

**DRUG AND ALCOHOL SERVICE PROVIDERS ORGANIZATION OF
PENNSYLVANIA**

**PENNSYLVANIA HOUSE OF REPRESENTATIVES
HUMAN SERVICES COMMITTEE
NOVEMBER 19, 2019**

Good morning Representative DiGirolamo, Representative Cruz and members of the Committee.

My name is Deb Beck and I am here representing the Drug and Alcohol Service Providers Organization of Pennsylvania. DASPOP is a statewide organization comprised of alcohol and drug addiction treatment and prevention programs providing services in all sixty-seven counties in the state. We represent the full continuum of services including prevention, education, hospital and non-hospital detoxification, hospital and non-hospital inpatient rehabilitation, outpatient, partial hospitalization, halfway houses, transitional living facilities, criminal justice treatment and dual-diagnosis programs.

Our programs provide counseling for drug and alcohol addiction and use medications (MAT), including suboxone/buprenorphine as appropriate, based on individualized assessments and determinations.

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That being said, we are deeply worried about the direction Pennsylvania is taking and concerned about diversion. We are in constant contact with people with addictions, people in recovery, drug and alcohol addiction treatment programs and we review the professional literature with great care.

The problem of misuse and diversion of suboxone/buprenorphine is right in front of us and must be addressed. Also, remedies to reduce diversion and ensure safe and proper use are also available.

Here's why we are worried.

(1) ***“Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program,”*** American Society of Addiction Medicine, 2015. The study investigates the use of buprenorphine financed through state Medicaid from 2007 to 2012.

- Medicaid enrollees filling **Medicaid-funded prescriptions** for buprenorphine **increased from 2,985 to 12,69** from 2007 to 2012
- Depending on the year, **between 26.2% and 32.0%** of Medicaid enrollees filling prescriptions for buprenorphine had **no diagnosis of OUD**. (Opiate Use Disorder)
- Depending on the year, **34.7% to 38.0%** of Medicaid enrollees also had concomitant **Medicaid claims for other opioids and benzodiazepines** in addition to the buprenorphine claim.
- **Only 60.1%** of Medicaid enrollees who received buprenorphine had **at least one urine drug screen** and **only 41.0%** had **behavioral health counseling services**.
- **24%** of prescriptions for buprenorphine **were not preceded by a physician visit** thirty days prior to the prescription.

Look at this! One-third of Medicaid enrollees got a prescription for buprenorphine with no diagnosis of a drug and alcohol problem and over a third got Medicaid prescriptions for other opiates and benzodiazepines during the same time. (p 470)

In addition to these problems, according to the authors of the study, there were a number of indicators of poor quality of care among individuals receiving buprenorphine treatment. These quality of care measures not being met include: *“physician visits before buprenorphine fills, receipt of counseling for substance use disorders during the same year as buprenorphine treatment, and receipt of any urine drug screens during the year of buprenorphine treatment”* (p 471).

(2) ***“Many Patients Receive Prescription Opioids During Medication-Assisted Treatment for Opioid Addiction and the Majority Continue to Receive Opioid Prescriptions After Buprenorphine Treatment”***, John Hopkins Bloomberg School of Public Health, 2017

- More than two in five people receiving buprenorphine are given prescriptions for other opioid painkillers
 - Two-thirds are prescribed opioids after treatment is complete
 - 43% of patients who receive buprenorphine filled an opioid prescription during treatment and
 - 67% of patients filled an opioid prescription during the 12 months following buprenorphine treatment
- (3) ***“Medication-Assisted Treatment and Opioid Use Before and After Overdose in Pennsylvania Medicaid”***, Journal of American Medical Association, 2017. This research reports high rates of opioid prescribing for patients even after a nonfatal opioid overdose.
- (4) ***“The relationship between diversion-related attitudes and sharing and selling buprenorphine”***, Journal of Substance Abuse Treatment, 2017. Among the study participants who had been prescribed buprenorphine, 50.5% reported sharing buprenorphine and 28.0% reported selling it.
- (5) ***“Buprenorphine Initiation and Linkage to Outpatient Buprenorphine do not Reduce Frequency of Injection Opiate Use Following Hospitalization”***, Journal of Substance Abuse Treatment, 2016. Linking hospital patients who inject opiates to outpatient buprenorphine did not significantly decrease the frequency of injection opiate use (IOU) by the patients.
- (6) ***“Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence”***, Journal of American Medical Association, 2015. Among opioid-dependent patients, ED-initiated buprenorphine treatment did not significantly decrease the rates of urine tests that were positive for opioids or of HIV risk.
- (7) ***“Emergency Department Prescription Opioids as an Initial Exposure Preceding Addiction”***, Annals of Emergency Medicine, 2016. Emergency Department opioid prescriptions may contribute to the development of addiction in some patients.

(8) ***“Erectile dysfunction in male heroin users, receiving methadone and buprenorphine maintenance treatment”***, Drug and Alcohol Dependence, 2007. Of patients on methadone maintenance or buprenorphine, the study reported 24% mild to moderate ED and 18% severe ED.

