY State Psychiatric Institute. Earn between \$3300 and \$3900. Call the Substance Use Research Center at (212) 543 6243.

# Added June 2018

## New York State Department of Health Announces Opioid Use to be Added as a Qualifying Condition for Medical Marijuana

## **Opioid Use Joins 12 other Qualifying Conditions Under the Compassionate Care Act**

ALBANY, N.Y. (June 18, 2018) - The New York State Department of Health today announced it will develop a regulatory amendment to add opioid use as a qualifying condition for medical marijuana.

"The opioid epidemic in New York State is an unprecedented crisis, and it is critical to ensure that providers have as many options as possible to treat patients in the most effective way," said New York State Health Commissioner Dr. Howard Zucker. "As research indicates that marijuana can reduce the use of opioids, adding opioid use as a qualifying condition for medical marijuana has the potential to help save countless lives across the state."

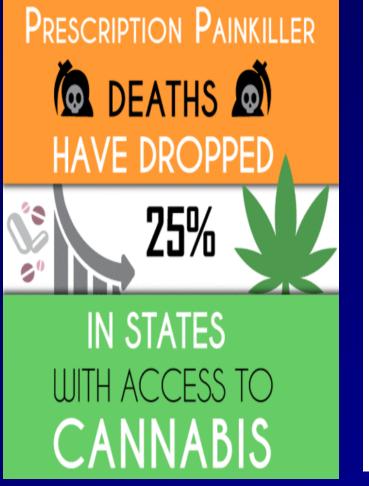
Opioid use joins 12 other qualifying conditions under the state's Medical Marijuana Program. Currently, patients can be eligible if they have been diagnosed with one or more of the following severe debilitating or life-threatening conditions: cancer; HIV infection or AIDS; amyotrophic lateral sclerosis (ALS); Parkinson's disease; multiple sclerosis; spinal cord injury with spasticity; epilepsy; inflammatory bowel disease; neuropathy; Huntington's disease; post-traumatic stress disorder; or chronic pain.

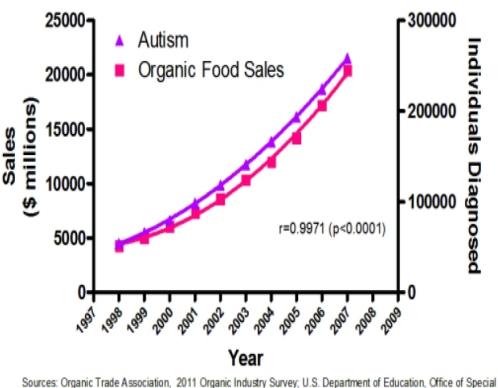
In New York State, overdose deaths involving opioids increased by about 180 percent from 2010 (over 1,000 deaths) to 2016 (over 3,000 deaths). While in 2002, it was still relatively rare to have an opioid overdose in most communities, it is now commonplace throughout the state. In addition to the dramatic increase in the number of deaths in the past few years, the opioid epidemic has devastated the lives of those with opioid use disorder, along with their families and friends. Those with opioid use disorder are at higher risk for HIV, Hepatitis C and chronic diseases.

Marijuana can be an effective treatment for pain, greatly reduces the chances of dependence and eliminates the risk of fatal overdose compared to opioid-based medications. Studies of some states with medical marijuana programs have found notable associations of reductions in opioid deaths and opioid prescribing with the availability of cannabis products. States with medical cannabis programs have been found to have lower rates of opioid overdose deaths than other states, perhaps by as much as 25 percent. Studies on opioid prescribing in some states with medical marijuana laws have noted a 5.88 percent lower rate of opioid prescribing. Adding prescribed opioid use as a qualifying condition for medical marijuana will allow individuals who use opioids to instead use medical marijuana for pain relief.

# "...any condition for which an opioid could be prescribed as a qualifying condition for medical marijuana."

"In addition, the regulation adds opioid use disorder as an associated condition. This allows patients with opioid use disorder who are enrolled in a certified treatment program to use medical marijuana as an opioid replacement."