We’ve only discussed a bit of the research available. However, there is additional literature and many, many articles that should be attended to by policymakers and should be ringing alarm bells all over the country.

A few examples from law enforcement:

- **The National Forensic Laboratory Information System (NFLIS) Finds Nearly Three Times more Buprenorphine than Methadone Reports in drug tests submitted by law enforcement for analysis**, U.S. DEA, NFLIS Annual Reports, 2015
- **Indivior Inc. Indicted for Fraudulently Marketing Prescription Opioid**, U.S. Department of Justice, April 2019. The U.S. Department of Justice has indicted a major suboxone/buprenorphine company, Indivior, Inc. for engaging in an illicit nationwide scheme to increase inappropriate prescriptions of suboxone through connecting *“opioid-addicted patients to doctors the company knew were prescribing opioids at high rates and in a clinically unwarranted manner.”* *“Our indictment alleges a wide-ranging and truly shameful scheme to put profits over the health and well-being of patients trying to manage substance use disorder and opioid dependence.”* The criminal trial against Indivior is scheduled to begin in May 2020.

Let me repeat. Indivior knew the doctors “were prescribing opioids at high rates and in a clinically unwarranted manner” and connected patients to these very doctors.

- **Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History**, July 2019. The Press Release describes a federal investigation of the marketing of suboxone.
- **Five Pennsylvania Physicians Charged with Unlawfully Distributing Buprenorphine and Defrauding Medicare and Medicaid**, U.S. Department of Justice, Western District of Pennsylvania, May 2018.

- **These Doctors are Illegally Prescribing Addiction Medications but Should They be Prosecuted?** Associated Press, October 2018. Addiction clinics in and around Pittsburgh have become a legal battleground with federal prosecutors charging 13 people for fraudulently prescribing suboxone.
- **Manager of opioid treatment facilities in PA and WV indicted for distributing suboxone, health care fraud,** Pittsburgh PA, March 2018
- **Drug-dealing South Philly doc admits earning \$5 million selling pills to patients,** Philly News, February 2017. *“As he overprescribed medications such as the anti-anxiety drug Klonopin and Suboxone . . . patients openly bought and sold his prescriptions in his waiting room.”*, *“It was like an assembly line, . . . ”*, *“ . . . a healthy trade in Suboxone-positive urine samples sprung up in Summers’ waiting room among patients who were not taking the drugs the doctor had prescribed, but selling them on the streets instead.”* Waiting lines of 100 deep were reported.
- **In Blair county, more than 70 people are facing drug charges,** August 2018. Nearly half the arrests were for people selling Suboxone. According to Attorney General Shapiro, “. . . the Suboxone traffic goes hand in hand with opioid addiction in this area and around the state and county.”
- **Three Doctors Indicted for Illegally Selling Prescriptions of Suboxone and Klonopin,** (in exchange for cash payments), U.S. Attorney’s Office, Eastern District of Pennsylvania, May 2016. One of the doctors illegally sold over \$5 million worth of controlled substances. The Eastern District of Pennsylvania U.S. Attorney Zane Memeger stated, “We have a public health crisis in this country involving prescription drug abuse that is exacerbated by doctors like these defendants.”
- **The FDA has begun to report deaths where buprenorphine products are involved.** The FDA Adverse Events Reporting System, a database on adverse drug events, reported almost 20,000 deaths from buprenorphine during 1998 through June 2018. For comparison purposes, there were 5,719 methadone deaths and 589 naltrexone deaths in the same time period. In the past, drugs related to **far fewer deaths have been removed from the market.** For example, Vioxx with 6,632 deaths was removed.

- In a 2017 performance audit entitled, **Opioid Treatment Audits**, the PA Office of the Auditor General noted: “Monitoring these physicians and their prescription writing practices is important because of the high potential for diversion among their patients. One way to monitor these physicians would be through additional licensing of their treatment practices through DDAP.” “This licensing would enable DDAP to monitor these physicians’ treatment practices to ensure that these are legitimate facilities and not ‘pill mills’.”
- The Office of the Auditor General also recommended that DDAP: *“Within the next six months, begin discussions with the Department of Health to develop regulations that would ensure that Pennsylvania physicians who have been authorized to prescribe buprenorphine-related medications are treating patients with opioid addictions in a safe, well-controlled environment.”* (pp 34-36)

We share the concerns raised and agree with the recommendations of the Auditor General as well as legislation that would ensure that suboxone/buprenorphine is prescribed in the context of drug and alcohol addiction treatment.