Sources: Organic Trade Association, 2011 Organic Industry Survey, U.S. Department of Education, Office of Special Education Programs, Data Analysis System (DANS), OMB# 1820-0043: "Children with Disabilities Receiving Special Education Under Part B of the Individuals with Disabilities Education Act

"Cannabis use was common in people with chronic non-cancer pain who had been prescribed opioids, but we found no evidence that cannabis use improved patient outcomes. People who used cannabis had greater pain and lower self-efficacy in managing pain, and there was no evidence that cannabis use reduced pain severity or interference or exerted an opioid*sparing effect.* As cannabis use for medicinal purposes increases globally, it is important that large well designed clinical trials, which include people with complex comorbidities, are conducted to determine the efficacy of cannabis for chronic non-cancer pain." Source: Lancet Public Health 2018: 3: e341-50

# Effect of cannabis use in people with chronic non-cancer pain prescribed opioids: findings from a 4-year prospective cohort study

Gabrid le Campbell, Wayne D Hall, Amy Peacock, Nicholas Lintzeris, Raimondo Bruno, Briony Larance, Suzanne Nielsen, Milton Cohen, Gary Chan, Richard P Mattick, Fiona Blyth, Marian Shanahan, Timothy Dobbins, Michael Farrell, Louisa Degenhardt

### Summary

Background Interest in the use of cannabis and cannabinoids to treat chronic non-cancer pain is increasing, because of their potential to reduce opioid dose requirements. We aimed to investigate cannabis use in people living with chronic non-cancer pain who had been prescribed opioids, including their reasons for use and perceived effectiveness of cannabis; associations between amount of cannabis use and pain, mental health, and opioid use; the effect of cannabis use on pain severity and interference over time; and potential opioid-sparing effects of cannabis.

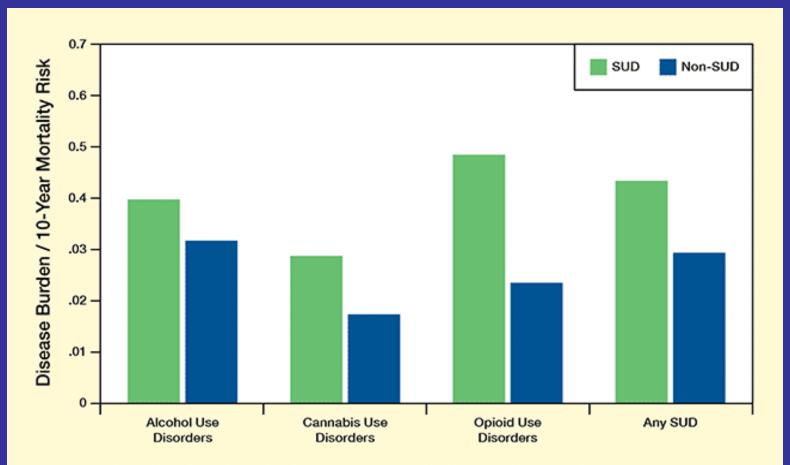
Methods The Pain and Opioids IN Treatment study is a prospective, national, observational cohort of people with chronic non-cancer pain prescribed opioids. Participants were recruited through community pharmacies across Australia, completed baseline interviews, and were followed up with phone interviews or self-complete questionnaires yearly for 4 years. Recruitment took place from August 13, 2012, to April 8, 2014. Participants were asked about lifetime and past year chronic pain conditions, duration of chronic non-cancer pain, pain self-efficacy, whether pain was neuropathic, lifetime and past 12-month cannabis use, number of days cannabis was used in the past month, and current depression and generalised anxiety disorder. We also estimated daily oral morphine equivalent doses of opioids. We used logistic regression to investigate cross-sectional associations with frequency of cannabis use, and lagged mixed-effects models to examine temporal associations between cannabis use and outcomes.

Findings 1514 participants completed the baseline interview and were included in the study from Aug 20, 2012, to April 14, 2014. Cannabis use was common, and by 4-year follow-up, 295 (24%) participants had used cannabis for pain. Interest in using cannabis for pain increased from 364 (33%) participants (at baseline) to 723 (60%) participants (at 4-years). At 4-year follow-up, compared with people with no cannabis use, we found that participants who used cannabis had a greater pain severity score (risk ratio 1.14, 95% CI 1.01-1.29, for less frequent cannabis use; and 1.17, 1.03-1.32, for daily or near-daily cannabis use), greater pain interference score (1.21, 1.09-1.35; and 1.14, 1.03-1.26), lower pain self-efficacy scores (0.97, 0.96-1.00; and 0.98, 0.96-1.00), and greater generalised anxiety disorder severity scores (1.07, 1.03-1.12; and 1.10, 1.06-1.15). We found no evidence of a temporal relationship between cannabis use and pain severity or pain interference, and no evidence that cannabis use reduced prescribed opioid use or increased rates of opioid discontinuation.

Interpretation Cannabis use was common in people with chronic non-cancer pain who had been prescribed opioids, but we found no evidence that cannabis use improved patient outcomes. People who used cannabis had greater pain and lower self-efficacy in managing pain, and there was no evidence that cannabis use reduced pain severity or interference or exerted an opioid-sparing effect. As cannabis use for medicinal purposes increases globally, it is important that large well designed clinical trials, which include people with complex comorbidities, are conducted to determine the efficacy of cannabis for chronic non-cancer pain.