- According to legal documents filed by the Attorney General of Massachusetts, Purdue developed **Project Tango**, “a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction.” Kathe Sackler and the Purdue Pharma staff, “concluded that millions of people who become addicted to opioids were the Sacklers’ next business opportunity.” Purdue “identified eight ways that Purdue’s experience getting patients on opioids could now be used to sell treatment for opioid addiction.” In February of 2015, Project Tango was presented to the Board. “The plan was for a Joint Venture controlled by the Sacklers to sell the addiction medication suboxone.” Purdue staff “noted the opportunity to capture customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.” Commonwealth of Massachusetts v. Purdue, 2019.
- **Oxycontin Maker Offers Free Opioid Therapy in Legal Talks**, Bloomberg Business, September 2018. The very company that brought us the deadly opiate epidemic is now recommending suboxone/buprenorphine as the remedy for the problem that they created.

- **McKinsey Advised Purdue Pharma How to ‘Turbocharge’ Opioid Sales, Lawsuit Says, New York Times, February 2019.** In a lawsuit filed by the Massachusetts Attorney General, documents disclosed that McKinsey & Company advised Purdue on how to “turbocharge” sales of oxycontin, how to counter efforts by law enforcement and how to counter the “emotional messages from mothers with teenagers that overdosed”. In addition, McKinsey advised Purdue to aim its sales force at doctors who were prolific prescribers of oxycontin and suggested that Purdue lobby the leaders of Walgreen pharmacy to increase its sale of oxycontin after the pharmacy chain had reached a settlement with the Justice Department to crack down on illegal sales.
- According to the **New York Times, February 2019, “In 2018, after it spent years advising Purdue on how to increase sales of Oxycontin, McKinsey published a report titled: ‘Why we need bolder action to combat the opioid epidemic’”, McKinsey & Company, September 2018.** This report recommends increasing medication-assisted treatment capacity.

Friends, almost 5,000 Pennsylvanians a year have died needlessly due to the unspeakable, irresponsible marketing of oxycontin in the state.

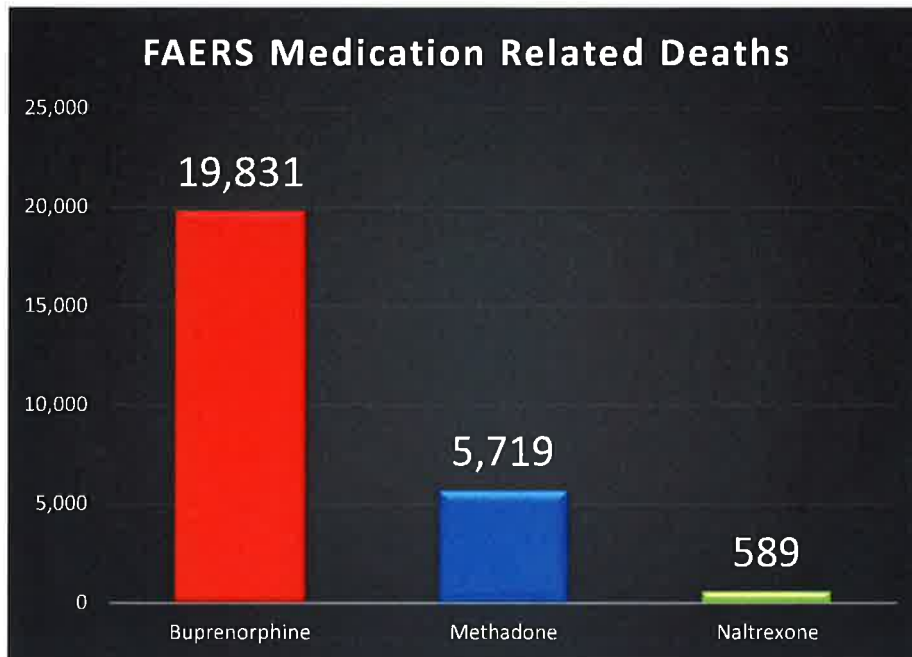
And now Purdue Pharma and McKinsey & Company are recommending suboxone/buprenorphine as the remedy!

Once again, suboxone/buprenorphine products can play an important role in addressing opiate addiction but only in the context of drug and alcohol addiction treatment.

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Attachment:
FDA Adverse Reporting Chart

Buprenorphine and FAERS Data



SOURCE: <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>

Detailed FDA Adverse Events Reporting 1998-2018

Notes: Data included is updated quarterly. This includes data through June 2018.

Data verification steps:

1. Open FDA FAERS website:
<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>
2. Click button for FAERS public dashboard in center of page
3. Click Read disclaimer and accept
4. Click search on upper left corner
5. Type drug name (methadone, buprenorphine, naltrexone) (these are the generic names, while additional ones are listed, so these numbers are underestimates)
6. Click on the single generic drug name to select, then press "go"
7. Top right has total numbers of cases, serious cases and deaths. (chart below it is broken out by year.

Various selections can be made from there)

Considerations:

Just like all medications in this database, the data are based on physician reporting, and deaths include multiple substances. Note also that the database includes some data from other countries, but the data are primarily from US sources. These numbers are updated quarterly, so they change regularly. These numbers are based on the generic drug listing so they are comparable across medications. However, there are additional deaths associated to specific brand name formulations of these generic medications, so these numbers may be underestimates of the total number of deaths. See also FAERS database cautions on data use of this public database.