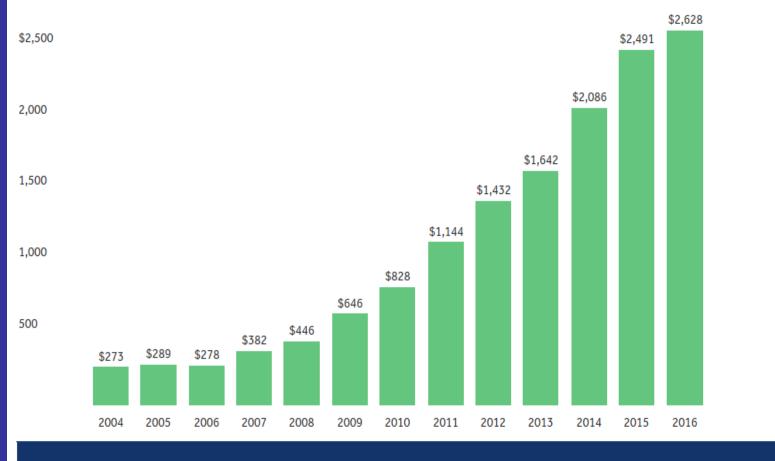
Funding National Health and Medical Research Council and the Australian Government.

# Patients With Substance Use Disorders (SUDs) Have an Increased Risk of Major Medical Conditions



Adapted from Bahorik et al. 2017; permission for use of data provided by Dr. A. Bahorik.

# Total amounts paid for opioid addiction and overdose treatment diagnoses for enrollees in large employer plans, in millions, 2004-2016



Source: Kaiser Family Foundation analysis of Truven MarketScan data, 2004-2016 • Get the data • PNG

Peterson Kaiser Health System Tracker

- Insurance needs to control expenses, especially high-cost care (inpatient, E.R., hospital-based care, etc.)
- Some insurers made access to treatment more difficult, including...
  - Pre-approval for admissions
  - "Fail-first" policies
  - Caps on treatment stays and/or medications
  - -Vague admission or continued stay criteria
  - -Etc.

# New York State legislation now states...

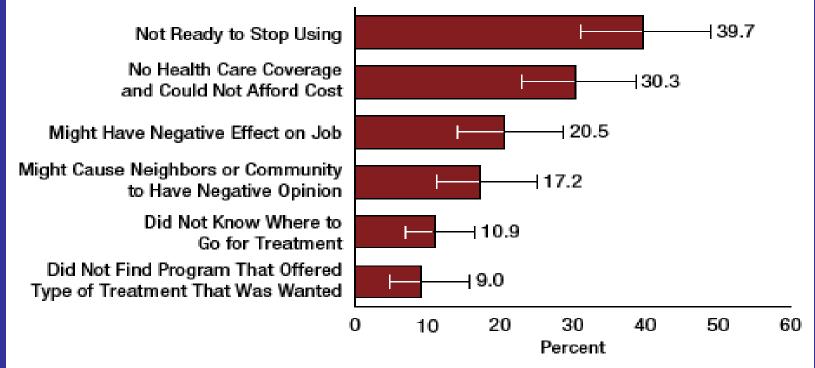
- No prior authorization or concurrent review for first 14 days of most levels of care that are deemed medically necessary care.
  - But, must notify insurer within 48 hrs. of admission and provide initial treatment plan
- Admission based on OASAS-approved clinical criteria tool (e.g. LOCADTR 3.0, ASAM PPC)
- More regulated review and appeals processes (including use of LOCADATR 3.0 for review)

Reforms & enforcement of insurance law

 Require coverage for "medically necessary" addiction medications Elimination of arbitrary limits

# Harm Reduction

Figure 67. Reasons for Not Receiving Substance Use Treatment in the Past Year among People Aged 12 or Older Who Felt They Needed Treatment in the Past Year: Percentages, 2017



Note: Respondents could indicate multiple reasons for not receiving substance use treatment; thus, these response categories are not mutually exclusive.

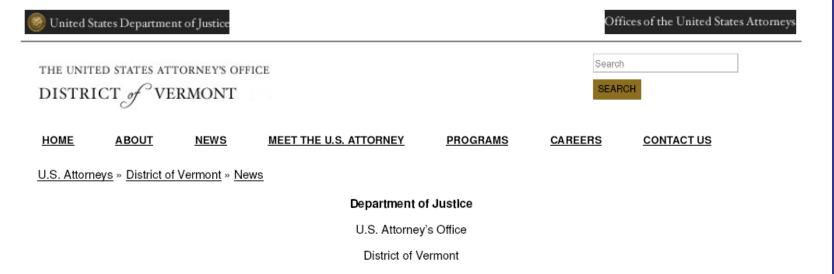
De Blasio Moves to Bring Safe Injection Sites to New York City



Mayor Bill de Blasio, in endorsing a plan to open safe injection sites in New York, said the program would "save lives and get more New Yorkers into the treatment they need," Holly Pickett for The New York Times



Corrections officer Anthony Willingham displays Naloxone nasal spray, part of an opioid anti-overdose medicine kit for inmates to take with them upon release, during a training session for inmates at the Queensboro Correctional Facility in Queens, New York, U.S., April 9, 2018. REUTERS/Shannon Stapleton



## FOR IMMEDIATE RELEASE

Wednesday, December 13, 2017

## Statement of the U.S. Attorney's Office concerning Proposed Injection Sites

In studying safe injection facilities (SIFs), the Chittenden County State's Attorney (CCSA) and the Commission members were motivated by their desire to save lives and combat the scourge of opiate addiction in Vermont. Everyone in the law enforcement community shares these goals. The U.S. Attorney's Office, however, disagrees with the recommendation of the Commission that SIFs be established in Vermont. SIFs are counterproductive and dangerous as a matter of policy, and they would violate federal law.

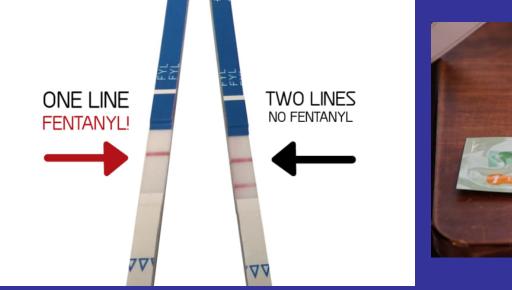
As to policy, the proposed government-sanctioned sites would encourage and normalize heroin use, thereby increasing demand for opiates and, by extension, risk of overdose and overdose deaths. Opiate users, moreover, all-to-often believe they are purchasing heroin when, in fact, they are purchasing its common substitute, fentanyl, ingestion of which gives rise to greatly enhanced dangers of overdose and fatality. Introduction of fentanyl to SIFs would create additional public health risks, not only for the users, but for SIF staff members who might come in contact with that highly potent substance. Further, heroin and other opiates are not Vermont products, but rather, introduced to Vermont from out-of-state. End users – no matter the location they use – fuel the national and international market. When users purchase heroin (or fentanyl) for injection at an SIF, those transactions will stimulate the heroin market and put money into the hands of out-of-state profit-driven dealers and drug trafficking organizations, while doing nothing to ensure that consumers stop purchasing and injecting heroin. SIFs would, thus, frustrate and undermine years of hard work by those in Vermont law enforcement and the treatment community to decrease opiate use and trafficking. Such facilities



 Exercise

 Exercise

# Fentanyl Test Strips





# The Internet



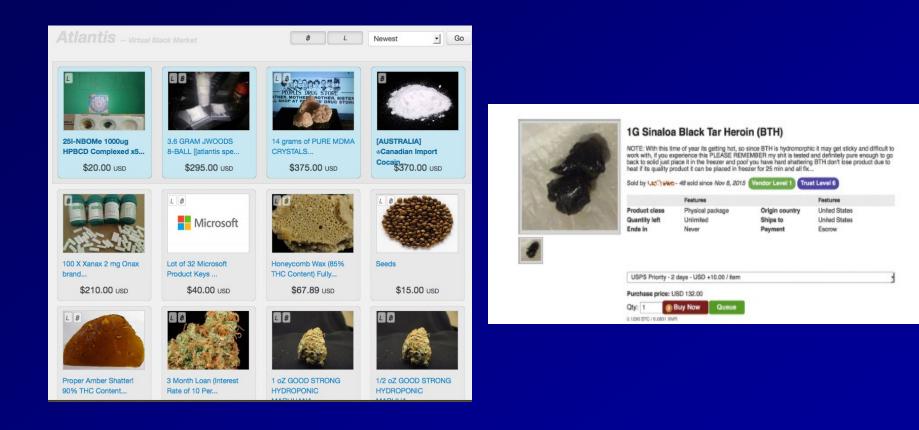


# Dark Web (Darknet)

Subset of Deep Web
 Hidden Services

Some parts of the web can only be accessed through anonymising software (e.g. Tor, I2P, etc.). This part of the internet is often called the "darknet" or the hidden web and allows for additional privacy or anonymity.

# Cryptomarkets







### DOMESTIC USA to USA 30mL FENTANYL HCI NASAL SPRAYERS 1666ug/mL \*HIGHEST QUALITY\*

\*\*\*Express shipping is NOT available with this item, sorry. Express is available with all of my other products but not the nasal sprayers!\*\*\* Each order includes (2) nasal sprayers, each one contains 15mL and is approximately 150 sprays. Each nL contains 1666ug of PURE Fentanyl HCi. This is by FAR the easiest and SAFEST way to use Fentanyl HCI. Unlike other sellers, my product quality is gu.

#### Sold by xxxMDMA - 266 sold since Jan 31, 2016 Vendor Level 8 Trust Level 6

|               | Features         |           |
|---------------|------------------|-----------|
| Product class | Physical package | Origin co |
| Quantity left | Unlimited        | Ships to  |
| Ends in       | Never            | Payment   |

|              | Features        |  |
|--------------|-----------------|--|
| igin country | Worldwide       |  |
| ips to       | Worldwide       |  |
| yment        | FE Listing 100% |  |
|              |                 |  |

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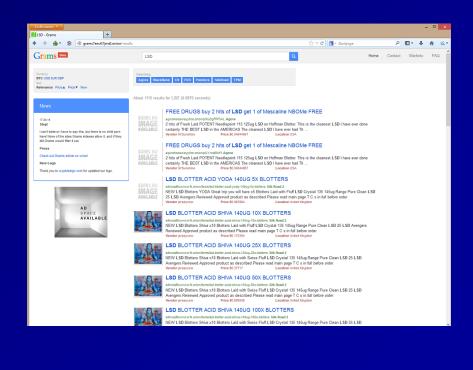
Safe, fast, Priority Mail shipping! - 3 days - USD +10.00 / item

#### Purchase price: USD 130.00 Qty: 1 Buy Now Queue 0.2845 BTC



# Cryptomarket: an online marketplace that

hosts multiple vendors provides participants with anonymity via its location on the hidden web and use of cryptocurrencies (e.g. Bitcoin) for payment aggregates and displays customer feedback ratings and comments.

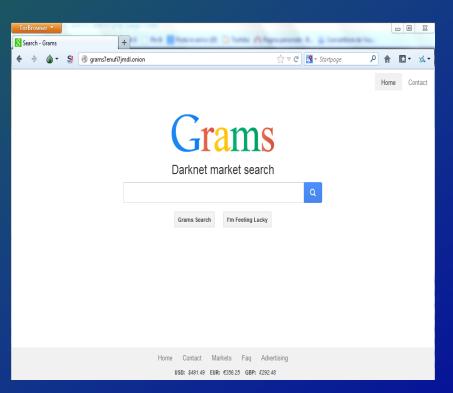


Attractions of drug cryptomarkets include:

- Accessing drugs you can't get locally (including painkillers!)
- Anonymity
- Removal from street drug market violence
- Information and advice from a community of users
- Quality control (e.g. non-adulterated opioids in a fentanyl-saturated area)
- Local delivery

# "My biggest trigger is the Fed Ex truck"





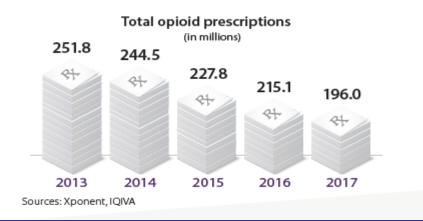
# Change how we prescribe

# Opioid prescriptions are decreasing nationwide.

Between 2013 and 2017, the number of opioid prescriptions decreased by more than **55 million**—a **22.2 percent decrease** nationally. All 50 states have seen a decrease in opioid prescriptions over the last five years.<sup>1</sup>

The nation saw a **9 percent decrease**—more than **19 million fewer** prescriptions—between 2016 and 2017 alone.

The American Medical Association (AMA) urges physicians to continue to make judicious prescribing decisions to ensure comprehensive, compassionate pain care and to talk with their patients about safe storage and disposal of all unused and unwanted medications.



# **Regulatory Responses**

## **Prescription Monitoring Database**

Eliminate paper prescriptions; mandate e-scripts



## In New York State: I-STOP (Internet System for Tracking Over-Prescribing - Prescription Monitoring Program)

- Effective August 27, 2013, most prescribers are required to consult the Prescription Monitoring Program (PMP) Registry when writing prescriptions for Schedule II, III, and IV controlled substances.
- Patient reports will include all controlled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past six months.

## Practitioners & Pharmacists **Questions About the Online PMP** Registry? If you have questions about New York's online Prescription Monitoring Program Registry, contact: New York State Department of Health Bureau of Narcotic Enforcement 1-866-811-7957 www.health.ny.gov/professionals/narcotic Additional resources relating to prescription drug abuse treatment: New York State Office of Alcoholism and Substance Abuse Services 1-877-8-HOPENY 1-877-846-7369 www.oasas.ny.gov/ Substance Abuse and Mental Health Services Administration (SAMHSA), Find Substance Abuse and Mental Health Treatment www.samhsa.gov/treatment/ is Available Online NEW YOR New York State Department of Health 1084 3/13 **Bureau of Narcotic Enforcement**

## Making a Difference: State Successes

## 2012 Action:

New York required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

**New York** 

75%.

## 2013 Result:

3

Saw a 75% **drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.



## 2010 Action:

Florida regulated pain clinics and stopped health care providers from dispensing prescription painkillers from their offices.

2012 Result:

Saw more than 50% decrease in overdose deaths from oxycodone.



## 2012 Action:

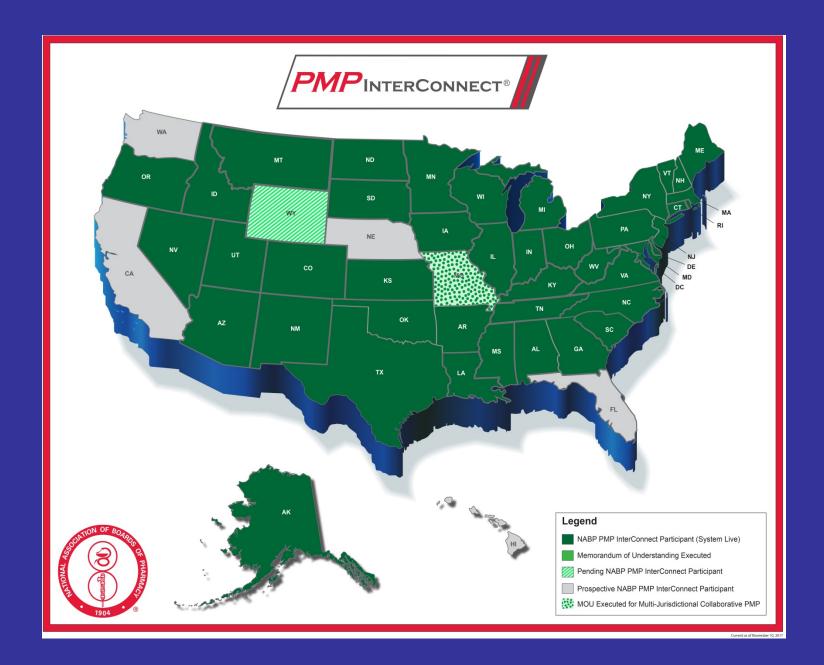
Tennessee required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

## 2013 Result:

Saw a 36% **drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

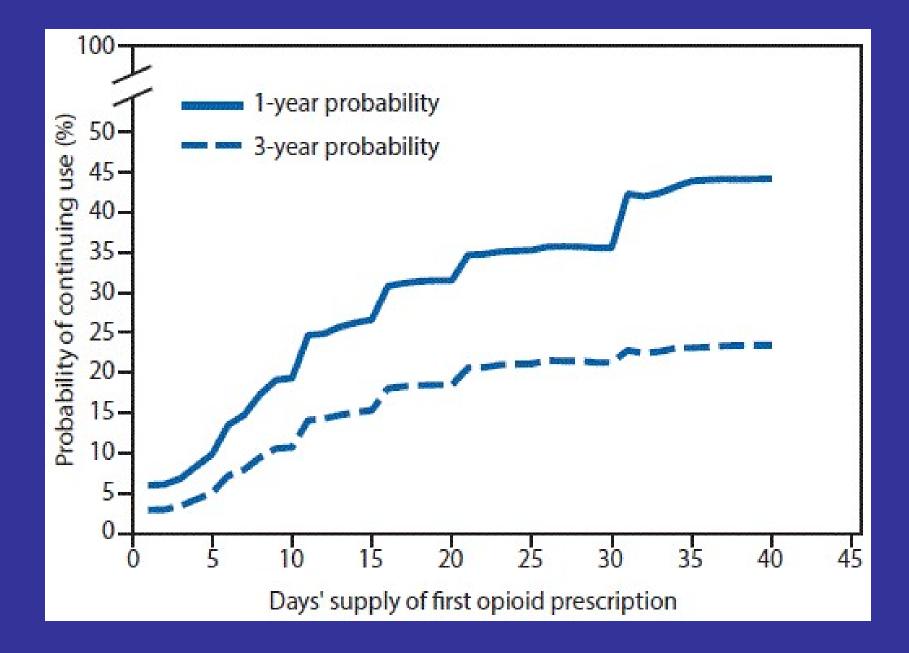
SOURCES: NY, TN: PDMP Center of Excellence at Brandeis University, 2014. FL: Vital Signs Morbidity and Mortality Weekly Report, July 1, 2014.

 Did tighter monitoring of painkiller prescribing result in driving more opioid users toward illicit versions?



# Law Change

- In NYS (effective July 2016) : Limit the prescription to seven days for acute pain at initial consultation
  - -Applies to schedule II, III and IV opioids
  - Defines "acute pain" as pain that the practitioner reasonably expects to last only a short period of time
  - Excludes chronic pain, pain being treated as part of cancer care, hospice or palliative care practices





## FOR IMMEDIATE RELEASE

August 16, 2018

Contact: DEA Public Affairs

(202) 307-7977

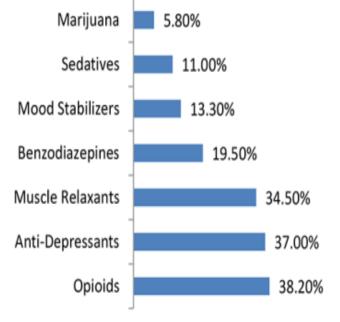
## Press Release

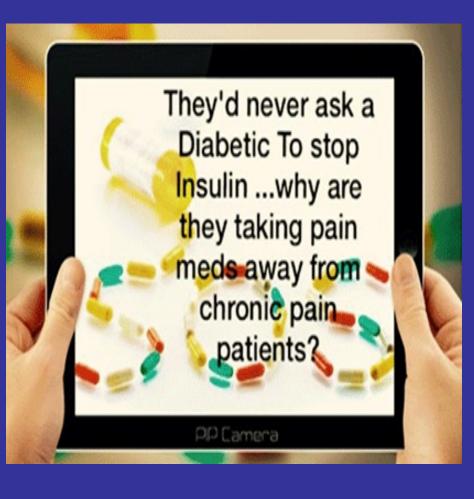
## Justice Department, DEA propose significant opioid manufacturing reduction in 2019

WASHINGTON – The Department of Justice and U.S. Drug Enforcement Administration have proposed a reduction for controlled substances that may be manufactured in the U.S. next year. Consistent with President Trump's "Safe Prescribing Plan" that seeks to "cut nationwide opioid prescription fills by one-third within three years," the proposal decreases manufacturing quotas for the six most frequently misused opioids for 2019 by an average ten percent as compared to the 2018 amount. The Notice of Proposed Rulemaking marks the third straight year of proposed reductions, which help reduce the amount of drugs potentially diverted for trafficking and used to facilitate addiction.

# Medications Americans Take for Chronic Pain

Hazelden Betty Ford Foundation, "Chronic Pain in America: Consequences, Treatments and Addiction," 2014.





OPEN ACCESS Effect of restricting the legal supply of prescription opioids on buying through online illicit marketplaces: interrupted time series analysis

lames Martin.<sup>1</sup> lack Cunliffe.<sup>2</sup> David Décarv-Hétu.<sup>3</sup> ludith Aldridge<sup>4</sup>

#### Abstract Department of Social Objective

Design

Setting

elsewhere.

Sciences, Swinburne University, Melbourne, Australia <sup>2</sup>School of Social Policy, Sociology and Social Research, University of Kent, Canterbury, Kent CT2 7 NF, UK <sup>3</sup>École de criminologie, Université de Montréal, Montréal, Canada <sup>4</sup>School of Law, University of Manchester, Manchester, UK Correspondence to: | Cunliffe id.cunliffe@kent.ac.uk Additional material is published online only. To view please visit the journal online.

Cite this as BMJ 2018;361:k2270 http://dx.doi.org/10.1136/bmjk2270

Accepted: 22 April 2018

#### Results

The sale of prescription opioids through US cryptomarkets increased after the schedule change. with no statistically significant changes in sales of prescription sedatives, prescription steroids, prescription stimulants, or illicit opioids. In July 2016 sales of opioids through US cryptomarkets represented 13.7% of all drug sales (95% confidence interval 11.5% to 16.0%) compared with a modelled estimate of 6.7% of all sales (3.7% to 9.6%) had the new schedule not been introduced. This corresponds to a 4 percentage point yearly increase in the amount of trade that prescription opioids represent in the US market, set against no corresponding changes for comparable products or for prescription opioids

To examine the effect on the trade in opioids through

Drug Enforcement Administration's ruling in 2014 to

31 of the world's largest cryptomarkets operating from

The proportion of total transactions, advertised and

active listings for prescription opioids, prescription

stimulants, and illicit opioids, and the composition

of the prescription opioid market between the US and

sedatives, prescription steroids, prescription

online illicit markets ("cryptomarkets") of the US

reschedule hydrocodone combination products.

Interrupted time series analysis.

October 2013 to July 2016.

Main outcome measures

### WHAT IS ALREADY KNOWN ON THIS TOPIC

The over-supply of opioid analgesics has contributed to the quadrupling of deaths from overdose in the United states since 1999

Limiting the legal supply of these drugs through the US Drug Enforcement Administration's ruling in 2014 to reschedule hydrocodone combination products, narrowed the circumstances in which opioids could be prescribed and stopped automatic repeat prescriptions

There are concerns that opioid users will source their drugs from illicit markets (cryptomarkets) rather than from pharmacies

#### WHAT THIS STUDY ADDS

The proportion of US cryptomarket drug trade attributable to prescription opioids increased immediately after the schedule change, with no statistically significant changes in other drug categories

The composition of the prescription opioid supply on cryptomarkets also changed, with fentanyl being the least purchased drug in July to September 2014, then the second most frequently purchased drug by July 2016

sold outside the US. This change was first observed for sales, and later observed for product availability. There was also a change in the composition of the prescription opioid market: fentanyl was the least purchased product during July to September 2014. then the second most frequently purchased by July 2016.

#### Conclusions

The scheduling change in hydrocodone combination products coincided with a statistically significant, sustained increase in illicit trading of opioids through online US cryptomarkets. These changes were not observed for other drug groups or in other countries. A subsequent move was observed towards the purchase of more potent forms of prescription opioids. particularly oxy codone and fentanyl.

#### Introduction

Since 1999, deaths from overdose in the United States have quadrupled, 1 in large part due to the over-supply of opioid analgesics.23 Recent evidence suggests that a "supply-side" approach-to limit the legal supply of these products-might have some utility, with research showing a reduction in the number of prescriptions issued for opioid analgesics in the United States between 2010 and 2015.4 Although the legitimate supply of opioids might have decreased, overall consumption will remain unchanged if users decide to source their drugs from illicit markets rather than from pharmacies.

The general efficacy of supply side interventions in drug markets is, however, under-researched.5 Although understanding has been limited by a lack of detailed information connected to illicit drug supply, knowledge has improved in recent years with the emergence of online illicit marketplaces, or "cryptomarkets." These cryptomarkets share many characteristics with legal online marketplaces such as eBay, including the provision of a decentralised digital marketplace in which geographically disparate vendors create "seller pages" to advertise goods for sale, and the use of customer feedback scores to rank sellers in terms of perceived product quality and service.68 Cryptomarkets facilitate anonymous use through their "darknet" location and payment by cryptocurrencies such as Bitcoin.7-9

The internet has facilitated the sale of licit and illicit drugs for more than 15 years, 10-13 but when the first cryptomarket. Silk Road 1, came online in 2011. illicit drugs began to be traded in large quantities. The annual turnover of drug sales conducted through cryptomarkets is estimated to be in the hundreds of millions of dollars. 14 with most transactions involving

Will morerestrictive prescribing drive pain management patients onto cryptomarkets?

# Challenges to 42 CFR

## PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF OVER 30 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

July 28, 2017

The Honorable Tim Murphy United States House of Representatives 2332 Rayburn House Office Building Washington, DC 20515 The Honorable Earl Blumenauer United States House of Representatives 1111 Longworth House Office Building Washington, DC 20515

Dear Representatives Murphy and Blumenauer:

The undersigned members of the Partnership to Amend 42 CFR Part 2 (Partnership) and additional stakeholder organizations applaud your leadership on the issue of substance use disorder privacy records and strongly support your bill, the Overdose Prevention and Patient Safety (OPPS) Act, H.R. 3545, to align 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of health care treatment, payment, and operations (TPO). We appreciate the provision in your bill that strengthens protections against the use of substance use disorder records in criminal proceedings.

The Partnership is a coalition of over 30 health care stakeholder organizations committed to aligning Part 2 with HIPAA to allow appropriate access to patient information that is essential for providing whole-person care.

The federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, Part 2, set requirements limiting the use and disclosure of patients' substance use records from certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care, which are part of our current health care framework. Part 2 regulations may lead to a doctor treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a substance use disorder. Separation of a patient's addiction record from the rest of that person's medical record creates several problems and hinders patients from receiving safe, effective, high quality substance use treatment and coordinated care.

# **Confidentiality Concerns**

- Knowing about a patient's substance use history and treatment is vital to proper and safe medical care. Having information on diagnosis, treatment and care can assist in medical treatment planning and reduce risk of errors.
- But, disclosure also risks misuse or inappropriate disclosure which could lead to loss of job or license, increase barriers to health, disability or life insurance coverage, or even the possibility of criminal prosecution.

# Coming Up



#### AMERICA

Drug Distributors Shipped 20.8 Million Painkillers To West Virginia Town Of 3,000

January 30, 2018 · 5:36 PM ET

LAUREL WAMSLEY



NEWSCAS

A House commerce committee investigation found that two drug wholesalers had sent more than 20 million pain pills to two pharmacies in the small town of Williamson, W.Va., seen in 2016. Steve hibber/AP



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